

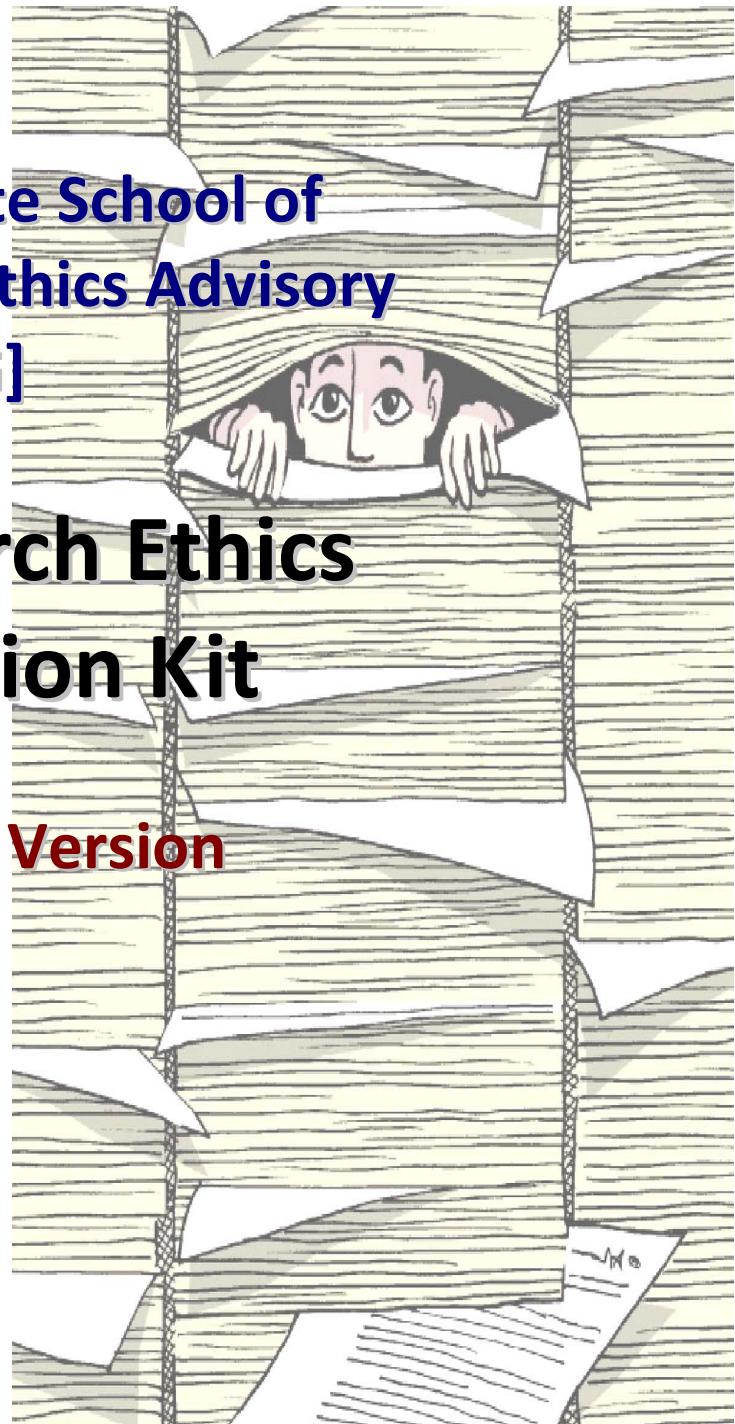
# Ethics

AMAZING! THE INSCRIPTION APPEARS TO BE AN ANCIENT CONSENT FORM FOR AN EXPERIMENTAL MUMMIFICATION PROCESS!

## Melbourne Graduate School of Education Human Ethics Advisory Group [MGSE HEAG]

## Human Research Ethics 2012 Information Kit

**Hardcopy of Online Version**



## **Who takes the "social risks" in research? by Tania Smith**



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# **SECTION 1: Background Information**

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# Melbourne Graduate School of Education Research

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## Human Research Ethics

All research projects involving humans are subject to review and prior approval by The University of Melbourne Human Research Ethics Committee (HREC). Research involving human subjects can not and must not proceed until clearance has been obtained.

The HREC has established sub-committees and Advisory Groups to review staff and student ethics applications. The Graduate School Human Ethics Advisory Group (GSHEAG) suggests that you read the information below on the procedures for submitting an ethics application, taking particular note of the GSHEAG scheduled deadline. The GSHEAG strongly advises you to visit the [HREC](#) website to obtain information about the processes and the requirements of successfully completing an ethics application.

Administration within MGSE is provided by the Research Ethics Officer, [Mr Tim Mattingsbrooke](#) [8344 8662], who is happy to provide advice and assistance.

A detailed [Human Research Ethics Kit](#) [10MB PDF file] is available for download.

## Ethics Applications and Procedure

- [Who should complete an application?](#)
- [What are 'high risk' and 'low risk projects'?](#)
- [On-line application through Themis Where do I log in?](#)
- [How can students submit an on-line application through Themis?](#)
- [When should I submit an application?](#)
- [Who do I submit the application to?](#)
- [How long will it take?](#)
- [What will the GSHEAG do?](#)
- [What do I do if the GSHEAG approves it without amendment?](#)
- [What do I do if the GSHEAG suggests changes?](#)
- [What happens after the GSHEAG approval?](#)
- [What happens at the HESC?](#)

### Who should complete an ethics application?

#### 1. *Staff*

All researchers who are members of staff of the Graduate School, who aim to conduct research which involves humans as participants, must submit an application to the GSHEAG for review and approval.

#### 2. *Students*

All postgraduate students in the Graduate School of Education who are enrolled in a thesis subject, and are gathering data from human subjects must submit an application to the Graduate School Human Ethics Advisory Group (GSHEAG) for review and approval. In the case of student projects, the student completes the ethics application in consultation with their supervisor. The application form must be read and signed by the supervisor (as the Principal Investigator) before being submitted. Project applications must also have the approval of the relevant Human Ethics Sub-Committee, of the Human Ethics Committee (HREC)

before undertaking any research involving human subjects. In the case of Education projects, this is usually the Humanities and Applied Sciences Sub Committee (HAPS).

### What are 'high risk' and 'low risk' projects?

For ethics purposes, projects are classified as being either 'high risk' or 'low risk' depending on the nature of the enquiry being undertaken and the nature of the participants. As a general indication, projects involving children, persons undergoing medical treatment or any person likely to be seen as vulnerable will be 'high risk'. Projects involving consenting adults with non-controversial subject matter will be 'low-risk'. The online process through Themis will make these distinctions clearer, and will usually ensure that the appropriate forms are used.

Low-risk projects generally take less time to approve than high-risk.

### On-line application through Themis: Where do I log in?

All ethics applications are lodged through the Themis Ethics module, as follows:

1. Log in to [www.themis.unimelb.edu.au](http://www.themis.unimelb.edu.au) for the online form
2. Click on UOM Research Service
3. Click on Human Ethics Workbench
4. Follow the instructions

### How can students submit an on-line application through Themis?

1. *Students must first be eligible for a Themis account*

Student access to the Themis Human Ethics module is now available for "research-active" students [those enrolled in a recognised research degree, such as the PhD]. Students will be assigned the Responsibility of UOM Research Student Self-Service. For the Human Ethics module this will give them access to the same functionality as staff researchers - namely the Human Ethics Workbench, Meeting Schedules and Reporting functionality. Students who are not research-active cannot access Themis. It is possible for individual students to have their status set to "research active", either individually or as a cohort.

2. *The Themis account must then be activated*

Students activate their Themis account via Account Registration System (ARS) just as Staff do. They will need the following information to activate their Themis account:

Full name  
Student number  
Date of Birth (format is DD-MON-YYYY)  
Postcode of home residence  
Library BarCode

Using this information, the student logs in to the Accounts Registration System (ARS):  
<http://accounts.unimelb.edu.au/>

### When should I submit an application?

**Deadlines for submission** are devised each year by the GSHEAG. As a guide, applications should be

submitted at the beginning of a month for consideration at the Humanities and Applied Sciences HESC for the following month.

#### **Who do I submit the application to?**

A hard-copy original application signed by all the investigators and supporting documentation must be forwarded to Mr Tim Mattingsbrooke, Room 428, Alice Hoy Building.

Tim will process your application and send copies of the application to GSHEAG reviewers for comment.

#### **How long will it take for the GSHEAG to review my application?**

Approximately two months should be allowed for the processing of a high-risk project, whereas low-risk projects which undergo expedited review application usually take up to one month, depending on the extent of any required changes.

#### **What will the GSHEAG do?**

The GSHEAG will review your application and do one of two things.

1. Approve an application without amendment or;
2. Suggest amendment to the application before forwarding to the HESC for consideration

#### **What do I do if the GSHEAG approves my application without amendment?**

If no amendments are required by the GSHEAG, the signed original hard-copy application is forwarded to the GSHEAG Chair and the Associate Dean (Research & Research Training) for approval.

#### **What do I do if the GSHEAG recommends changes?**

If the GSHEAG requires amendments, [Tim Mattingsbrooke](#) will contact the principal investigators via email or internal mail with details of the GSHEAG comments and suggestions.

The investigators, or the student in consultation with his/her supervisor, will make the recommended amendments or provide appropriate arguments why the change should not be made.

Amended pages can be submitted to Tim either in electronic form or hard-copy.

The amended original is forwarded to the GSHEAG Chairperson and Associate Dean (Research & Research Training) for approval.

#### **What happens after the GSHEAG has approved the application?**

The original approved applications are returned to Tim to make the required number of copies. The original

and copies are sent to the Humanities and Applied Sciences HESC for consideration on behalf of the HREC.

### What happens at the Humanities and Applied Sciences HESC?

The Humanities and Applied Sciences HESC will review the application and make a recommendation. For details of this part of the process (including timelines, amendments and conditions of approval) please visit the [MRO Human Ethics](#) website.

## Useful Links for Human Ethics

### Checklists

The MGSE has developed the following documents to assist with the process of ethics application

- o Checklist for completion of [normal ethics applications](#) and;
- o Checklist for completion of ['low risk' ethics applications](#)
- o [Required letterhead](#) for consent form and plain language statement
- o Requirements of the [Consent Form](#) with [sample](#)
- o Requirements of the [Plain Language Statement](#) with [Subheadings](#), [Letter](#) and [Children's](#) sample models

### Presentation

Dr Michele de Courcy, former Chair of the GSHEAG gives and insight into the ethics application process

- o [Powerpoint presentation](#) on human research and ethics

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**AFFIX CURRENT MELBOURNE RESEARCH OFFICE  
HUMAN RESEARCH ETHICS BROCHURE HERE**

**(If no brochure is affixed please see  
your Human Ethics Officer to obtain one)**

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## Introduction

The University of Melbourne Code of Conduct for Research, Regulation 17.1R8, prescribes standards of responsible and ethical conduct expected of all persons (academic staff, students, technical and other support staff) engaged in research at the University (referred to in the Code as 'research workers').

The Code sets out the obligations on all University researcher workers to be aware of the ethical framework governing research at the University and comply with institutional and regulatory requirements.

University policy requires that research workers familiarise themselves with the Code and ensure that its provisions are observed. Failure to comply with the provisions of the code may be a ground for disciplinary action.

This brochure contains the full text of the Code. The Code is available on the web at [www.unimelb.edu.au/ExecServ/Statutes/r171r8.html](http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html), but it is such an important document that paper copies also provide a useful reference and can be used as the basis for discussion among research workers.

This brochure also contains some pointers to resources which provide more detailed information and advice on specific aspects of the Code and research integrity in general.

## Our commitment to research integrity

The University is committed to creating an environment that promotes responsible conduct by embracing standards of excellence, trustworthiness, and lawfulness.

For the individual staff member or student, research integrity embodies above all a commitment to intellectual honesty and personal responsibility for one's actions and to a range of practices that characterise the responsible conduct of research, including but not limited to

- intellectual honesty in proposing, performing, and reporting research;
- accuracy in representing contributions to research proposals and reports;
- fairness in peer review;
- collegiality in scientific interactions, including communications and sharing of resources;
- transparency in declaring and managing actual or perceived conflicts of interest or potential conflicts of interest;
- protection of human participants in research;
- humane care of animals in the conduct of research; and
- compliance with environmental health and safety standards.\*

\* This description of research integrity has been adapted from the US National Academies report *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct* (2002), [www.nap.edu/books/0309084792/html](http://www.nap.edu/books/0309084792/html)

## Resources for researchers

### Research Integrity website

[www.research.unimelb.edu.au/admin/res.conduct/code.html](http://www.research.unimelb.edu.au/admin/res.conduct/code.html)

An overview of the University's policies and procedures, summaries of the various elements of responsible conduct of research, links to resources, where to get advice and direct complaints. A useful starting point for new staff members, new researchers and as a resource for heads and managers leading discussions or providing information to their groups on this topic.

### Checklist for Research Students and their Supervisors

[www.research.unimelb.edu.au/admin/res.conduct/code.html#supervisor](http://www.research.unimelb.edu.au/admin/res.conduct/code.html#supervisor)

This checklist is designed to assist supervisors and students to not only meet their obligations under the University's Code of Conduct for Research but also engage in a broader dialogue about research integrity and the responsible conduct of research. It is recommended that supervisors and their students use this checklist at the commencement of candidature, come back to it during various phases of the project and review it at least annually.

### University of Melbourne Learning Resources

[webrft.its.unimelb.edu.au/999003/pub/](http://webrft.its.unimelb.edu.au/999003/pub/)

The Responsible Conduct of Research is an online resource for staff and students at the University of Melbourne. The module has twelve main topics and features a short self-administered quiz to test your understanding of key issues and knowledge of the University's Code of Conduct for Research.

### Office of Research Integrity Learning Resources

[ori.dhhs.gov/education/rcr\\_resources.shtml](http://ori.dhhs.gov/education/rcr_resources.shtml)

The US Office of Research Integrity's Education Resources webpage provides access to a range of online education programs.

## Specific topics

### Academic Honesty and Plagiarism

[academichonesty.unimelb.edu.au/](http://academichonesty.unimelb.edu.au/)

### Animal Experimentation Ethics

[www.research.unimelb.edu.au/animalethics/](http://www.research.unimelb.edu.au/animalethics/)

### Conflict of Interest

[www.research.unimelb.edu.au/admin/res.conduct/coi.html](http://www.research.unimelb.edu.au/admin/res.conduct/coi.html)

### Environment, Health and Safety

[www.pb.unimelb.edu.au/ehs/](http://www.pb.unimelb.edu.au/ehs/)

### Gene Technology and Biosafety

[www.research.unimelb.edu.au/genetech/](http://www.research.unimelb.edu.au/genetech/)

### Human Ethics

[www.research.unimelb.edu.au/humanethics/](http://www.research.unimelb.edu.au/humanethics/)

### Intellectual Property

[www.research.unimelb.edu.au/ridg/ip/](http://www.research.unimelb.edu.au/ridg/ip/)

### Management of Research Data and Records

[www.research.unimelb.edu.au/policy/researchrecords/](http://www.research.unimelb.edu.au/policy/researchrecords/)

## The University's Research Integrity and Ethics website

[www.research.unimelb.edu.au/ethics/](http://www.research.unimelb.edu.au/ethics/)

"The ... research enterprise, like other human activities, is built on a foundation of trust. [Researchers] trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt ... to describe the world accurately and without bias. The level of trust ... has characterized [research and] science and its relationship with society ... But this trust will endure only if the [research] community devotes itself to exemplifying and transmitting the values associated with ethical [research] conduct."

Adapted from *On Being A Scientist: Responsible Conduct In Research*, National Academy Press (1995), [www.nap.edu/readingroom/books/obas/](http://www.nap.edu/readingroom/books/obas/)

# CODE OF CONDUCT FOR RESEARCH (REGULATION 17.1.R8)

## MELBOURNE RESEARCH OFFICE





# CODE OF CONDUCT FOR RESEARCH

## (REGULATION 17.1.R8)

### 1. PRINCIPLES

#### (1) Statement of Guiding Principles

This Code of Conduct ('the code') prescribes standards of responsible and ethical conduct expected of all persons (academic staff, students, technical and other support staff) engaged in research ('research workers') in the University based upon the following guiding principles—

- (a) Research is original investigation undertaken in order to gain knowledge and understanding and make this widely available.
- (b) Research workers should, in all aspects of their research—
  - (i) demonstrate integrity and professionalism;
  - (ii) observe fairness and equity;
  - (iii) demonstrate intellectual honesty;
  - (iv) effectively and transparently manage conflicts of interest or potential conflicts of interest, and
  - (v) ensure the safety and well-being of those associated with the research.
- (c) Research methods and results should be open to scrutiny and debate.

#### (2) Observance of the code

Research workers must familiarise themselves with the code and ensure that its provisions are observed.

#### (3) Breach of the code

Failure to comply with the provisions of the code may be a ground for disciplinary action.

#### (4) Advice

Where a research worker or any other member of the University is in doubt about the applicability of provisions of the code, or about the appropriate course of action to be adopted in relation to it, advice should be sought from a faculty associate dean (research and research training) or a member of the Research Integrity Committee. Such advice should be provided on a confidential basis.

### 2. SPECIFIC REQUIREMENTS

#### (1) Research Data and Records

- (a) Research workers must comply with the University's 'Policy on the Management of Research Data and Records' and related policies that may be promulgated from time to time. This policy includes, but it is not limited to, the following requirements—
  - (i) data and records should be accurate, complete and in sufficient detail to enable verification of research results and to reflect what was communicated, decided or done;
  - (ii) data (including electronic data) must be recorded in a durable and retrievable form, be appropriately indexed and comply with relevant privacy protocols;
  - (iii) data must be retained intact for a period of at least five years from the date of any publication which is based upon them or longer than this if discussion of results continues, if there are regulatory or sponsor requirements, or if the data has historical or archival value;
  - (iv) a research unit or department must establish procedures for retention of data and maintain a register of the data and records and their location; data and records will normally be kept in the department or unit where the research was conducted;
  - (v) data forming the basis of publications must be available for discussion with other research workers; where confidentiality provisions apply, the data should be kept in a way that allows reference by third parties without breaching confidentiality; and
  - (vi) when data are obtained from limited access data bases, or via a contractual arrangement, written indication of the location of the original data, or key information regarding the data base from which it was obtained, must be retained by the research worker or research unit.

#### (2) Authorship

- (a) For a person to be recorded as an author of a publication requires that he or she is directly involved in the creation of the publication by—
  - (i) conceiving it, analysing and interpreting the data on which it is based;
  - (ii) writing or revising the intellectual content; and
  - (iii) giving final approval of the version to be published.
- (b) The right to authorship is not tied to position or profession; ghost, gift, or honorary authorship is unacceptable. Authorship should honestly reflect the contribution to the work being published. Participation solely in the acquisition of funding, or the collection of data, or general supervision of the research group is not sufficient for a person to be attributed as an author of a publication.

- (c) Any part of an article critical to its main conclusion must be the responsibility of at least one author.

- (d) An author's role in a research output must be sufficient for that person to take public responsibility for at least that part of the output in that person's area of expertise.
- (e) No person who is an author, consistent with this definition, may be excluded as an author without their permission in writing.
- (f) When there is more than one co-author of a research output, one co-author (by agreement amongst the authors) should be nominated as executive author for the purposes of administration and correspondence and when there is more than one co-author of a research output, the authors should discuss and reach agreement on the order in which authors shall be listed.
- (g) Other persons who contributed to the work who are not authors should be named in Acknowledgements and those individuals and organisations who have provided facilities or material should also be acknowledged (where the publisher provides for this, and in a manner consistent with the norms of the research field or discipline). An author must ensure that the work of research students, research assistants and technical officers is recognised in a publication derived from research to which they have made a contribution.
- (h) Research workers must comply with authorship criteria appropriate to their discipline, and/or according to the requirements of the journal their work is to be published in.

#### (3) Publications

- (a) Publication of more than one paper based on the same set(s) or subset(s) of data is not acceptable, except where each subsequent paper fully cross-references and acknowledges the earlier paper or papers as the case may be (for example, in a series of closely related work, or where a complete work grew out of a preliminary publication and this is fully acknowledged).
- (b) An author who submits substantially similar work to more than one publisher must disclose this to the publishers at the time of submission.
- (c) Publications must include information on the sources of financial support for the research and must include a disclosure of any potential conflicts of interest. Financial sponsorship that carries an embargo on such naming of a sponsor should be avoided.
- (d) Confidentiality provisions to protect intellectual property rights may be agreed between the University, the research worker and a sponsor of the research. Where such agreements limit free publication and discussion, limitations and restrictions must be explicitly agreed.

#### (4) Supervision of Students Undertaking Research

- (a) Supervision of doctor of Philosophy students should be carried out in accordance with the 'Guidelines on PhD candidature for departments, supervisors' set out in the PhD Handbook.
- (b) Supervision of all other students undertaking research should be carried out in accordance with the requirements set down by the relevant faculty, school or department.

#### (5) Conflict of Interest

- (a) A research worker has a conflict of interest in any circumstances where that person has a real, perceived or potential opportunity to prefer their own interests, or those of any other person or organisation, to the interests of the University. Examples of conflicts of interest in research include but are not limited to situations—

- (i) where the research is sponsored by a related body;
- (ii) where the research worker or a related body may benefit, directly or indirectly, from any inappropriate dissemination of research results (including any delay in or restriction upon publication of such results);
- (iii) where the research worker or a related body may benefit, directly or indirectly, from the use of University resources;
- (iv) where the research worker conducts a clinical trial which is sponsored by any person or organisation with a significant interest in the results of the trial; and
- (v) where private benefits or significant personal or professional advantage are dependent on research outcomes.

A related body is any person or body with which the research worker has an affiliation or a financial involvement.

A financial involvement includes a direct or indirect financial interest, provision of benefits (such as travel and accommodation) and provision of materials or facilities.

An indirect financial interest is a financial interest or benefit derived by the research worker's relatives, personal or business associates, or research students.

It is important to recognise that real or perceived opportunities to give preference to personal interests arise from competing obligations and can be other than financial.

- (b) The responsibility for managing a conflict of interest rests, in the first instance, with the individual.

- (i) A research worker must make a full disclosure of a conflict of interest or of circumstances that might give

rise to a perceived or potential conflict of interest as soon as reasonably practicable as follows—

- (A) where the research worker is a head of department, to the dean of the relevant faculty;
- (B) where the research worker is a dean of a faculty, to the deputy vice-chancellor (research);
- (C) in all other cases, to the research worker's head of department.

For the conduct of clinical trials, full disclosure must include the nature of the sponsorship and the relationships between the sponsor, trial subjects and the clinical investigator.

- (c) Disclosures shall be handled as follows—

- (i) the officer in receipt of the disclosure referred in paragraph (i) above must discuss the matter with the staff member concerned and determine a procedure for the management or elimination of the conflict of interest. The procedure must be documented, the research worker advised in writing and a copy of the agreement held in the department's records.
- (ii) a research worker must comply with the direction of the officer referred to in section 5 (e)(i) above in relation to the management of the conflict of interest.
- (iii) unless involved directly, it is the responsibility of heads of departments to ensure that conflicts of interest in research involving their staff members are managed appropriately.
- (iv) when a head of department has a conflict of interest in research, the dean of the faculty will be responsible for recommending to the deputy vice-chancellor (research) appropriate management arrangements.
- (v) when a dean of a faculty has a conflict of interest in research, the deputy vice-chancellor (research) will be responsible for recommending to the vice-chancellor appropriate management arrangements.
- (d) a head of department must not be a director of any organisation sponsoring research in that department or have a direct or indirect financial interest in excess of 5% equity in such an organisation unless full disclosure has been made and the vice-chancellor has approved an exception to this policy.
- (e) the deputy vice-chancellor (research), when deciding whether to accept sponsored research or contract research funding on behalf of the University, may seek information regarding disclosure and management of any conflict of interest that may result.

### 3. ADDITIONAL REQUIREMENTS

- (1) Any special standards of work performance and ethical conduct imposed by law or by the University in relation to particular categories of research are deemed to be included in this code in their application to persons engaged in that kind of research in the University. These include that where research procedures are of a kind requiring approval by a human or animal experimentation ethics committee, gene technology regulation committee or by a safety or other validly constituted regulatory committee, research must not proceed without such prior approval.
- (2) Research workers should endeavour to safeguard the interests of all parties in relation to intellectual property in accordance with the Intellectual Property Statute of the University and other guidelines as may be promulgated from time to time.
- (3) Every research worker should be provided with access to material on applicable institutional guidelines for the conduct of research, including those covering ethical requirements for studies on humans or animals, requirements for confidentiality, and occupational health and safety matters.
- (4) Academic staff must make a declaration as part of their annual reporting requirements that they have complied with the provisions of the code.

### 4. RESEARCH MISCONDUCT

- (1) Research misconduct is constituted by a failure to comply with the principles or specific provisions of the code and includes but is not limited to conduct in, or in connection with, research that is (a) dishonest, reckless or negligent and (b) seriously deviates from accepted standards within the scientific and scholarly community for proposing, conducting or reporting research, such as the following—
  - (a) the fabrication or falsification of data or results;
  - (b) the use of another person's ideas, work or data without appropriate acknowledgement;
  - (c) misleading ascription of authorship to a publication including the listing of authors without their permission, attributing work to people who have not in fact contributed to the publication, the lack of appropriate acknowledgment of work primarily produced by a research student/trainee or associate; and
  - (d) failure to disclose conflicts of interest or cases where a conflict of interest might reasonably be perceived to exist.
- (2) Procedures for dealing with allegations of misconduct in research by staff are set out in the Personnel Policy and Procedures Manual.
- (3) Procedures for dealing with allegations of misconduct in research by students are set out in Statute 13.1 - Student Discipline."

## Conducting Research in Victorian Government Schools

The Department acknowledges the importance of research in developing and refining strategies to meet the changing needs of students. It welcomes high quality proposals for school level research designed to add to the understanding of students and the effectiveness of educational programs.

The nature and volume of requests being made for research in schools has significant potential implications for the efficient operation of schools and the well-being of students and staff. It is therefore necessary for the education system to manage and validate research requests to minimise disruption and to protect students and staff.

The Department must approve all proposals to conduct research in schools before researchers approach schools. There are three stages to the approval process:

1. Review of proposal: gaining Departmental approval to approach school principals
2. Consent of schools: gaining the approval of principals to conduct research in their schools
3. Consent of participants: gaining the agreement of students (and where necessary their parents) and/or staff for participation in the research

Details of these stages are outlined in the document *Application Procedures for Research in Victorian Government Schools*. Under some circumstances exceptions may be made to the approval process. Details of these circumstances are provided in Section 2.4 of the document.

## Procedure

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Researchers should read the *Application Procedures for Research in Victorian Government Schools*, before completing the *Application to Conduct Research in Schools*. The application must include sufficient information to enable a full understanding of the aims, methodology and procedures of the research, together with copies of:

- the approval for the research from the relevant human research ethics committee (HREC), where applicable. If approval is yet to be granted, please include a statement indicating whether the study has been submitted to an HREC and, if so, the status of that submission
- the proposed letter to school principals requesting approval to conduct the research in their schools
- a statement in plain language (no more than two pages) describing the research, which will be provided with the above letter to the school principals
- the proposed letter to the participants inviting their involvement in the research
- the proposed letter to parents, where appropriate, requesting approval for their students to participate in the research
- a statement in plain language (no more than two pages) describing the research, which will be provided to the participants and where appropriate to their parents
- consent forms to be provided to all participants and, if necessary, parents
- all questionnaires, surveys and interview questions (a sample is not adequate)

Note: Where the development of instruments forms an integral part of the research process, approval may be given for the developmental stage only, with full approval being withheld until the final versions of the instruments are submitted for approval.

To ensure all required documentation is provided, researchers should complete the *Checklist of Research Attachments* and include it with their application.

## Submission

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Send one hard copy of your application to:

Research Branch  
Education Policy and Research Division

---

Office for Policy, Research and Innovation  
Department of Education and Early Childhood Development  
GPO Box 4367  
Melbourne VIC 3001

## Documents

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- [Application Procedures for Research in Victorian Government Schools \(Word - 62Kb\)](#)
- [Application to Conduct Research \(Word - 191Kb\)](#)
- [Checklist to Conduct Research \(Word - 35Kb\)](#)

## More information

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External applicants may contact the Research Branch for further information at [research@edumail.vic.gov.au](mailto:research@edumail.vic.gov.au)

Information on conducting research in early childhood settings is available at: [Early Childhood Research](#)

For information on accessing data sets owned or managed by the Department, please contact the Data, Outcomes and Evaluation Division at: [early.childhood.research@edumail.vic.gov.au](mailto:early.childhood.research@edumail.vic.gov.au)

**Website Created on:** July 21, 2006

**Page Last Updated:** July 8, 2009

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## CEOM Policy 2.8

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### Researchers in Catholic Schools and Access to Data on Catholic Schools

#### RATIONALE

This policy provides information for individuals or organisations who are seeking:

- i. **access to Catholic schools for the purpose of undertaking research; or**
- ii. **access to data related to Catholic schools held by the Catholic Education Office Melbourne (CEOM).**

It is expected that when researchers conduct research in Catholic schools, they do so on the basis that the findings may assist to improve student outcomes and increase school effectiveness. Research in areas beyond the immediate concerns of schools should be conducted only when it can be demonstrated that the findings may have a potential benefit for the participants themselves.

The data held by the CEOM are collected from Catholic schools for accountability requirements of governments and for the purpose of providing leadership and support services to schools. Individuals and organisations seeking access to CEOM data collections will need to demonstrate that release of the data will have potential benefit for students in Catholic schools.

#### PRINCIPLES

##### Capacity building

The CEOM is a learning organisation which values the sharing of knowledge across the education sector in order to encourage creativity, innovation and collaboration.

##### Adding value

Research findings and access to information should provide a potential contribution to existing knowledge and a balance between short-term and long-term benefits.

##### Maintaining propriety

In order to protect the welfare and rights of individuals, access to information and exchange of knowledge must conform to legal and ethical requirements. This CEOM policy reflects the obligations on researchers outlined in the National Health and Medical Research Council (NHMRC) documents: *National Statement on Ethical Conduct in Human Research (2007)* and *Australian Code for the Responsible Conduct of Research (2007)*. The NHMRC statements can be viewed at [www.nhmrc.gov.au](http://www.nhmrc.gov.au).

#### PROCEDURES

##### A. Seeking access to Catholic schools for the purpose of research

###### *CEOM Approval*

All non school-based researchers, and school personnel wanting to conduct research related to their postgraduate studies, need to seek CEOM approval to conduct research in a Catholic school.

Procedures to be followed for obtaining approval from the CEOM and an [application form](#) are appendices to this policy.

###### *Ethics Approval*

The NHMRC sets out guidelines for the review of research proposals by a Human Research Ethics Committee (HREC). Since research conducted in schools falls within the requirements of the NHMRC, approval from an Ethics Committee is normally required. [\*\*Appendix 1 – Procedures for Obtaining Approval to Conduct Research in a Catholic School\*\*](#) provides details about the categories of researchers required to seek the approval of an Ethics Committee.

###### *School Approval*

As collection of data can be time consuming for schools and may divert attention away from higher priority tasks, the ultimate decision to allow the research to proceed within a particular school rests fully with the principal. [\*\*Appendix 1 – Procedures for Obtaining Approval to Conduct Research in a Catholic School\*\*](#) provides detail about the information to be provided to schools when seeking their participation.

##### B. Seeking access to data related to Catholic schools held by the CEOM

Requests for access to data held by the CEOM must be in writing (post, email or fax) and specify what data are being sought and for what purpose.

When considering requests for access to data, the CEOM will comply with confidentiality and privacy requirements and take into account other areas of sensitivity related to Catholic schools, the CEOM and the Catholic Education Commission of Victoria Ltd (CECV).

Generally, access to data is provided to:

- government departments and Catholic agencies for the purpose of accountability and provision of services;
- Catholic schools to assist in their planning and reporting activities;
- people engaged directly in education;
- people undertaking research in education or other areas of community benefit;
- non-profit organisations involved in activities likely to provide a benefit to schools and the wider community.

The CEOM will **not** normally provide data to commercial or marketing organisations, including those offering educational services.

In cases where the data are already publicly available, the person making the request will be referred to their location.

If some or all of the requested data are not available, or where access is denied, the person making the request will be informed.

Data are provided by the CEOM on the condition that it is used only for the purposes stated in the request for access.

All requests for access to data held by the CEOM must be made in writing to the Director by

**post:** Director of Catholic Education  
Attention: Knowledge Management Unit (PG9)  
Catholic Education Office  
PO Box 3  
EAST MELBOURNE VIC 8002  
**or email** [km@ceomelb.catholic.edu.au](mailto:km@ceomelb.catholic.edu.au)  
**or fax** (03) 9415 9325  
Attention: Knowledge Management Unit (PG9)

**Attachments:**

Appendix 1 [Procedures for Obtaining Approval to Conduct Research in a Catholic School](#)  
Appendix 2 [Application to Conduct Research in Catholic Schools](#)  
Appendix 3 [CEOM Requirements for Ethics Approval of Research Proposals](#)

*CEOM September 2007 (Revised)*

[Service Agreement](#)  
[Disclaimer | Privacy Policy](#)

**The University of Melbourne**

**Human Research Ethics Committee**

**UNIVERSITY RESEARCH OR RELATED WORK THAT DOES NOT  
REQUIRE REVIEW BY THE HUMAN RESEARCH ETHICS COMMITTEE<sup>1</sup>**

The University of Melbourne is committed to the highest standard of integrity in research.

The University Code of Conduct for Research sets out the obligations on all University researchers (staff and students) to be aware of the ethical framework governing research at the University and comply with institutional and regulatory requirements.<sup>2</sup>

*The National Statement on Ethics Conduct in Research Involving Humans<sup>3</sup>* provides for individual institutions to define what constitutes research that merits ethical review.<sup>4</sup>

The University of Melbourne has resolved that the following categories of research or potentially research-related work **do not require review** by the Human Research Ethics Committee (HREC) or its Sub-Committees:

1. Use of data freely available in the public domain
2. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, public archive materials or third-party interviews (such research only requires HREC review if persons are approached directly for interview or for access to private papers)
3. Pure observation studies of public behaviour (i.e. human action that occurs in a forum open to the general public) that is non-invasive and requires no interaction with participants, such as standing on a footpath or other public venue and noting the actions of passers-by (HREC review will be required if participants will be identified by name or by other identifiers (e.g. facial photographs) and if the disclosure of recorded observations would place those identified participants at risk of harm or social stigma or legal prosecution)
4. Pure observation studies in established or commonly accepted educational settings, involving normal educational practices, researching current education instructional strategies; or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods (however, the inclusion of any element of intervention, as distinct from observation, would mean that such research would require some level of ethical review)
5. Quality assurance/audit projects that do not involve access to or the collection of private, sensitive or health data.<sup>5</sup>
6. Testing within normal educational requirements and in accordance with the host institution's normal practices and approvals
7. Student education and training exercises and practical classes among students. (All training exercises and practical classes involving student learning through testing procedures on each other must have an ethics component, appropriate training in procedures or use of equipment, appropriate supervision, and the opportunity for students to decline to participate).
8. Student coursework assignments and essays.
9. University of Melbourne Evaluation Cycle Surveys of University staff and students, including student evaluation of teaching
10. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use declared safe, or agricultural chemical or environmental contaminant at or below the level and for a use declared safe, by the relevant national food safety agency (e.g. Australian Food Standards Safety Authority or US Food and Drug Administration).

University staff and students do not need to submit any documentation to the University to confirm the status of a project that is defined above as not requiring HREC ethical review.

/2

If the University is conducting work of the type described above as not requiring review under the University's policy but that work is being funded under an external grant or contract and the conditions of that grant or contract require the project to be reviewed by an ethics committee, then a proposal must be submitted to the HREC.

Staff or students undertaking work in the ten (10) categories described above are not absolved from their duty under the University Code of Conduct for Research to adhere to acceptable ethical standards and at all times

- demonstrate integrity and professionalism,
- observe fairness and equity,
- avoid conflicts of interest, and
- ensure the safety of those associated with a project.

The University Code of Conduct for Research (Regulation 17.1.R8 - Code of Conduct for Research) can be found at <http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html>. Failure to comply with the Code of Conduct could result in disciplinary action.

In terms of projects carried out by *undergraduate students*, Academic Board in December 2001 endorsed the following position on the recommendation of the Research and Graduate Studies Committee:

- Research experience projects at undergraduate level should not normally be of the type that would require approval by the HREC; these projects should have an education, training and practical experience focus and not place the student or the participants in a situation of risk.
- Where an academic department considers that there are special reasons why a particular undergraduate research project should or may need to be referred to the HREC for review, this should be discussed in the first instance with the Executive Officer of the HREC, and a plan of action agreed.<sup>6</sup>

If researchers are in any doubt as to the status of a particular project, they should in the first instance consult with the Chair or other designated member of the relevant Department Human Ethics Advisory Group (DHEAG) or their Head of Department. Failure to obtain appropriate ethics approval for research involving humans may result in disciplinary action resulting from a breach of the Code of Conduct for Research.

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<sup>1</sup> Approved by the Human Research Ethics Committee, Meeting 1/03, March 2003

<sup>2</sup> See <http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html>.

<sup>3</sup> See <http://www.research.unimelb.edu.au/humanethics/policy/national/>.

<sup>4</sup> The National Statement holds that in general such review is warranted where there is the potential to cause harm to the well-being of participants, whether physically, psychologically, spiritually or emotionally; or in the exploitation of cultural knowledge and/or property, where their involvement, or the use of their personal or community-based information, has a potential for infringement of their privacy or of the confidentiality or ownership that attaches to that information; or where their involvement imposes burdens with little benefit.

<sup>5</sup> In 2003, the NHMRC published advice on 'When does quality assurance in health care require independent ethical review?' – see <http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>.

<sup>6</sup> For contact details, see <http://www.research.unimelb.edu.au/humanethics/policy/contact/>.



THE UNIVERSITY OF

MELBOURNE

## Requirements of Statement of Written Information to be given to participants (Plain Language Statement)

### Informed Consent

The informed consent process requires the full disclosure of all information relating to the study by the researcher to the participant so that the participant can make informed decisions about whether to take part or not. (For further details please refer to the [Guidelines for Informed Consent](#).)

Consent is usually obtained from participants in writing by use of an information sheet and a consent form. Participants are given written information about the study, disclosing all information that will be necessary for them to make an informed decision concerning participation. In addition to written information the researcher will usually take time to explain the study to the participant and to answer any queries or concerns the participant may have. Depending on the intrusiveness and complexity of the study potential participants should be given time to think about the study before they agree to participate. Potential participants should be encouraged to discuss the project with others before they decided to participate.

Information in a plain language statement should be presented in a format that is appropriate to the particular subject group and which can be easily understood by them. This may vary according to the particular research context. At times it may be appropriate to set this out in the form of a letter to participants. It may be useful to use headings and sometimes diagrams, especially when conveying complex information. It may also be necessary to provide this information in other languages.

### Include Plain Language Statement with Ethics Application

All applications for ethics approval must include a copy of any written information describing the project which is to be given to potential participants (plain language statement).

Please note that the HREC or its sub-committees can only approve a final version of the information statement for participants. This must be submitted before data collection can commence.

Please ensure there are no spelling or grammatical errors in the information statement as this could result in participants' misunderstanding the information they are being given.

### [What to include in the Plain Language Statement](#)

### [Features of a good Plain Language Statement](#)

### [Examples of Plain Language Statements](#)

Date Created: 14 June 2005  
 Last Modified: 12 November 2006  
 Authorised By: Dr Glenn Swafford, Vice-Principal (Research)  
 Maintainer: Melbourne Research Office  
 Web Admin: Hoo Ward Ng  
 Email: [webadmin](mailto:webadmin)

The University of Melbourne ABN: 84 002 705 224  
 CRICOS Provider Number: 00116K ([More information](#))  
[Course Enquiries](#)

## **Requirements of the Plain Language Statement**

In the plain language statement the project should be described so that potential participants, after reading the description, will be able to choose freely whether or not to participate in the project. The written description should contain the following information:

### **Researcher Details**

Clear identification of the:

1. University (statement to be printed on University letterhead);
2. Department or departments involved;
3. Project title;
4. Principal (and other) investigator(s) (including contact numbers for these);
5. Supervisor, if it is a student research project;
6. Degree for which the research is being undertaken, if it is a student research project.

### **Procedures/Risks**

- An explanation, in language that the participants will understand, of the aim of the project and the procedures to be followed (e.g., surveys, interviews, video-taping, audio-taping, blood testing, etc). This should include a description of what participants are expected to do if participating in the project, the anticipated time involved, and any possible risks, discomfort or inconvenience resulting from these procedures. If children are the participants in research a statement should be provided for them in language they can understand as well as a statement suitable for their parents/guardian.

### **No Prejudice**

- If provision of services, benefits, medical treatment, education or other care is involved, a clear statement that involvement or non-involvement in the project will not affect ongoing management, treatment, assessment/results or employment situation.

### **Right to Withdraw**

1. A clear indication that participation in the project is voluntary, and that participants may withdraw consent to participate and discontinue participation at any time until data become processed. Participants should also be advised that they may, if they wish, withdraw any unprocessed data previously supplied;
2. Participants must be informed that withdrawing from the research will not jeopardise their relationship with the researchers in any way (e.g., teacher/student relationship; medical treatment);
3. A participant must be free at any time to withdraw consent to further involvement in the research. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained.

### **Confidentiality Procedures/Data use and Storage**

1. Details of the anticipated use of the data (e.g., thesis, publication, whether or not copies of reports will be given to participants, sponsors etc.);
2. An explanation of procedures adopted to ensure confidentiality of data. Participants should also be advised of limits to confidentiality -i.e. subject to legal requirements, requirement to report by some professions (mandatory reporting requirements), duty of care to third party etc. Information about how the data will be used should also be included and, where necessary, the steps to be taken to ensure that participants will not be identified. (For example, if case histories are to be written up in a report of the research, a statement will

need to be included to indicate that information will be disguised by use of pseudonyms or other devices so that identification of the participant will not be possible).

### Funding

- Identification of funding bodies and sponsors of the research needs to be included.

### Further Assistance

Outlining:

1. An offer to answer any questions and a contact name and telephone number if any further explanation is required;
2. Arrangements for debriefing or follow-up where this is necessary to secure the well-being of participants;
3. A statement that if participants have any concerns regarding the conduct of the research project that they can contact the Executive Officer, Human Research Ethics, the University of Melbourne , Vic 3010, ph: (03) 8344 2073; fax: (03) 9347 6739

## Plain Language Statement Checklist

Confirm that the Plain Language Statement:

	YES	NOT APPLICABLE
1. is printed on University of Melbourne letterhead	<input type="checkbox"/>	<input type="checkbox"/>
2. includes clear identification of the University, the Department(s) involved, the project title, the Principal and Other Researchers (including contact details), and the study level if it is a student research project.	<input type="checkbox"/>	<input type="checkbox"/>
3. provides details of the purpose of the research project	<input type="checkbox"/>	<input type="checkbox"/>
4. provides details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-taping of events), and estimated time commitment	<input type="checkbox"/>	<input type="checkbox"/>
5. provides details of any risks involved and the procedures in place to minimise these.	<input type="checkbox"/>	<input type="checkbox"/>
6. advises that the project has received clearance by the HREC	<input type="checkbox"/>	<input type="checkbox"/>
7. (if the sample size is small), states that this may have implications for protecting the identity of the participants	<input type="checkbox"/>	<input type="checkbox"/>
8. includes a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health (if relevant)	<input type="checkbox"/>	<input type="checkbox"/>
9. states that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied	<input type="checkbox"/>	<input type="checkbox"/>
10. provides advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see ** below)	<input type="checkbox"/>	<input type="checkbox"/>
11. provides advice as to whether or not data is to be destroyed after a minimum period (if relevant)	<input type="checkbox"/>	<input type="checkbox"/>
12. provides in the footer, the project HREC number, date and version of the PLS	<input type="checkbox"/>	<input type="checkbox"/>
13. provides advice that if participants have any concerns about the conduct of this research project that they can contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739	<input type="checkbox"/>	<input type="checkbox"/>



## Features of a good Plain Language Statement

- An inviting tone, or being expressed as an invitation to participate
- Language appropriate for the level of participants (eg. adults vs. children, experts vs. non-experts)
- A level of detail specifically targeted at participants
- Giving the names and department of the researchers
- Giving any degree(s) for which the research will be used
- Telling participants why and how they were selected
- Letting participants know how you accessed any private contact details
- Assuring participants that their participation is completely voluntary
- Assuring participants that they are free to withdraw
- Assuring participants that they can also withdraw data at any time *until it becomes processed, or is irreversibly removed from any identification*
- Explaining every stage of participation
- Explaining the alternative to participation, such as *research in schools: will everyone do the same activity with data collected only from consenting participants? Or will the participating and non-participating students do different things?*
- Giving an estimate of the time commitment involved
- Being clear about any potential discomfort or inconvenience
- Describing any possible risks, and explaining plans to minimize or avoid them
- Recognizing participants' possible fears about being identified, or having their data made public, ie. the security of anonymity (see risks, above)
- Telling participants what you will do to keep their "raw" responses private, ie. protect confidentiality
- Informing participants that there are legal limits to confidentiality *unless you intend to collect completely anonymous data*
- Letting participants know about the option of being named, *if it is available*
- Telling participants how you will secure the data once you have gathered it
- Informing participants when you will destroy the data *if you intend to do so*; or else informing them about the purposes of keeping the data, such as *in a longitudinal study where you may need to re-contact them*
- Telling participants about any debriefing arrangements
- Notifying participants about how to find out about the project results *if you intend to make them available*
- Providing the Human Ethics contact details
- Giving instructions about what they should do if they would like to participate
- Thanking participants for reading the information

*The above list is based on typical Humanities & Applied Sciences research that does not use deception of participants. In such cases, many of the above features of good plain language statements would be provided in a Debriefing Statement, where participants would be made aware of the 'real' objectives of the research.*

### To check that the Plain Language Statement is a good, ask yourself the following:

- Would I be likely to participate if I received this information without having ever been involved in research, or having any understanding of the topic?
- How would I feel if my son/daughter, mother/father, or grandparent was given this information and asked to consent to participate?
- If I was a suspicious person and I received this statement 'cold', what would I think when I read (such and such a sentence/paragraph); what information could be included to appease these concerns?
- You might also give it to a friend who is NOT involved in your field, and ask them if they can understand it, and what extra questions they might have. This is a great way to make sure you really have used "plain language" and covered all the important points

Date Created: 19 December 2005

Last Modified: 12 November 2006

Authorised By: Dr Glenn Swafford, Vice-Principal (Research)

Maintainer: Melbourne Research Office

Web Admin: Hoo Ward Ng

Email: [webadmin](mailto:webadmin)

The University of Melbourne ABN: 84 002 705 224

CRICOS Provider Number: 00116K ([More information](#))

[Course Enquiries](#)

- This sample statement is NOT a prescribed statement, but gives an indication of the kind of information which should be included in a Plain Language Statement.
- The project discussed is fictional and is intended to give an idea about how you could word your plain language statement and how to include all the required information. The essential points for inclusion can be found in the checklist on the previous page.
- If your project takes a different approach to confidentiality and anonymity. You can view example alternate descriptions of confidentiality arrangements at <http://www.research.unimelb.edu.au/humanethics/external/>
- The letterhead for Plain Language Statements can be found at: [http://www.education.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20For\\_ms.doc](http://www.education.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20For_ms.doc)

## PLAIN LANGUAGE STATEMENT [Sample Letter Model]

"Explaining the ethics process: communicating procedures to applicants"

Dear Participant,

You are invited to participate in the above research project, which is being conducted by Dr Jane Doe (supervisor) and Mr John Smith (Honours student) of the Department of Communications at The University of Melbourne. Your name and contact details have been drawn at random from a database of former applicants for ethics approval, with the permission of the General Manager of the Melbourne Research Office. This project will form part of Mr Smiths honours thesis, and has been approved by the Human Research Ethics Committee.

The aim of this study is to investigate whether the instructions and information provided by the ethics web page regarding consent forms needs to be improved, and if so, in what ways. Should you agree to participate, you would be asked to contribute to this in two ways. First we would ask you to look at the ethics web site and complete a 5 minute questionnaire, at a time convenient to you. This questionnaire would ask you to indicate your reactions to the web site, and your opinion of its efficacy in conveying information. Second, we would ask you to participate in a brief interview of about 15 minutes, so that we can get a more detailed picture of what improvements could be made. With your permission, the interview would be tape-recorded so that we can ensure that we make an accurate record of what you say. When the tape has been transcribed, you would be provided with a copy of the transcript, so that you can verify that the information is correct and/or request deletions. We estimate that the time commitment required of you would not exceed 30 minutes.

We intend to protect your anonymity and the confidentiality of your responses to the fullest possible extent, within the limits of the law. Your name and contact details will be kept in a separate, password-protected computer file from any data that you supply. This will only be able to be linked to your responses by the researchers, for example, in order to know where to send your interview transcript for checking. In the final report, you will be referred to by a pseudonym. We will remove any references to personal information that might allow someone to guess your identity; however, you should note that as the number of people we seek to interview is very small, it is possible that someone may still be able to identify you.

Once the thesis arising from this research has been completed, a brief summary of the findings will be available to you on application at the Department of Communications. It is also possible that the results will be presented at academic conferences. The data will be kept securely in the Department of Communications for five years from the date of publication, before being destroyed.

Please be advised that your participation in this study is completely voluntary. Should you wish to withdraw at any stage, or to withdraw any unprocessed data you have supplied, you are free to do so without prejudice.

If you would like to participate, please indicate that you have read and understood this information by signing the accompanying consent form and returning it in the envelope provided. The researchers will then contact you to arrange a mutually convenient time for you to view the web site and to complete the questionnaire and interview.

Should you require any further information, or have any concerns, please do not hesitate to contact either of the researchers; Dr Doe: 8344 0000, Mr Smith: 6546 4564. Should you have any concerns about the conduct of the project, you are welcome to contact the Executive Officer, Human Research Ethics, The University of Melbourne, on ph: 8344 2073, or fax: 9347 6739.

Yours ... etc.

**Dr Jane Doe (Supervisor)**

**Mr. John Smith (Honours Student)**

HREC: XXXXXX; Date: 21/09/09; Version: X.X

**Melbourne Graduate School of Education**

The University of Melbourne Victoria 3010 Australia

T: +61 3 8344 8285 F: +61 3 8344 8529 W: [www.education.unimelb.edu.au](http://www.education.unimelb.edu.au)

- This sample statement is NOT a prescribed statement, but gives an indication of the kind of information which should be included in a Plain Language Statement.
- The project discussed is fictional and is intended to give an idea about how you could word your plain language statement and how to include all the required information. The essential points for inclusion can be found in the checklist on the previous page.
- If your project takes a different approach to confidentiality and anonymity, You can view example alternate descriptions of confidentiality arrangements at <http://www.research.unimelb.edu.au/humanethics/external/>
- The letterhead for Plain Language Statements can be found at: <http://www.education.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20orms.doc>

### **PLAIN LANGUAGE STATEMENT [Sample Model for Children]**

**"What do grade five children in public schools know about politics?"**

Hello! My name is Jane Smith. I am a student at the University of Melbourne. I am doing a project to find out what people your age know about politics. When I finish my project it will be part of my degree, called a "PhD". My teacher, Dr John Somebody, helps me with my project. He is called my "supervisor". We both work in "the Department of Political Science".

Your school principal and your teacher have given me permission to send you this letter to tell you a bit about my project. Once you have read the letter you can decide if you would like to take part. You should talk to your parents about the project too.

If you want to be part of the project, I would ask you to read and answer some questions about politics, using a booklet. You and all the other people from your class who are taking part would go into a spare room for about 30 minutes to read the questions and write answers. I will be there to explain about the questions and collect the answers at the end. If you want to stop doing the questions, you can tell me and go back to the classroom any time you like. If you don't know an answer, or you don't want to answer a question, that's fine too. The rest of your class will be doing silent reading with your teacher.

Only my supervisor and I will see your answers, so please don't worry that your teacher might look at them. The project will have nothing to do with your school report or your grade for SOSE. You don't even have to write your name on the booklet, so no one will be able to tell which answers are yours.

After the project is over, I will lock all the booklets away safely in the Department of Political Science for 5 years. I have to do this because it is a University rule. After that my supervisor will destroy them.

Remember, you don't have to take part unless you want to. If you have any questions you should talk to your teacher or a parent. If they don't know the answer to your question, they can contact me, or my supervisor, or the Research Ethics Office at the University for you.

If you want to be part of my project, and your parent/s agree, please sign your name on the next page where it says "student", and get your parent or guardian to sign as well.

Yours ... etc.

**Dr. John Somebody (Supervisor)**

ph. 8344 0000

email: [j.somebody@unimelb.edu.au](mailto:j.somebody@unimelb.edu.au)

**Ms. Jane Smith (Honours Student)**

ph: 6546 4564

email: [j.smith1@unimelb.edu.au](mailto:j.smith1@unimelb.edu.au)

HREC: XXXXXX; Date: 21/09/09; Version: XX

**Melbourne Graduate School of Education**

The University of Melbourne Victoria 3010 Australia

T: +61 3 8344 8285 F: +61 3 8344 8529 W: [www.education.unimelb.edu.au](http://www.education.unimelb.edu.au)

- This sample statement is NOT a prescribed statement, but gives an indication of the kind of information which should be included in a Plain Language Statement.
- The project discussed is fictional and is intended to give an idea about how you could word your plain language statement and how to include all the required information. The essential points for inclusion can be found in the checklist on the previous page.
- If your project takes a different approach to confidentiality and anonymity. You can view example alternate descriptions of confidentiality arrangements at <http://www.research.unimelb.edu.au/humanethics/external/>
- The letterhead for Plain Language Statements can be found at: [http://www.education.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20For\\_ms.doc](http://www.education.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20For_ms.doc)



## PLAIN LANGUAGE STATEMENT [Sample Subheading Model]

**Project: "Explaining the ethics process: communicating procedures to applicants"**

### Introduction

Your name and contact details have been drawn at random from a database of former applicants for ethics approval with the permission of the General Manager of the Melbourne Research Office. As someone who has experience in applying for ethics approval, we would like to invite you to participate in our research project. The aim of the study is to investigate whether the instructions and information provided by the ethics web page needs to be improved, and if so, in what ways. This project has been approved by the Human Research Ethics Committee.

### What will I be asked to do?

Should you agree to participate, you would be asked to contribute in two ways. First we would ask you to look at the ethics web site and complete a 5 minute questionnaire, at a time convenient to you. This questionnaire would ask you to indicate your reactions to the web site, and your opinion of its efficacy in conveying information. Second, we would ask you to participate in a brief interview of about 15 minutes, so that we can get a more detailed picture of what improvements could be made. With your permission, the interview would be tape-recorded so that we can ensure that we make an accurate record of what you say. When the tape has been transcribed, you would be provided with a copy of the transcript, so that you can verify that the information is correct and/or request deletions. We estimate that the total time commitment required of you would not exceed 30 minutes.

### How will my confidentiality be protected?

We intend to protect your anonymity and the confidentiality of your responses to the fullest possible extent, within the limits of the law. Your name and contact details will be kept in a separate, password-protected computer file from any data that you supply. This will only be able to be linked to your responses by the researchers, for example, in order to know where we should send your interview transcript for checking. In the final report, you will be referred to by a pseudonym. We will remove any references to personal information that might allow someone to guess your identity; however, you should note that as the number of people we seek to interview is very small, it is possible that someone may still be able to identify you. The data will be kept securely in the Department of Communications for five years from the date of publication, before being destroyed.

### How will I receive feedback?

Once the thesis arising from this research has been completed, a brief summary of the findings will be available to you on application at the Department of Communications. It is also possible that the results will be presented at academic conferences.

### Will participation prejudice me in any way?

Please be advised that your participation in this study is completely voluntary. Should you wish to withdraw at any stage, or to withdraw any unprocessed data you have supplied, you are free to do so without prejudice. The researchers are not involved in the ethics application process. Your decision to participate or not, or to withdraw, will be completely independent of your dealings with the ethics committee, and we would like to assure you that it will have no effect on any applications for approval that you may submit.

### Where can I get further information?

Should you require any further information, or have any concerns, please do not hesitate to contact either of the researchers on the numbers given above. Should you have any concerns about the conduct of the project, you are welcome to contact the Executive Officer, Human Research Ethics, The University of Melbourne, on ph: 8344 2073, or fax: 9347 6739.

### How do I agree to participate?

If you would like to participate, please indicate that you have read and understood this information by signing the accompanying consent form and returning it in the envelope provided. The researchers will then contact you to arrange a mutually convenient time for you to view the web site and to complete the questionnaire and interview.

**Dr. John Somebody (Supervisor)**

ph. 8344 0000

email: [j.somebody@unimelb.edu.au](mailto:j.somebody@unimelb.edu.au)

**Ms. Jane Smith (Honours Student)**

ph: 6546 4564

email: [j.smith1@unimelb.edu.au](mailto:j.smith1@unimelb.edu.au)

HREC: XXXXXX; Date: 21/09/09; Version: X.X

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## Consent Guidelines / Sample consent forms

[Guidelines for informed consent](#)

[Requirements of the plain language statement](#)

[Requirements for consent forms](#)

[Sample Consent Form](#)

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### Guidelines for informed consent

For a copy of the guidelines for informed consent in research involving humans please select:

MS Word, 44 KB

### How to use the guidelines

This document was written with a view to help researchers reflect on the issues relating to developing procedures for gaining informed consent in their particular research context.

**Researchers need to obtain the informed consent of participants before the research can proceed . For an overview of what is meant by informed consent, see Sections 1 and 2 ; for a discussion of cases where informed consent is not needed, see Section 4 . In many cases, obtaining informed consent is straightforward, but in others the questions are more complex. For an outline of some of the issues which complicate obtaining informed consent, see Section 3.**

**In the most straightforward of cases, the researcher will provide participants with a plain language statement, which outlines the nature of the project, and explains fully the nature of their participation.** This plain language statement will be on University letterhead, will contain the title of the project, the name of the researcher (and the supervisor, if the researcher is a student). It will also provide a contact number for the participants to contact the researchers, and the contact details for the office for Research should there be any complaints. For a further explanation of the plain language statement, see Sections 2 and 5 . For a full outline of the requirements for a plain language statement please refer to Requirements of Statement of Written Information to be Given to Participants.

**In straightforward cases participants are to read and sign a consent form to enable the researcher to document obtaining informed consent .** The consent form will also be on University letterhead, and will outline what the participants are agreeing to take part in. It is to be stored securely by the researcher separate to any research data collected. For further information on the consent form, see Sections 5 and 6 . For further comment on the requirements of the consent form, and a sample consent form, see below . For a discussion of times when such documentation may not be appropriate, and some other available options, see Section 8.

## Requirements of the Consent Form

A statement of evidence of informed consent should contain the following information:

1. Clear identification of:
  - a. the University - the consent form is to be printed on University letterhead
  - b. the department or departments involved
  - c. the project title
  - d. the principal (and/or) other investigator(s);
2. A statement to the effect that the participant understands the nature of the project and what is expected of him or her, and his or her agreement to participate on that basis;
3. Acknowledgment by participants (where applicable) that they:
  - a. have read the written information about the project and have received a copy of that information;
  - b. have received an adequate explanation of all likely risks, effects, discomforts or inconvenience arising from participation in the project;
  - c. understand participation is voluntary and they have the right to withdraw from participation at any time and that they may withdraw any data they have supplied (up to the point of analysis/publication);
  - d. understand they will be video-taped, audio-taped, photographed ( if applicable )
  - e. are satisfied that the confidentiality of the information they have provided will be safeguarded subject to any legal limitations;
  - f. understand they will not be identified in any publication arising from the research; ( where participants elect to be identified, a tick-box could be included on the consent form to record this );
  - g. understand any special risks involved (e.g. mandatory reporting).
4. Signatures of participant and investigator. Where the participant is under the age of 18 years, and is participating on an individual basis, the parent or guardian should also sign a consent form. It may be appropriate for separate forms to be used for parents and children, alternatively both sign the same form. The signature of a third party witness may also be necessary (please refer to section 7 of the guidelines). Evidence of consent can also be recorded by way of signature of a third party who witnessed the informed consent process.

## Consent Form Checklist

Confirm that the Consent Form:

	YES	NOT APPLICABLE
1. is printed on University of Melbourne letterhead	<input type="checkbox"/>	
2. includes the title of the project and names of researchers	<input type="checkbox"/>	
3. states that the project is for research purposes	<input type="checkbox"/>	
4. states that involvement in the project is voluntary and that participants are free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied	<input type="checkbox"/>	
5. states particular requirements of participants including, for example, whether interviews are to be audio and/or video-taped	<input type="checkbox"/>	<input type="checkbox"/>
6. includes arrangements to protect the confidentiality of data	<input type="checkbox"/>	
7. includes advice that there are legal limitations to data confidentiality (see below)**	<input type="checkbox"/>	
8. (if the sample size is small) addresses implications for protecting the identity of the participants	<input type="checkbox"/>	<input type="checkbox"/>
9. (once signed and returned) states it will be retained by the researcher	<input type="checkbox"/>	

- This sample form is NOT a prescribed form but gives an indication of the kind of information which should be included in a consent form. The consent form is to be printed on University letterhead. Please delete explanatory information from your final consent form.
- Where participants are less than 18 years of age, space needs to be provided for the parent/guardian to sign the consent form. For some research it may be more appropriate to develop separate consent forms for the child and the parent/guardian.
- The letterhead for Consent Forms can be found at:  
<http://www.education.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20orms.doc>



## **CONSENT FORM [Sample Model for Persons Participating in Research]**

**PROJECT TITLE:**.....

Name of participant:

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Name of investigator(s):

---

1. I consent to participate in the project named above, the particulars of which - including details of ..... (*include terms relevant to the methodology of the research, e.g., "tests or procedures", "interviews and questionnaires"*) - have been explained to me. A written copy of the information has been given to me to keep.
2. I authorise the researcher or assistant to use for this purpose the ..... (*include phrase used at 1 above*) referred to under (1) above.
3. I acknowledge that:
  - (a) the possible effects of the ..... (*include phrase used at 1 above*) have been explained to me to my satisfaction;
  - (b) I have been informed that I am free to withdraw from the project at any time without explanation or prejudice and to withdraw any unprocessed data previously supplied;
  - (c) The project is for the purpose of research /  
The project is for the purpose of research and not for treatment; (*for medical research*)
  - (d) I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements.
  - (e) (*include other clauses as relevant, e.g., consent to interviews being audio-taped, acknowledgement that copies of transcripts will be returned to participant for verification, participants to be referred to by pseudonym or identified by name in any publications arising from the research, and in instances where a dependent relationship is involved confirmation that participation or non-participation in the research will have no affect on grades/assessment/employment*)

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Participant)

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Parent/Guardian) [if required – see section 3.6 of guidelines]

HREC: XXXXXX; Date: 21/09/09; Version: XX

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**TELEPHONE TRANSCRIPT GUIDELINES**  
**incorporating the PLAIN LANGUAGE STATEMENT and CONSENT**

**THE TELEPHONE TRANSCRIPT SHOULD:**

1. State clearly the University and the Department(s) involved; the project title; all named Researchers, and (if relevant: the study level if it is a student research project).
2. State that the project has received ethics clearance by the University and the Department(s) involved, identifying the 'Ethics Id. Number' and 'Date' clearance was received.
3. State the purpose of the research project.
4. State the requirements of the participant, including for example, whether the telephone interview is to be audio-taped, and the estimated time commitment.
5. (If relevant) state clearly any dependent relationship/conflict of interest between researcher/participant/sponsor and stakeholder involved and/or associated with the project, and that this will not affect ongoing assessment/grades/management or treatment of health.
6. State that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data supplied.
7. Confirm arrangements to protect the confidentiality of data, as well as advise that there are legal limitations to data confidentiality (**see below**) \*\*.
8. (Relevant when the sample size is small) confirm that there may have implications for protecting the identity of the participants.
9. (If relevant) confirm to the participant whether or not their data will be destroyed after a minimum period and state that period.
10. State if participants have any concerns about the conduct of the research project that they can contact in writing to: **The Executive Officer, Human Research Ethics, The University of Melbourne, Victoria 3010** or telephoning: **8344 2073** or faxing: **9347 6739**.
11. State (upon obtaining verbal consent) this will be recorded and retained by the researcher (and if appropriate, offer an opportunity for the participant to receive a copy of the research outcomes).

[\*\* Re 7 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state these limitations]

# Melbourne Research Human Ethics

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## Completing an ethics application: A step by step guide

All human ethics applications are created using the Human Ethics module in [Themis](#). Most researchers should have automatic access but some students may need to arrange this through the [Themis Helpdesk Service Centre](#). The module allows researchers to submit and track their applications electronically, from drafting through to the completion of research. Appropriately signed hard copies of applications are also required.

**Follow the steps below to complete and submit your human ethics application:**

1. [Application types](#)
2. [When to apply](#)
3. [Starting the application](#)
4. [Completing attachments](#) (inc. Plain Language Statement and Consent Form)
5. [Submitting hard copies](#)
6. [Making revisions](#)

[Using the Human Ethics Workbench in Themis](#) (pdf, 89kb)

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# Melbourne Research Human Ethics

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## 1. Application types

There are several types of human ethics application available on Themis. You will be automatically directed to the appropriate form as you complete the online application. If you need advice contact your [Human Ethics Advisory Group](#) (HEAG) or the [Human Ethics office](#).

### Minimal risk application

Used for projects that present low risk according to a checklist of criteria. Applicants complete the risk checklist within the Themis online application form to determine whether this route may be appropriate. The ultimate decision as to whether the application is eligible for minimal risk review lies with the HEAG. HEAGs have delegated authority to approve Minimal Risk applications.

- [Creating a Minimal Risk application](#) (pdf, 114kb)

### Standard project application

Used for projects that present more than low risk as defined by the National Statement on Ethical Conduct in Human Research. A Standard Project must be first reviewed by the HEAG before being submitted to the Human Ethics Sub Committee (HESC) for review and approval.

- [Creating a Standard Project application](#) (pdf, 88kb)

### Program application

A Program application covers a program of research within which a series of related individual research projects are to be undertaken. For example, a research program might identify a common research question which is then explored via individual projects using standard methodologies. A Program application requires HEAG review and HESC approval. Refer to the [Guidelines relating to the Program Application](#) model for more information.

Once the Program has been approved by the HESC, the individual projects are then reviewed and approved by the HEAG using a Project-within-Program application.

- [Creating a Program application](#) (pdf, 90kb)
- [Creating a Project-within-Program application](#) (pdf, 95kb)

### Registration of approved application

Used when a University researcher needs to register an ethics approval obtained from another institution's human research ethics committee, and where the approving institution will remain the responsible committee. For example, where a student's research is undertaken in one of the teaching hospitals and ethics approval is gained through the hospital. While the approving human ethics committee will remain responsible for the oversight of the project, the researcher will need to register the details of the approval with the University and provide annual reports.

- [Creating a Registration of External Ethics Clearance](#) (pdf, 102kb)

## Transfer application

Used where a researcher wishes to transfer ethics approval obtained from a human research ethics committee at another institution, so that the University of Melbourne will become responsible for the research. For example, where a researcher has moved from another university and will be continuing existing research projects.

- [Creating a Transfer application](#) (pdf, 104kb)

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Maintainer: Human Ethics, Melbourne Research Office Email: [research-web@unimelb.edu.au](mailto:research-web@unimelb.edu.au)

# Melbourne Research Human Ethics

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## Program Application guidelines

- [Overview](#)
- [Who can submit a Program Application?](#)
- [Who cannot submit a Program Application?](#)
- [What does a Program Application need to include?](#)
- [Approval process](#)
- [What does the HEAG need to do?](#)
- [Specific requirements](#)

### [Overview](#)

The University of Melbourne's Human Research Ethics Committee (HREC) has developed a model for the submission of ethics applications for use by Departments seeking ethical approval for a program of research encompassing multiple research projects. The model is designed to expedite the approval of standard/routine research.

Each Program application must identify a common set of ethical issues within an approved research framework. A Program application may either identify one common research question, which uses a number of methodologies, or one cohesive methodological approach, which may be applied to a number of differing research questions.

Once a Program application has received the approval of a Human Ethics Sub-Committee (HESC) the appropriate Human Ethics Advisory Group (HEAG) can then approve projects which fit within this Program application. Departures from the approved protocol must be submitted back to the relevant HESC for approval.

### [Who can submit a Program Application?](#)

Any researcher or group of researchers in a department which has an established HEAG can submit Program applications to the HESC for review and approval. The model is designed to allow research groups or departments to conduct a program of research, within which individual projects can be identified to be undertaken as part of the program.

Some researchers may find it advantageous to submit a Program application for the following types of research:

- student research (especially at honours level) where the aims/methodologies do not vary greatly;
- research which involves repetitive administration of standard tests/procedures/questionnaires on a sample group;
- where supervisor/s identify an integrated research question and then various aspects of that research are addressed as projects by supervisor and students;
- where standard methodologies used in certain disciplines are well accepted but the actual research questions may differ.

### [Who CANNOT submit a Program Application?](#)

Researchers in departments without an established HEAG cannot submit Program applications and need to submit an individual Standard Project application for review by the relevant HESC.

Researchers undertaking studies towards a PhD would NOT normally have their research approved as part of a Program application. Candidates would be required to obtain ethical clearance for their research by submitting a Standard Project application. As candidates for the PhD would normally be undertaking research of a novel nature, over a number of years, preparation of the Standard Project application is considered a valuable activity in conceptualising and developing the research plan for research involving human subjects.

## What does a Program Application need to include?

In preparing an application it is important to ensure a cohesive approach. Each Program application must identify a common set of ethical issues within an approved research framework. There must be one core shared theme which will operate in all projects under the Program application. This would involve either:

- the identification of an integrated question of research which would form the basis of all Project within Program Applications, under which there may be a number of identified methodologies to be used; or
- the identification of one cohesive methodological approach which could be used by researchers addressing a range of research questions.

Note that a Program application would not normally be developed to cover both of the above

The information that is required in the Program Application is to be sufficient to ensure that the potential ethical issues raised by a given research program can be evaluated by others, with special reference to those who claim no professional expertise in the discipline. Specific details to be included in the application are detailed in the Program Application.

## Approval process for a Program Application

Once the Program application has been finalised by the researchers it should be submitted through the HEAG and Head of Department to the relevant HESC for approval. The approval process is the same as for Standard project applications.

The HESC will review the Program Application, recommend any changes and/or approve the application. The application will normally be valid for five years from the date of approval.

Individual projects falling within the approved program can be approved by the HEAG during that period. Researchers seeking approval to conduct projects within a program, need to complete a Project-within-program application and forward the application to the relevant HEAG for approval.

Details of approved Project-within-program applications are submitted regularly to the relevant HESC for ratification, with auditing by the Sub-Committees of specific projects also taking place.

## What does the HEAG need to do?

HEAGs are responsible for ensuring that the Project-within-program applications submitted for approval fit appropriately within the approved Program.

After approving a Project-within-program application, the HEAG is to forward one copy to the Executive Officer, Human Research Ethics at the Melbourne Research Office for noting by the relevant HESC.

The HEAG must keep appropriate records, including original applications of all Project-within-program applications approved by that Department. These records will be subject to audit by the relevant HESC.

## Specific requirements

### (a) Program Application

It is important for researchers to include some general information about the types of projects that will be

submitted as part of the Program. In particular, researchers need to consider the ethical issues that will arise from this research, with specific attention paid to identifying risks and risk management strategies.

Researchers should attach a draft of a typical advertisement, plain language statement and consent form with the Program application.

## (b) Project-within-Program Application

Approval of a Program application does not mean that a specific research project can commence. This will require the submission of a Project-within-program application to the HEAG.

Researchers undertaking a project which is part of an approved Program need to complete the Project within a Program Application and submit it to their relevant HEAG for approval. When completing the application, researchers must ensure they have obtained a copy of the approved Program application for reference. Once approved by the HEAG, the project can commence.

All Project-within-program applications MUST share the following elements in common with the corresponding Program application:

- theoretical structure
- integrated research question or methodological approach
- investigators - i.e., at least one of Principal Investigators nominated in program must be associated with Project-within-Program applications
- sample population
- risk/inconvenience to participants
- confidentiality/informed consent
- risks to researchers

If a Project-within-program differs substantively from the approved Program in any of the above areas it will be necessary to either submit an application for an amendment to the Program or treat the application as a Standard Project application (unrelated to the Program), which will need to be reviewed by the relevant HESC. Researchers need to give particular attention to differences that will have ethical implications (e.g., the sample population, methodological approach, risks to participants/researchers).

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# Melbourne Research Human Ethics

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## 2. When to apply

It is important to allow sufficient time for the review of your application as your research cannot commence until you have received ethics approval. Some applications require a two-stage review process, and this should be accounted for when considering your project commencement date:

- Minimal Risk applications are reviewed and approved by the Human Ethics Advisory Group (HEAG).
- Standard Project applications are first reviewed by the HEAG then forwarded to the Human Ethics Sub Committee for final approval.

### HEAG review

- [Find HEAG contact](#)

Researchers should consult with their HEAG administrator to identify submission dates for applications. Following assessment of the application, the HEAG may ask you to make certain changes ahead of approval or recommendation to the HESC. Also allow time for the sign off of all researchers and the endorsement of the Head of Department.

### HESC review

- [Find HESC meeting dates and deadlines](#)

In the case of Standard Project applications and Program applications, HESC review will follow HEAG approval. HESCs meet monthly during semester, with submission deadlines around 10 working days before each meeting. Arrange your project commencement date to account for any revisions that the HESC may ask for prior to approval. Such revisions may require resubmission to the next HESC meeting.

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# Melbourne Research Human Ethics

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## 3. Starting the application

For all new applications follow these initial steps:

1. Log into the Themis Research System
2. Select the Research - Self Service menu
3. Select the Human Ethics Workbench and click on the Create button
4. Complete the online screens, making sure that: all questions are answered (the notation "N/A" may be inserted); responses to questions seeking a 'yes' or 'no' response are clear; and the specified word limits are observed. The following Reference Cards will help you complete different screens within the form:
  - o [Creating an external researcher in the ethics module](#) (pdf, 33kb)
  - o [Completing the Other Ethics Clearance screen](#) (pdf, 39kb)
  - o [Completing the Sponsored Projects screen](#) (pdf, 27kb)
  - o [Completing the Drug Trials screen](#) (pdf, 23kb)
  - o [Completing the Aboriginal and Torres Strait Islanders screen](#) (pdf, 24kb)
  - o [Completing the Clinical Trials screen](#) (pdf, 27kb)
  - o [Completing the Location of Research screen](#) (pdf, 32kb)
  - o [Completing the Other \(Non-Ethics\) Approvals screen](#) (pdf, 38kb)
5. Click on the link provided to the appropriate Ethics Application Form (e.g. Minimal Risk Project). This MS Word form should be downloaded onto your computer, completed offline, then electronically attached to the Themis record prior to submission.
6. Electronically attach subsidiary documents (e.g. Plain Language Statement).
7. Submit your electronic application (an email confirmation will be sent to all researchers). It will now appear in Themis as 'Lodged'.
8. You can track the progress of your application by logging back into Themis.

[Creating a Human Ethics application overview](#) (pdf, 36kb)

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# Melbourne Research Human Ethics

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## 4. Completing attachments

Make sure that all required documents are included as attachments to your application within Themis. This includes:

- Recruitment advertisements
- Plain Language Statement
- Consent form (one example not all signed copies)
- Copies of all supporting documentation
- Letters approving the conduct of the research from other organisations

If final versions of these documents are not available, please include drafts initially. Final versions must be provided before ethics approval can be given.

- [Attaching documents to a Human Ethics application](#) (pdf, 48kb)

### Informed consent requirements

Researchers need to obtain the informed consent of participants before research can proceed, and attach evidence of this to their application. Generally this will be in the form of a Plain Language Statement and a consent form. Section Two of the [National Statement on Ethical Conduct in Human Research](#) (NHMRC) contains general advice on when informed consent is needed, and on circumstances which may allow the qualification or waiving of consent.

#### (a) Plain Language Statement (PLS)

The PLS describes the project and the nature of participation, enabling informed decision-making by participants. It should be presented in a format appropriate to the particular study group (consider headings, diagrams, use of language suitable to age and educational standard).

- [Requirements and example statements](#)

#### (b) Consent form

Participant signing of consent forms enables a researcher to document the gaining of informed consent. Signed forms should be stored securely, separate to any research data collected. A blank copy of the consent form should be submitted for review, not forms signed by participants.

- [Requirements and sample form](#)

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# Melbourne Research Human Ethics

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## Plain Language Statements

### Example statements

It is not intended that all PLSs resemble the models provided below. They are illustrative examples taken from real applications.

- [Letter model](#)
- [Subheadings model](#)
- [Children's model](#)
- [Intercultural models](#)

### What to include in a Plain Language Statement (PLS)

The PLS should be written in an inviting tone (i.e. as an invitation to participate), and should tell participants why and how they were selected. It should contain the following:

#### Researcher details

Clear identification of the:

- University (statement to be printed on University letterhead).
- Department or departments involved.
- Project title.
- Principal and other investigator(s) with contact details (inc. a direct telephone number)
- Supervisor, if it is a student research project.
- Degree for which the research is being undertaken (if student project).

#### Procedures/risks

An explanation, in language that the participant will understand, of the aim of the project and the procedures to be followed (e.g. surveys, interviews, video-taping, audio-taping, blood testing). This should include a complete description of what participants are expected to do, the anticipated time involved, and any possible risks, discomfort or inconvenience resulting from these procedures (and plans to minimize or avoid them). If children are the participants a statement should be provided in language they can understand, as well as a statement suitable for their parents/guardian.

#### No prejudice

If provision of services, benefits, medical treatment, education or other care is involved, a statement that involvement or non-involvement in the project will not affect ongoing management, treatment, assessment/results or employment situation should be included.

#### Right to withdraw

Clear indication that participation in the project is voluntary, and a statement that consent, participation

and previously supplied data may be withdrawn at any time until data is processed. If consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained.

## Confidentiality procedures/data use and storage

- Details of the anticipated use of the data (e.g. thesis, publication) and whether or not copies of reports will be given to participants.
- An explanation of procedures adopted to ensure confidentiality of data, and any limits to confidentiality (subject to legal requirements, mandatory reporting requirements, duty of care to third party etc).
- Information about how the data will be used and, where necessary, the steps to be taken to ensure that participants will not be identified. (For example, if case histories are to be written up, a statement to indicate that information will be disguised by use of pseudonyms or other devices).
- An explanation of when you will destroy the data if you intend to do so; or else informing them about the purposes of keeping the data, such as in a longitudinal study where you may need to re-contact them.

## Funding

Identification of funding bodies and sponsors of the research.

## Further assistance

- An offer to answer any questions and a contact name and direct telephone number for the research team if any further explanation is required.
- Arrangements for debriefing or follow-up where this is necessary to secure the well-being of participants.
- A statement that if participants have any concerns regarding the conduct of the project, which they do not wish to discuss with the research team, they can contact: Executive Officer, Human Research Ethics, University of Melbourne, VIC 3010. Tel: (03) 8344 2073.

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Date created: 09 Jul 2008 4:11pm Last modified: 29 Sep 2009 10:19am Authoriser: Executive Director, Research  
Maintainer: Human Ethics, Melbourne Research Office Email: [research-web@unimelb.edu.au](mailto:research-web@unimelb.edu.au)

# Melbourne Research Human Ethics

## Consent forms

### Sample consent form

The sample consent form below must be tailored to the details of your particular research project.

- [Sample consent form](#)

### What to include in a consent form

See also sections 5, 6 and 8 the University's [Guidelines for Informed Consent in Research Involving Humans](#). Section 8 includes a discussion of circumstances when such documentation may not be appropriate, and some other available options.

#### 1. Identification of the:

- University (i.e. printed on University letterhead).
- Department or departments involved.
- Project title.
- Principal and other investigator(s).

#### 2. A statement to the effect that the participant understands the nature of the project and what is expected of them, and his or her agreement to participate on that basis.

#### 3. Acknowledgment by participants that they:

- have received a copy of and read the Plain Language Statement;
- have received an adequate explanation of all likely risks, effects, discomforts or inconvenience arising from participation in the project;
- understand participation is voluntary, that they have the right to withdraw at any time, and that they may withdraw any data they have supplied (up to the point of analysis/publication);
- understand if they will be video-taped, audio-taped, photographed;
- are satisfied that the confidentiality of the information they have provided will be safeguarded subject to any legal limitations, and understand any special risks involved (e.g. mandatory reporting);
- understand they will not be identified in any publication arising from the research (where participants elect to be identified, a tick-box could be included on the consent form to record this).

#### 4. Signatures of participant and investigator

Where the participant is under 18 years of age, and is participating on an individual basis, the parent or guardian would normally also sign a consent form. It may be appropriate for separate forms to be used or for both to sign the same form. In some cases others may be involved in the consent process. See: [National Statement on Ethical Conduct in Human Research \(2.2.12 and 2.2.13\)](#).

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# Melbourne Research Human Ethics

## 5. Submitting hard copies

Submitting an ethics application involves BOTH electronic submission via Themis and hardcopy submission to your Human Ethics Advisory Group (HEAG) and, where necessary, the Human Ethics Sub Committee (HESC).

### Preparing hard copies

The hard copy version of an ethics application will include:

- Application Summary (data entered directly into Themis)  
See [Printing your Human Ethics application summary](#) (pdf, 97kb)
- Application Form (the form you completed, saved and attached to Themis).
- Other Attachments (either electronically attached via Themis or provided in hard copy only)

Assemble documents in this order and obtain all the necessary researcher signatures. The printed version is now ready for submission.

### Submitting to a HEAG

- [Contact your HEAG](#) and establish its submission procedures (such as how many hard copies they require) and deadlines. Once the application is printed and signed by all researchers, submit it to the HEAG Chair.
- Following HEAG sign off, applications need endorsement by the Head of Department. A Responsible Researcher on the project cannot sign off as Chair of HEAG or Head of Department, if they also hold that role. The Acting Head/Chair will sign off in this instance.
- For Minimal Risk and Project-within-program applications, save a copy for yourself and await revision request or written notification of approval from the HEAG.

### Submitting to a HESC

After initial assessment by the HEAG, Standard Project applications and Program applications also require HESC review and approval.

- When? Find out the HESC [meeting dates and application deadlines](#).
- How many? Send the original (single-sided) signed application (including any attachments) plus 14 double-sided copies.
- Where? Human Ethics, Melbourne Research Office, University of Melbourne (Level 5, Alan Gilbert Building, 161 Barry Street). Tel: 8344 2071.
- What happens next? Save a copy for yourself and await notification of the outcome of the HESC review. Do not start your research before approval has been received.

#### Note on 'Commercial in Confidence'

Approved hardcopy applications are held in a formal register of projects which, under certain circumstances, may be accessed by others. If your project includes commercial or patentable information this should be sent separately as part of your application and clearly marked "confidential" or "commercial in confidence".

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# Melbourne Research Human Ethics

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## 6. Making revisions and updates

### Human Ethics Advisory Group (HEAG) requests

Following the initial review of your application, the HEAG may ask you to include more information or make certain other changes prior to approval, or recommendation to the HESC. The [HEAG administrator](#) will advise you on this process.

### Human Ethics Sub Committee (HESC) requests

Following review of an application, you will be contacted by the HESC in one of two ways:

1. If the application is approved a written approval letter will be sent to the Responsible Researcher.
2. If the application is not yet approved an email will be sent to the researchers requesting changes and any additional information if required. The response will be considered by the HESC.

If you are asked to make changes or provide additional information:

- Do not submit a new application, unless specifically requested to do so.
- Prepare your response to each issue raised, citing item number. Lengthy responses should be prepared as word documents.
- Attach any documents (e.g. Plain Language Statement, consent form, survey) that have been revised as a result of any changes made.
- Email the response with attachments back to the [HESC Secretary](#).

### Updating an application after submission

Sometimes an application may require updating after it has been submitted (e.g. updates to the registry information for clinical trials, updating additional ethics or other approvals, and providing details of location of research). The Human Ethics Workbench allows a researcher access to these screens in order to update details where required.

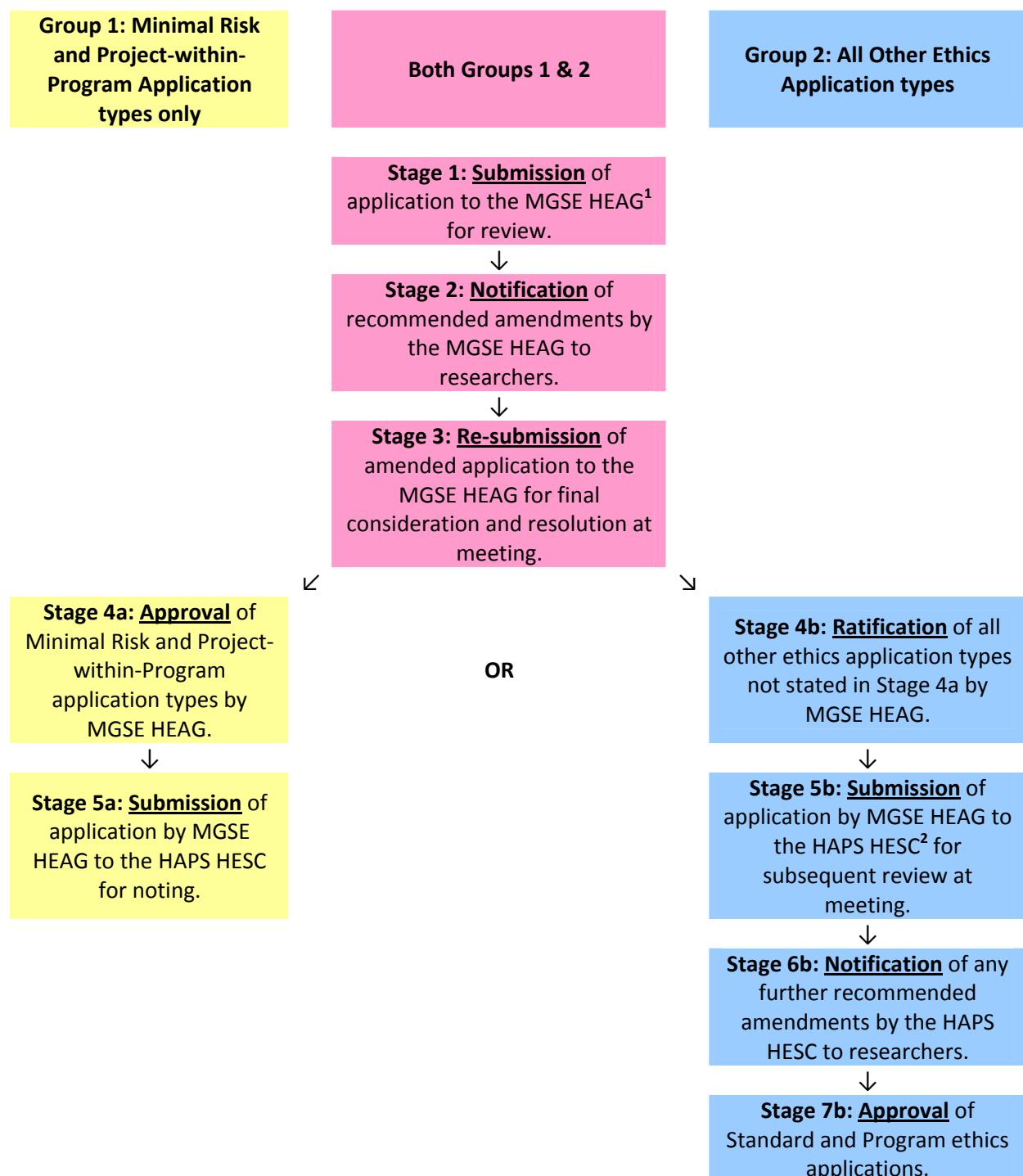
- [Updating an Ethics Application via the Workbench](#) (pdf, 34kb)

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**Melbourne Graduate School of Education**  
**Human Ethics Advisory Group**

## The process for handling ethics applications



Note:

<sup>1</sup> MGSE HEAG is the Melbourne Graduate School of Education Human Ethics Advisory Group

<sup>2</sup> HAPS HESC is the Humanities and Applied Science Human Ethics Sub-Committee

**THE MELBOURNE GRADUATE SCHOOL OF EDUCATION**  
**HUMAN ETHICS ADVISORY GROUP**

**General Guidelines of Roles in the MGSE Ethics Process**

(Ratified by MGSE HEAG on 19 March 2008)

**Role of the Chairperson**

The Chairperson of the HEAG undertakes the following responsibilities:

1. To convene and Chair at least 4 meetings of the HEAG per year
2. To provide an annual report to the HREC
3. To attend a HREC meeting to discuss the annual report
4. To liaise with the Chair and Administrative Officer of the HREC regarding projects in the department
5. To attend compliance training with the University's Legal and Compliance Office
6. To attend University ethics training sessions
7. To provide advice to staff on individual ethics applications
8. To organise workshops for staff and students on ethical issues and applications
9. To monitor all reviews conducted by HEAG and checking that comments are attended to
10. To sign off on applications
11. To monitor submission of annual reports from individual academics

**Role of the Deputy Chair**

The Deputy Chairperson of the HEAG undertakes the following responsibilities:

1. To attend and in the absence of the Chair, deputise at meetings of the HEAG.
2. To attend training sessions
3. To review applications
4. To liaise directly with staff regarding reviews on behalf of the committee
5. To attend compliance training with the University's Legal and Compliance Office
6. To provide advice to staff on individual ethics applications
7. To sign off applications in the absence of the Chair

## **Role of the Research Ethics Officer**

The Research Ethics Officer undertakes the following responsibilities:

1. To enter project data into Themis
2. To manage HEAG business via Themis
3. To attend ethics meetings, record the minutes and follow-up actions
4. Process correspondence relating to human ethics business
5. Photocopying and scanning of applications
6. To assist the HEAG Chair
7. To provide technical assistance to researchers & research administrators
8. To attend Themis ethics training
9. To provide general advice
10. To liaise with the Research Office and Themis Help Desk

## **Role of HEAG committee members [i.e. reviewers]**

The HEAG committee members undertake the following responsibilities:

1. To attend 2 HEAG meetings per semester
2. To review applications<sup>1</sup> and submission of comments to the HEAG Administrative Officer
3. To return reviewed applications within **five** working days
4. To be familiar with the University's policy on Human Research Ethics
5. To be familiar with the National Statement on Human Research Ethics
6. To provide advice to individual applicants in their relevant discipline area

## **Role of the Applicant, including Supervisors**

### All applicants

1. To be familiar with the University's policy on Human Research Ethics
2. To be familiar with the National Statement on Human Research Ethics
3. To check that the application is complete and compliant
4. To sign off on the application
5. To respond to comments from the reviewers promptly

### Supervisors

1. Where applicable, to advise students on the ethics application process
2. To support students in the development of their application, including issues such as feasibility, theoretical justification, ethical considerations
3. In the case of student applications to advise the applicant on the reviewers' comments and ensure that the student addresses them
4. To submit an annual report on the status of the project

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<sup>1</sup> The expected ethics application review commitment is: one review per month for 0.5 & 0.6 eft appointed staff; two reviews per month for 0.7 & 0.8 eft appointed staff; and three reviews per month for 0.9 & 1.0 eft appointed staff.

# Melbourne Graduate School of Education

## Human Ethics Application Cycle – 2012

(Confirmed as at 30/01/2012 – Version 2.1)

Cycle Month	Submission Deadline to MGSE HEAG Administrator	Researchers Notified of Feedback	MGSE HEAG Completed Application Deadline for Sign-off	MGSE HEAG Meeting	Submission Deadline to HAPS HEAG Administrator	HAPS HESC Meeting Date	HAPS HESC Feedback sent for subsequent Approval thereafter
Day of Week	Monday	Monday: two weeks later	Monday: one week later	Thursday^	Tuesday: one week later	Thursday: two weeks later	Tuesday
<b>Note 1:</b>	<u>Minimal Risk and Project-within-Program Timeline: White Section</u>						
Jan	3 January (Tuesday)	13 January (Friday)	16 January	19 January [Full]	24 January	9 February	14 February
Feb	23 January	6 February	13 February	16 February [Exec]	21 February	8 March	13 March
Mar	20 February	5 March	12 March	15 March [Exec]	20 March	3 April (Tuesday)	6 April (Friday)
Apr	2 April	23 April	30 April	3 May [Exec]	8 May	24 May	29 May
May	7 May	21 May	28 May	31 May [Full]	5 June	21 June	26 June
Jun	NO CYCLE				NO MEETING OF HAPS HESC <sup>#</sup>		
Jul	18 June	9 July	16 July	19 July [Full]	24 July	9 August	14 August
Aug	30 July	13 August	20 August	23 August [Exec]	28 August	13 September	18 September
Sep	27 August	10 September	17 September	20 September [Exec]	25 September	11 October	16 October
Oct	24 September	8 October	15 October	18 October [Exec]	23 October	8 November	13 November
Nov	22 October	5 November	12 November	15 November [Exec]	20 November	6 December	11 December
Dec	19 November	3 December	10 December	13 December [Full]	NO MEETING OF HAPS HESC <sup>#</sup>		
<b>Note 2:</b>	<u>Standard Project and Program Timeline: White, plus Yellow Sections</u>						

PLEASE NOTE:

These dates above should be used as a GUIDE when preparing an ethics application for submission and subsequent approval.

Ratification and/or approval of an ethics application can take up to a week after the respective ethics committee has met.

Public Holidays the University observes in 2012:

- Australia Day – Thursday 26 January
- Easter Tuesday – Tuesday 10 April

<sup>#</sup> means there are NO HAPS HESC (Central Committee) Meeting for the June or December cycles – so NO project or program applications can be approved and will be held over by the HAPS HESC (Central Committee) to the following meeting.

<sup>^</sup> means the Graduate School Human Ethics Committee meets to ratify project & program applications and approve all other (Minimal Risk, Project within Program, etc.) ethics applications received in that cycle.

- (Exec) is the MGSE HEAG Executive Committee (i.e. the Chair, Deputy Chair of the HEAG with the Research Ethics Administrator);
- (Full) is the full MGSE HEAG Committee.

## **SECTION 2:**

# **Themis On-line**

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# Setting/resetting your Themis password

Before using Themis you will need to set (or reset) your **themisprod** password in the Account Registration System (ARS).

**Important:** to comply with audit requirements this password must be different to your email password.

You must have an active email account (staff or research student) in order to set/reset your Themis password. As it takes 24 hours to create an email account, you will not be able to create your email account and Themis account on the same day.

## To set your Themis password

- 1 Open a web browser and navigate to the ARS website (<http://accounts.unimelb.edu.au/>).
- 2 Click on the **Staff** or **Student** button.

The associated login screen (staff or student) will display. The example below displays the Staff Login screen.

**Staff Login**

Name :	Brandon Z Cattle	(Enter all given names followed by family name)	
Staff ID :	0001234	(Numeric component only)	
Birthdate :	14	August	1975
Postcode :	3010		
Pin :	****	(as set in Themis, or last 4 digits of primary bank account)	
<input type="button" value="Login"/>			

- 3 Enter your staff or student details and click the **Login** button.

- Staff will need to provide: full name, staff ID, date of birth, postcode, bank account or Themis PIN.
- Students will need to provide: full name, student ID, date of birth, postcode, library barcode.

- 4 Click on the **Set/Reset** button for your *themisprod* password in the appropriate section of the screen.

**Note:** if you are setting your password for the first time, your screen will be divided into two sections: New Accounts available for Activation and Existing Accounts.

**List Accounts**

**Existing Accounts**

	Host	Description	Username	Group
	budgie	WWW Server	bcattle	webusers
Reset	forte	WebMenu/Employee Kiosk	bcattle	users
Reset	mail	Staff Central E-mail Service	bcattle	popmail
Reset	themisprod	Themis Service	bcattle	users

- 5 Enter and confirm your new password then click the **Submit** button.

**Resetting password: themisprod**

Please enter a new password for your account.

Password :	<input type="password"/>
Password confirmation :	<input type="password"/>
<input type="button" value="Submit"/>	

If your change has been successful, the phrase "Password changed on themisprod" will appear in red.

- 6 Remember to log out of your ARS session when you have finished resetting your passwords.

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# Using the Human Ethics Workbench in Themis

The Human Ethics Home Page - Research Worklist screen in Themis allows you to view all human ethics applications you have created as well as those where you have been nominated as a researcher. In addition, it allows you to access your ethics application records to either view a summary of the application or update/modify the application details.

## To access the Human Ethics Home Page

- 1 Log on to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.

The Human Ethics Home Page will display.

Human Ethics Home Page - Researcher Worklist						
Create New Documents						
Ethics Application (including transfers and registrations): <a href="#">Create</a>						
ITEMS REQUIRING ACTION						
Items below are awaiting action before they can be approved. If you will not be actioning the item, ensure you ask the relevant researcher (who must be named against the ethics application to have access) to do so. Whilst they will not see the item in the 'Items Requiring Action' section of their worklist, they will be able to access the relevant application from their 'Current Applications' section.						
<b>Revisions Required</b>						
Ethics Id	Document Type	Application Type	Responsible Researcher	Title		Update
No items						
<b>Draft Items Not Yet Submitted</b>						
Ethics Id	Document Type	Application Type	Responsible Researcher	Title		Update
0600106.1	Ethics Application	Minimal Risk	SMART, PROFESSOR VERI	Did the aliens create the Great Pyramids?		
0600209.1	Ethics Application	Registration	BUTTS, DR SEYMOUR	How to exit a bean bag with style		
<b>Annual Reports Due</b>						
Ethics Id	Application Type	Responsible Researcher	Title			Update
No items						
<b>CURRENT APPLICATIONS</b>						
Ethics applications below are those on which you are named as a contributing researcher. Applications included are those that have been submitted for review, currently under review, or have been approved (and still current). If you wish to view any applications which have not yet been submitted (and which are not included in the above section) or which are inactive, you can locate these via the search option.						
<a href="#">► Refine Search</a>						
Ethics Id	Application Type	Responsible Researcher	Title	Status		View
0600140.1	Project Application	CLASS, PROFESSOR HEDDA D	The family brain-cell - how to maximise its usage	Lodged		
0600148.1	Program Application	BALL, DR CRYSTAL	Mystery and the Occult	Approved HESC		
0600149.1	Transfer	TONIC, DR GINNY	Drinking and the Pink Elephant Phenomenon	Lodged		

## Rewards Required

When a HREO or HEAG administrator requires amendments to an ethics application and changes the application status to **Rewards Required**, the application will display in this section. Either the Responsible Researcher or the creator of the application will be able to access the application to make the amendments requested. Any other named researcher will be able to search for and view the application.

## Draft Items Not Yet Submitted

Any human ethics application that has been **Saved as Draft** but not yet submitted will display in this section. Either the Responsible Researcher or the creator of the application will be able to access the application to continue to work on it. Any other named researcher will be able to search for and view the application.

## Annual Reports Due

Any human ethics applications that have been submitted and approved or ratified by the HESC (in a system status of **Finalised**) have reporting obligations. Any applications with a report due will display in this section. Either the Responsible Researcher or the creator of the application will be able to access the annual report to complete and submit. Any other named researcher will be able to search for and view the annual report.

## Current Applications

This section displays any current ethics applications on which you are named as a contributing researcher (including applications that have been submitted for review, are currently under review, or have been approved and are still current). To locate applications with the status of **Not Submitted** (and not present in Items Requiring Actions) or **Inactive** use the Refine Search link (for details on how to search for an ethics application not displayed, refer to the **Searching for an Application in the Human Ethics Workbench** information sheet).

## To view application details

- 1** Locate the appropriate ethics record and click on the associated **View** icon .

For details on how to search for an ethics application not displayed, refer to the **Searching for an Application in the Human Ethics Workbench** information sheet.

An overview of the ethics record will display. **Note:** If your ethics application record has had multiple versions, you will be able to access these past versions from this overview screen.

Ethics Record Overview									
Ethics ID	Last Date Record Updated	Last Update By	Status	Status Reason	Status Date				
0600180	21-Jul-2006	Drink, Ms Anita	Active	New	21-Jul-2006				
<b>Application Type:</b> Project Application		<b>Approval Category:</b> HESC		<b>Responsible HEAG:</b> University Systems Project					
<b>Approval Date:</b>		<b>HESC:</b> Behavioural and Social Sciences		<b>Special Conditions of Approval:</b> <input type="checkbox"/>					
<b>Annual Expiry Date:</b>		<b>Maximum Expiry Date:</b>		<b>Administering Department:</b> University Systems Project					
<b>Related Documents</b>									
Application Versions									
Version Name	System Status	Operational Status	Status Set By	Last Update	Last Updated By				
0600180.1	Initiated	Draft	Drink, Ms Anita	21-JUL-2006	Drink, Ms Anita				
					 				

- 2** Locate the application version you wish to access and click on the **View** icon.

A summary of the selected ethics application will display.

Available Pages	Ethics Application ID	Approval Category	Responsible HEAG	HESC	Status								
Project Details	0600180.1	HESC	University Systems Project	Behavioural and Social Sciences	Draft								
<b>Title:</b> Beer Goggles													
Application Type: Project Application													
Project Type: Staff Project													
Description: I wish to fully investigate the "beer goggle" effect and see how the variables (e.g.: size and drinking history of subject, composition of drinks, etc) affect the amount of drinks required to achieve the ultimate beer google level.													
Proposed duration of the WHOLE research Project: JUL-2006 To: OCT-2008													
Proposed Start Date for Data Collection of the project: 31-Jul-2006													
<b>Selected Research Checklist Items</b>													
Research undertaken at locations other than or in addition to the University of Melbourne													
<b>Associated Personnel</b>													
Name	Role	Type	Department/Organisation										
Tonic, Ms Ginni	Responsible Researcher	Staff	University Systems Project										
Drink, Ms Anita	Co researcher	External	Paddy's Bar										
<b>Additional Questions</b>													
Location of research													
Other ethics clearances required													
Approvals required from external bodies (non-ethics)													
<b>Additional Required Modules</b>													
No additional modules required.													
<b>Attached Hard Copy Documents</b>													
Attachment Type	Description												
No hard copy attachments.													
<b>Attached Electronic Documents</b>													
File Name	Type	Description	Category	Last Updated By	Last Updated	Usage	Update	Delete					
ethicscover.doc	File	my application	Application	GTONIC	21-Jul-2006	One-Time							

- 3** Use the links in the **Available Pages** menu located on the left of the screen to access other functions.

- Application Summary:** displays a summary of the selected application.
- Full Application Details:** displays additional details of the selected application (e.g.: responses to additional questions, details for responsible staff, etc.).
- Update Application:** opens the selected application to allow you to update the details. This is only available to the Creator or Responsible Researcher when the status of the application is Not Yet Submitted or Revisions Required.
- Additional Questions section:** allows you to access the additional question screens to view and update as required (e.g.: location, clinical trials, additional ethics clearances, etc). For further details on updating these screens refer to the **Updating a Human Ethics Application via the Workbench** information sheet.
- Document Review:** displays a history of the review process for the selected application (i.e.: committee review and outcomes).
- Status History:** displays a history of the application status and identifies any tracking steps that have been allocated.
- Correspondence:** displays a history of the system generated correspondence associated with the selected application (e.g.: submission acknowledgement email, committee review response, etc). Any researcher named on the application can view the text of the correspondence via this screen.
- Return to Ethics Record:** returns you to the Ethics Record Overview screen.

# Searching for an application in the Human Ethics Workbench



The Current Applications section of the Human Ethics Home Page - Research Worklist screen in Themis will display a list of all human ethics applications you have created as well as those where you are nominated as a researcher. If an application does not display in the Workbench (i.e.: it is a draft application on which you have been named, but you are not the creator or Responsible Researcher, or the project is no longer active) you may retrieve it using the search function in the Current Applications section.

## To search for current applications

- 1 Click on the [Refine Search](#) link located in the Current Applications section to display the search fields.
- 2 Enter one or more criteria on which to search.

Field	Action	Comment
Ethics ID	Enter the full or partial ID number of the ethics application record	
Title	Enter the full or partial title of the ethics record	<b>Note:</b> use the % wildcard to widen your search (e.g.: entering %protein% will retrieve all records with this word anywhere in the title).
Researcher Name	Enter the full or partial name of the researcher	<b>Note:</b> use the % wildcard to widen your search (e.g.: entering Free% will retrieve all records with researchers whose name begins with Free).
Status	Select the appropriate ethics application record status from the drop-down list	

- 3 Click on the **Search** button to perform the search.

The results will display in a table below the search criteria.

<span style="float: right;">( Previous 1-10 Next 10 )</span>					
Ethics Id	Application Type	Responsible Researcher	Title	Status	View
0600106.1	Minimal Risk	PATRA, MS CLEO	Did the aliens create the Great Pyramids?	Draft	
0600140.1	Project Application	VILLE, DR EVE	The Seven Dwarfs and why they really helped Snow White	Lodged	
0600143.1	Minimal Risk	MANEK, DR PRITI	Office Politics - How to use them to your benefit	Draft	

**Note:** the results table will only display 10 records. If your search retrieves more than 10 records, click on the **Next 10** link to view additional records.

Click on the [Close Refine Search](#) link to hide the search criteria when you have finished your search.

## To view application details

- 1 Locate the application record you wish to view and click on the associated **View** icon .
- Note:** If your ethics application record has had multiple versions, you will be able to access these past versions from this overview screen.

An overview of the ethics record will display.

Ethics Record Overview					
Ethics ID	Last Date Record Updated	Last Update By	Status	Status Reason	Status Date
0600180	21-Jul-2006	Drink, Ms Anita	Active	New	21-Jul-2006
Application Type:	Project Application		Approval Category:	HESC	
Responsible HEAG:	University Systems Project		HESC:	Behavioural and Social Sciences	
Approval Date:			Special Conditions of Approval:	<input type="checkbox"/>	
Annual Expiry Date:			Maximum Expiry Date:		
Administering Department	University Systems Project		Administering Centre (if applicable)		
Related Documents					
Application Versions		Version Name	System Status	Operational Status	Status Set By
0600180.1		Initiated	Draft	Drink, Ms Anita	21-JUL-2006
				Drink, Ms Anita	

- 2 Locate the application version you wish to access and click on the **View** icon.

A summary of the selected ethics application will display.

From the Application Summary screen you will be able to access the full application details, update the application if required (and if the status allows update), as well as check the status history and any related correspondence. For further information on using this screen refer to the **Updating a Human Ethics Application via the Workbench** information sheet.

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## Human Ethics Application - Overview of Research Checklist Items

Checklist Item	Description	Application Types Available for Completion	Additional Questions That Need to be Completed as Part of the Online Application	Related Module That Needs to be Completed Offline and then Attached	Additional Admin Only Questions/Screens
Locations other than/in addition to Uni of Melbourne	Research undertaken at locations other than or in addition to the University of Melbourne	Project Minimal Risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	No	No
Approvals (non-ethics) needed from external orgs	Approvals required from external organisations/authorities (other than ethics clearance)	Project Minimal Risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	No	External Approvals Ethics Clearances
Already has or requires other ethics approvals	Research that has already been given ethics approval by another institution or that will require ethics approvals from one or more ethics committees	Project Minimal Risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	No	External Approvals Ethics Clearances
Funded research (internal or external funding)	Funded research (internal or external funding)	Project Minimal Risk Program Project within Program Transfer Registration	Sponsored Project	No	No
Involves personal info obtained from Govt dept or NGO	Collection, use or disclosure of personal information obtained from a Commonwealth or State department or agency, or non-government organisation	Project Minimal Risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	Privacy (Except where transfer/registration which require no additional modules)	Privacy External Approval Ethics Clearance

Checklist Item	Description	Application Types Available for Completion	Additional Questions That Need to be Completed as Part of the Online Application	Related Module That Needs to be Completed Offline and then Attached	Additional Admin Only Questions/Screens
Data collected previously for another purpose	Data collected previously for another purpose	Project Transfer Registration	Locations External Approvals Ethics Clearances	No	External Approval Ethics Clearance
Involvement of health, personal or sensitive information	Collection, use or disclosure of health information, personal information or sensitive information, including genetic information	Project Minimal Risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	Privacy (Except where transfer/registration which require no additional modules)	Privacy External Approval Ethics Clearance
Collection or use of biospecimens	Collection or use of biospecimens	Project Program Project within Program Transfer Registration	No	Body Tissue (Except where transfer/registration which require no additional modules)	No
Collection and/or testing of DNA (genetic research)	Collection and/or testing of DNA samples (human genetic research)	Project Program Project within Program Transfer Registration	No	Body Tissue (and also) Genetic Research (Except where transfer/registration which require no additional modules)	No
Administration of ionising radiation	Administration of ionising radiation	Project Transfer Registration	No	Ionising Radiation (Except where transfer/registration which require no additional modules)	Ionising radiation
Clinical trial involving control comparison group	Clinical trial involving control comparison group	Project Program Project within Program Transfer Registration	Clinical trial involving control comparison group	No	Clinical trial
Participation in a Drug trial	Participation in a Drug trial	Project Transfer Registration	Clinical trial involving control comparison group Drug Trials	Drug Trials (Except where transfer/registration which require no additional modules)	Drug trial

Checklist Item	Description	Application Types Available for Completion	Additional Questions That Need to be Completed as Part of the Online Application	Related Module That Needs to be Completed Offline and then Attached	Additional Admin Only Questions/Screens
Multiple ethical review of research	Multiple ethical review of research	Project Transfer Registration	Locations External Approvals Ethics Clearances	No	External Approvals Ethics Clearance
Likely participants of social groups with special needs	Likely involvement of participants who are  - members of a socially identifiable group with special cultural or religious needs or political vulnerabilities	Project Minimal risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	No	External Approvals Ethics Clearance
Likely ATSI participants	Likely involvement of participants who are  - Aboriginal or Torres Strait Islanders	Project Minimal risk Program Project within Program Transfer Registration	Research Involving ATSI Locations External Approvals Ethics Clearances	No	ATSI External Approvals Ethics Clearances
Likely participants requiring consent of leaders/elders	Likely involvement of participants who are  - members of other collectivities where a leader or council of elders may need to give consent	Project Minimal risk Program Project within Program Transfer Registration	Locations External Approvals Ethics Clearances	No	External Approvals Ethics Clearances
None of the above	None of the above	Project Minimal Risk Program Project within Program Transfer Registration	No	No	No

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**THE MELBOURNE GRADUATE SCHOOL OF EDUCATION**  
**HUMAN ETHICS ADVISORY GROUP**

## Human Ethics ‘Minimal Risk’ Checklist

The checklist items below appear in Themis on screens 5, 6, 7, 8 of the Minimal Risk application. Screen 10 allows for a special case to be made for minimal risk review by the HEAG. Screen 2 in Themis has a research checklist to determine the application form suitable for the particular research and whether additional modules need to be completed. Some projects are ineligible for minimal risk e.g. drug trials.

Researchers respond to the checklist items below to ascertain whether their project would be eligible for review as minimal risk by the Human Ethics Advisory Group (HEAG). A HEAG can approve a minimal risk project. Student researchers are to discuss the checklist items with their supervisors. If researchers answer “YES” to 2 items in the checklist the project would normally not be eligible for minimal risk review. Researchers can make a special case for minimal risk review. Where no special case is to be made researchers complete a standard ethics application and submit it via the HEAG for full review by the relevant Human Research Ethics Sub-Committee.

### 1. EXTERNAL REQUIREMENTS

<b>Is the research being funded by an agency outside the University which requires Human Research Ethics Committee approval involving community representation? [If “YES” then researchers <u>must</u> fill out the standard ethics application form]</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Is data being collected overseas other than in New Zealand by any named researchers? [If “YES” then researchers <u>must</u> fill out the standard ethics application form]</b>	<input type="checkbox"/> YES <input type="checkbox"/> NO

### 2. RISK ASSESSMENT

#### A. Are any of the following topics to be covered in part or in whole?

• research about parenting	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• research investigating sensitive personal issues	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• research investigating sensitive cultural issues	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• explorations of grief, death or serious/traumatic loss	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• depression, mood states, anxiety	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• gambling	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• eating disorders	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• illicit drug taking	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• substance abuse	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• self report of criminal behaviour	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• any psychological disorder	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• suicide	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• gender identity	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• sexuality	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• race or ethnic identity	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• any disease or health problem	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• fertility	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• termination of pregnancy	<input type="checkbox"/> YES	<input type="checkbox"/> NO

#### B. Are any of the following procedures to be employed?

• use of personal data obtained from Commonwealth Gov’t Department/agency	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• use of personal data obtained from State Gov’t Department/agency	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Involves use of personal information from a non-government organisation	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• deception of participants	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• concealing the purposes of the research	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• covert observation	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• audio or visual recording without consent	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• recruitment via a third party or agency	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• withholding from one group specific treatments or methods of learning, from which they may “benefit” (e.g., in medicine or teaching)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• any psychological interventions or treatments	<input type="checkbox"/> YES	<input type="checkbox"/> NO

• administration of physical stimulation	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• invasive physical procedures	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• infliction of pain	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• administration of drugs	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• administration of other substances	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• administration of ionising radiation	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• tissue sampling or blood taking	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• collecting body fluid	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• genetic testing/DNA extraction	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• use of medical records where participants can be identified or linked	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• drug trials and other clinical trials	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• administration of drugs or placebos	<input type="checkbox"/> YES	<input type="checkbox"/> NO

#### C. Other Risks?

Are there any risks to the researcher, (e.g. research undertaken in unsafe environments or trouble spots)?  YES  NO

### 3. PARTICIPANT VULNERABILITY ASSESSMENT

Does the research specifically target participants from any of the following groups?

• those suffering a psychological disorder	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• those suffering a physical vulnerability	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• people highly dependent on medical care	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• minors without parental or guardian consent	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• people whose ability to give consent is impaired	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• residents of a custodial institution	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• people unable to give free informed consent because of difficulties in understanding information statement (e.g. language difficulties)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• members of a socially identifiable group with special cultural or religious needs or political vulnerabilities	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• those in dependent relationship with the researchers (e.g. lecturer/student, doctor/patient, teacher/pupil, professional/client)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• participants able to be identified in any final report when specific consent for this has not been given	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• indigenous Australians	<input type="checkbox"/> YES	<input type="checkbox"/> NO

### 4. RESEARCH IN OVERSEAS SETTINGS ASSESSMENT

Does the research involve any of the following?

• research being undertaken in a politically unstable area	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• research involving sensitive cultural issues	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• research in countries where criticism of government and institutions might put participants and/or researchers at risk	<input type="checkbox"/> YES	<input type="checkbox"/> NO

### 5. SPECIAL CASE ASSESSMENT

Reviewers are invited to make a special case if they have answered "YES" to an item in the checklist but still believe that because of the particular nature of the project and/or the participants the project may still be eligible for minimal risk review. The Human Ethics Advisory Group Executive then assesses whether the project can be reviewed as minimal risk. It is the HEAG Executive that decides if a project is minimal risk.

Type here . . .	<input type="checkbox"/> YES	<input type="checkbox"/> NO
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# Creating a Human Ethics Application in Themis

This reference card provides a summary of the steps required to create a Human Ethics Application in Themis. For detailed instructions on completing each type of ethics application refer to the specific information sheet.

- 1** Log in to Themis via **UOM Research Self Service** and navigate to the Human Ethics Workbench.
- 2** Click on the **Create** button.
- 3** Define the Project Type.  
You may select multiple project types, if appropriate. **Note:** some project types require you to complete additional information before progressing.
- 4** Complete the Research Checklist.  
The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.
- 5** Select the Application Type.  
If you select Minimal Risk, Program or Project Within a Program you will need to complete additional questions.
- 6** Enter the Project Details.  
This includes: responsible HEAG, title and brief description of the project, project start and end dates, and expected start date of data collection.
- 7** Enter the Participating Researchers.  
You may record the researchers (staff, student and external) associated with your project, the role they will take in the research as well as their contact, qualification and relevant training details.
- 8** Complete and attach the required documentation.  
The Additional Documentation Required screen will display any forms that you must complete and attach (via the Attachments screen) to your ethics application prior to submission.
- 9** Complete any additional questions required.  
This will be based on your selections at the Research Checklist and may include questions relating to sponsored research, other approvals, ethics clearances required, drug trials, clinical trials, etc.
- 10** Review the application and correct any validation errors.  
The Application Review screen will identify any validation errors or omissions in relation to your ethics application. You will need to correct these before you may submit your application for review.
- 11** Submit your application.  
Once you have corrected any errors you may submit your application for review by the nominated HEAG.

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# Creating a Minimal Risk Human Ethics Application

A Minimal Risk application is to be completed for an individual research project considered to be of minimal risk. If you are unsure whether your research fits within the guidelines for submission as minimal risk, you may select to complete the Minimal Risk option and related checklist to determine whether the project can be considered to be of minimal risk. A Minimal Risk application can be approved by a HEAG.

## Creating a Minimal Risk Application

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the **Create** button in the Create New Documents section.

<a href="#">Human Ethics Home Page - Researcher Worklist</a>	
<a href="#">Create New Documents</a>	
Ethics Application (including transfers and registrations): <a href="#">Create</a>	

The Project Type screen will display.

### Define the Project Type

- 1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

**Note:** you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

- 2 Click on the **Next** button.

The Research Checklist screen will display.

### Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

**Important:** you must select at least one item from the Available Checklist Item list before progressing (choose **None of the above** if applicable). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

- 1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 2 Click on the arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the arrow to remove an item from the Selected Checklist Items list, if required.

- 3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

- 4 Click on the **Next** button.

The Application Type screen will display.

## Select the Application Type

- 1 Click on the appropriate radio button (**Minimal Risk**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

- 2 Click on the **Next** button.

You will need to complete the Minimal Risk checklist before progressing through to the Application Message screen.

## Complete the Minimal Risk Checklist

The Minimal Risk Checklist requires you to answer a number of questions regarding the project for which you are submitting the ethics application.

### *External Requirements - Is the research funded by an overseas agency that requires Ethics Committee review that involves community representation?*

- 1 Click on the **Yes** or **No** radio button.

**Note:** if you answer **Yes** it means the project is not eligible for submission as Minimal Risk and requires full review by the HESC. You will be returned to the Project Type screen and will need to choose an alternate project type (normally Standard Project).

- 2 Click on the **Next** button to progress to the next checklist question.

### *Risk Assessment Topics - Are any of the following topics to be covered in part or in whole?*

- 3 Highlight the topic you wish to add from the Available Risk Assessment Topics list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 4 Click on the  arrow to move the highlighted topic to the Selected Risk Assessment Topics list (on the right).

Click on the  arrow to remove a topic from the list, if required.

**Important:** you must select at least one item from the list before progressing (choose **None of the above** if applicable).

- 5 Click on the **Next** button to progress to the next checklist question.

### *Risk Assessment Procedures - Are any of the following procedures to be employed?*

- 6 Highlight the item you wish to add from the Available Procedures list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 7 Click on the  arrow to move the highlighted item to the Selected Procedures list (on the right).

Click on the  arrow to remove an item from the list, if required.

**Important:** you must select at least one item from the list before progressing (choose **None of the above** if applicable).

- 8 Click on the **Next** button to progress to the next checklist question.

### *Risks to Researcher - Identify any risks to the researcher?*

- 9 Enter any identified risks to the researcher in the field.

**Note:** if no risks have been identified, leave the field blank.

- 10 Click on the **Next** button to progress to the next checklist question.

### Vulnerability Assessment - Does the research specifically target the following?

- 11** Highlight the item you wish to add from the Available Vulnerability Items list (on the left).  
**Note:** the description for the selected item will display in the field under the table.
- 12** Click on the  arrow to move the highlighted item to the Selected Vulnerability Items list (on the right).  
Click on the  arrow to remove an item from the list, if required.  
**Important:** you must select at least one item from the list before progressing (choose **None of the above** if applicable).
- 13** Click on the **Next** button to progress to the next checklist question.

### Overseas Research - Does the research involve any of the following?

- 14** Highlight the item you wish to add from the Available Overseas Research list (on the left).  
**Note:** the description for the selected item will display in the field under the table.
- 15** Click on the  arrow to move the highlighted item to the Selected Overseas Research list (on the right).  
Click on the  arrow to remove an item from the list, if required.  
**Important:** you must select at least one item from the list before progressing (choose **None of the above** if applicable).
- 16** Click on the **Next** button.  
The Minimal Risk Review screen will display.

### Review the Minimal Risk Application

The Minimal Risk Review screen will identify any validation errors (e.g.: checklist question unanswered). It will also identify whether or not the project is eligible for review as a minimal risk application - either as a Minimal Risk or Minimal Risk (Special Case) application.

#### If validation errors are identified

Minimal Risk Checklist Review		
Data validation errors have been identified in this the minimum risk component of this application. You cannot proceed until the errors specified in the table below have been corrected.		
Data Validation Error	Application Step	Go To Page
No risk assessment topics have been selected. Select 'None of the Above' if none required	Step 5	

- 1** Click on the associated  icon in the Go To Page column.  
This will link you directly to the appropriate page.
- 2** Update the information as required.
- 3** Use the drop down list ( Step 10 of 21) at the bottom of the screen to return to the review page.
- 4** Repeat **steps 1 to 3** above for each of the validation errors.
- 5** Click on the **Next** button.  
The Application Message screen will display.

#### If application ineligible to be submitted as a minimal risk

Minimal Risk Checklist Review	
This application is not eligible for submission as minimal risk. Please click 'Next' to return to the application page and select an alternative application type	

- 1** Click on the **Next** button.  
This will return you to the Application Type screen.
- 2** Select an alternate application type and proceed with the application.  
For assistance in completing alternate applications refer to the appropriate information sheet.

## If risks have been identified

<b>Minimal Risk Checklist Review</b>
The responses as summarised below, indicate that the research involves topics, methodologies, specific risks or vulnerable participant groups that would normally make this project ineligible for submission as a project involving minimal risk:
<b>Selected Minimal Risk Checklist Items</b>
<b>Minimal Checklist Item Selected</b>
Research undertaken in a politically unstable area
Gambling
<b>Minimal Risk Special Case</b>
<b>Please confirm whether you wish to present a special case or will proceed with submission for full review:</b>
<input type="radio"/> I will submit my application as a standard Project Application for full review by the relevant Human Ethics Sub-committee <input checked="" type="radio"/> I have discussed the research with my supervisor and/or HEAG and have support for presenting a Special Case - details provided below

- 1 Select the radio button to confirm whether you wish to present a special case or proceed with a full review.
- 2 If you indicate a special case enter your supporting statement in the field below.
- 3 Click on the **Next** button.  
 If you have indicated a **special case** the Application Message screen will display.  
 If you have indicated a **full review** you will return to the Application Type screen where you can select an alternate application type and proceed with the application.

## If no validation errors are identified

<b>Minimal Risk Checklist Review</b>
No data validation errors have been identified. Click 'Next' to proceed.

- 1 Click on the **Next** button.  
 The Application Message screen will display.

## Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.

<b>Step 11 - Application Message</b>			
<input type="button" value="Cancel"/> <input type="button" value="Save As Draft"/> <input type="button" value="Back"/> Step 11 of 21 <input type="button" value="Next"/>			
<b>Ethics Application ID</b> 0600143.1	<b>Status</b> Draft	<b>Application Type</b> Minimal Risk	<b>Approval Category</b> HEAG
Based on the responses provided this project will be submitted for review by the Responsible HEAG as a Minimal Risk (Special Case) application.			

- 1 Click on the **Next** button.  
 The Project Details screen will display.

## Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

### 1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	Select the appropriate HEAG from the drop-down list	
HESC	This field will default based on the HEAG selected above	
Project Title	Enter the title of your project	
Brief description of project	Enter a brief description of the project	The description, no more than 100 words, should outline the broad aims and key questions of the project.
Project From date	Use the drop-down list to select the month and year the project is expected to start	
Project To date	Use the drop-down list to select the month and year the project is expected to end	
Start date for data collection phase	Enter the proposed start date for the data collection phase of the project	<b>Important:</b> data collection may not commence until formal approval for the project has been granted and the date entered in this field should allow for a reasonable period of review of your application.

### 2 Click on the **Next** button.

The Participating Researcher screen will display.

## Enter the Participating Researchers

The Participating Researcher screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details.

### 1 Click on the **Add Researcher** button.

The Search Researchers screen will display.

Search Researchers	
<input style="width: 150px; height: 25px; border: none; background-color: #f0f0f0; border-radius: 5px; padding: 2px; margin-bottom: 5px;" type="button" value="Select Category"/> <input style="width: 150px; height: 25px; border: 1px solid #ccc; border-radius: 5px; padding: 2px; margin-bottom: 5px;" type="text"/>	
<input style="border: 1px solid #ccc; border-radius: 5px; padding: 2px 10px; margin-right: 5px;" type="button" value="Search"/> <input style="border: 1px solid #ccc; border-radius: 5px; padding: 2px 10px;" type="button" value="Create External"/>	
<b>Select Name</b>	<b>Department/Organisation</b>
No data exists.	
<input style="border: 1px solid #ccc; border-radius: 5px; padding: 2px 10px;" type="button" value="Select"/>	

### 2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

### 3 Enter the surname of the researcher for which you are searching in the bottom field.

### 4 Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to **Creating an External Researcher in Human Ethics** information sheet).

Select Name	Department/Organisation
<input checked="" type="radio"/> BALL, MS CRYSTAL	018-University Systems Project
<input type="button" value="Select"/>	

### 5 Click on the radio button to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

### Enter the Researcher Details

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

#### 6 Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 9.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. <b>Note:</b> the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	<b>Note:</b> these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. <b>Note:</b> you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

#### 7 Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select Researcher Role	Researcher Type	Researcher Name	Department/Organisation
<input checked="" type="radio"/> Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project
<a href="#">Add Researcher</a>	<a href="#">Delete Researcher</a>	<a href="#">Update Researcher</a>	

#### 8 Follow **steps 1 to 7** above to enter additional researchers if required.

**Note:** for any project there must be one and only one Responsible Researcher named against the project.

#### 9 Once you have added all the required researchers, click on the **Next** button to continue.

The Additional Documentation Required screen will display.

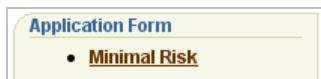
## Access Additional Documentation

The Additional Documentation Required screen will display any forms that you must complete and attach to your ethics application prior to submission. The forms are available on the Research Office web site but you will be able to download them via the hyperlink/s on this screen. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

- 1** **Important:** Click on the **Save As Draft** button before proceeding to download any additional documentation.

A confirmation message will display advising that the application has been saved.

- 2** Click on the hyperlink for the form you wish to download.



The link will access the relevant document from the Research Office web site and open it in a new browser window. In most cases the document will open at an instruction sheet, and you will need to scroll down from this page to view the body of the form.

- 3** Save the document to your PC/local server for later completion and attachment to Themis.

- 4** Close the browser window and reactivate your Themis session.

- 5** Complete **steps 2 to 4** above for all required documents.

- 6** Once you have accessed all the required documents, click on the **Next** button to continue.

The Attachments screen will display.

## Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

### Add an electronic attachment

- 1** Click on the **Add Attachment** button in the Attachment table.

The Add Attachment screen will display.

- 2** Complete the attachment details.

Field	Action	Comments
Add	Field will default to <b>Desktop File/Text/URL</b> , do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Interview, Miscellaneous, Plain Language Statement, and Test.</b> <b>Note:</b> you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	<b>If selecting File:</b> click on the <b>Browse</b> button to locate and select the document you wish to attach. <b>If selecting URL:</b> type the full internet address you wish to reference. <b>If selecting Text:</b> enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

If you wish to add multiple attachments, go to task # 3. Otherwise go to task #4.

- 3** Click on the **Add Another** button and repeat **step 2** for each new attachment.

- 4** Once you have added all your attachments click on the **Apply** button.

You will receive a confirmation that the attachment has been added but not saved.

- 5** Click on the **Save As Draft** button to save the attachment.

## Register a document to be provided in hard copy only

**1** Click on the **Add Another Row** button in the Supporting Documents table.

The Add Attachment screen will display.

**2** Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Evidence of Approval, Interview, Other, Plain Language Statement, and Questionnaire/Survey.</b>
Description	Enter a brief description of the document you will be submitting	

**3** Repeat **steps 1 and 2** for each document you wish to register.

**4** Once you have registered all your attachments click on the **Save As Draft** button.

You will receive a confirmation that the application has been saved.

**5** Once you have attached all the required documents, click on the **Next** button to continue.

The Application Review screen will display.

## Review the Application

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

*If validation errors are identified*

Application Review					
Data validation errors have been identified in this application. You cannot proceed to the submission page until the errors specified in the table below have been corrected.					
<b>Data Validation Error</b> Multiple electronic attachments of type 'Application' have been attached to this application	<table border="1"> <tr> <td><b>Application Step</b></td> <td><b>Go To Page</b></td> </tr> <tr> <td>Step 15</td> <td></td> </tr> </table>	<b>Application Step</b>	<b>Go To Page</b>	Step 15	
<b>Application Step</b>	<b>Go To Page</b>				
Step 15					

**1** Click on the associated icon in the Go To Page column.

This will link you directly to the appropriate page.

**2** Update the information as required and click on the **Save As Draft** button to commit your changes.

**3** Use the drop down list ( at the bottom of the screen to return to the review page.

**4** Repeat **steps 1 to 3** above for each of the validation errors.

**5** Click on the **Next** button.

The Submission screen will display.

## Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

**1** Read the submission confirmation statement.

**2** Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).

**Important:** if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

**3** Click on the **Submit Application** button.

A Confirmation of Submission screen will display.

**Note:** all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

## Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

- 1** Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

- 2** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).

- 3** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

- 4** Click on the **Output** icon to open the application in the web browser screen.

- 5** Select **File > Print** from the web browser Toolbar to print the application.

- 6** Ensure the application is signed by all responsible researchers.

- 7** Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

## Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	<p>For any project there must be a Responsible Researcher named against the project.</p> <p><b>Note:</b> there may only be one person with this role per application and only a member of staff may be named.</p> <p>In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects).</p> <p>Only the person named as Responsible Researcher, and the creator, will have access to update an application.</p>
Student Researcher	<p>There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.</p>
Co-researcher	<p>There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).</p>
Associated Personnel	<p>There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.</p>



THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE  
MINIMAL RISK APPLICATION

THE UNIVERSITY OF  
MELBOURNE

**PROJECT REFERENCE DETAILS**

Enter the Ethics ID number assigned by Themis Research to this ethics application.

Enter the title of the Project as recorded in Themis Research

Enter the name of the Responsible Researcher as recorded in Themis Research


**1. PROJECT DETAILS**

1.1 **EXECUTIVE SUMMARY IN PLAIN ENGLISH:** Provide a brief summary of the project outlining the broad aims, background, key questions, research design/approach, the participants in the study and what they will be asked to do, and the importance or relevance of the project. [This description must be in everyday language, free from jargon, technical terms or discipline-specific phrases. (No more than 300 words).]

1.2 **AIMS OF AND JUSTIFICATION FOR THE RESEARCH:** State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Also provide a brief description of current research/literature review, a justification as to why this research should proceed and an explanation of any expected benefits to the community. [No more than 500 words]

1.3 **METHOD**

(a) What data collection technique(s) will be used? [Tick as many as apply]

Questionnaire (attach a copy)

Interviews (attach a copy)

Observation of participants without their knowledge

Covert observation

Audio- or video-taping interviewees or events (with consent)

Other (Please give details. Use no more than 50 words):

(b) What tasks will participants be asked to do? What is the estimated time commitment involved? How will data be analysed?

1.4 **USE OF INDEPENDENT CONTRACTORS** Will parts of this project be carried out by independent contractors? (e.g. interviewing, questionnaire design and analysis, sample testing, etc)

YES       NO

If YES, confirm that the independent contractor will be engaged on the basis of relevant qualifications and experience and will receive from the first named Principal Researcher, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it. [The responsibility for effective oversight and proper conduct of the project remains with the Principal Researcher(s)]

## 1.5 MONITORING

- (a) How will researchers monitor the conduct of the project to ensure that it complies with the protocols set out in this application, the University's human ethics guidelines and the National Statement on Ethical Conduct in Research Involving Humans? [Address, in particular, cases where several people are involved in recruiting, interviewing or administering procedures, or when the research is being carried out at some distance from the Principal Researcher (i.e. interstate or overseas)]
- (b) For student research projects how will the student be supervised to ensure they comply with the protocols? If the student is working overseas, provide additional details of any local supervision arrangements.

## 2. PARTICIPANT DETAILS

### 2.1 TARGET PARTICIPANT GROUP

Please indicate the targeted participant group by ticking all boxes that apply. Expand any responses necessary in the space provided at "Other".

- Students or staff of this University  Adults (over 18 years old and competent to give consent)   
Children/legal minors (under 18 years old) (with parental consent)  Other (Please give details. Use no more than 50 words):   
People from non-English speaking backgrounds

### 2.2 NUMBER, AGE RANGE AND SOURCE OF PARTICIPANTS

Provide number, age range and source of participants.

### 2.3 JUSTIFICATION OF PARTICIPANT NUMBERS

[The quality and validity of research is an essential condition of its ethical acceptability (refer National Statement page 5)] Where applicable, provide a justification of sample size (including details of statistical power of the sample, where appropriate), explaining how this sample size will allow the aims of the study to be achieved.

### 2.4 PARTICIPANT RECRUITMENT

(a) Please indicate the method of recruitment by ticking the appropriate boxes. Tick all that apply.

- Mail out - see below  Email - see below  Telephone   
Advertisement - see below  Recruitment carried out by third party (eg. employer, doctor) - see below  Recruitment carried out by researcher/s Personal contacts   
Contact details obtained from public documents (eg. phone book)  Contact details obtained from private sources (eg. employee list, membership database) - see below   
Participants from a previous study  Snowball (participants suggest other potential participants)  Other (Please explain in no more than 50 words):

- If using a **mail out** or **email** who will be distributing it?
- If using an **advertisement**:
  - explain where will it be placed? [e.g. on waiting room wall, in newspaper, in newsletter]
  - have you attached a copy?

Yes  No  NA  If "No" please explain (no more than 50 words):

- If recruitment is to be conducted by a **third party**, (eg employer, doctor) have you attached an approval letter?

- requesting their assistance? [yes, no or not applicable]  
Yes  No  NA  If "No" please explain (no more than 50 words):

- confirming their willingness to assist?  
Yes  No  NA  If "No" please explain (no more than 50 words):

- that has been drafted for the third party to send to potential participants?  
Yes  No  NA  If "No" please explain (no more than 50 words):

- If contact details are to be obtained from **private sources**, have you attached an approval letter?  
Yes  No  If "No" please explain (no more than 50 words):

(b) Describe how, by whom, where potential participants are to be identified or selected for this research.

(c) Describe how, by whom, where potential participants are to be approached or invited to take part in this research.

## 2.5 DEPENDENT RELATIONSHIPS

[The issue of research involving persons in dependent or unequal relationships (e.g. teacher/student, doctor/patient, student/lecturer, client/counsellor, warder/prisoner, and employer/employee) is discussed in Section 7 of the National Statement. Such a relationship may compromise a participant's ability to give consent which is free from any form of pressure (real or implied)]. Are any of the participants in a dependent relationship with any of the researchers, particularly those involved in recruiting for or conducting the project?

YES  NO (If YES, explain the dependent relationship and the steps to be taken by the researchers to ensure that participation is purely voluntary and not influenced by the relationship in any way)

## 2.6 PAYMENT OR INCENTIVES OFFERED TO PARTICIPANTS

Do you propose to pay, reimburse or reward participants?

YES  NO (If YES, how, how much and for what purpose? Please justify the approach)

## 3. INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT

Before research is undertaken, the informed and voluntary consent of participants (and other properly interested parties) is generally required (refer sections 1.7 - 1.12 of the National Statement for more details). Information needs to be provided to participants at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. Such information is often provided in a written **Plain Language Statement**. Each participant's consent needs to be clearly established (e.g. by using a signed **Consent Form**, returning an anonymous survey or recording an agreement for interview).

### 3.1 PROVIDING INFORMATION FOR PARTICIPANTS

(a) Will you be providing participants with information in a written Plain Language Statement?

YES  NO (If NO, provide details of the protocol you will use to explain the research project to participants and invite their participation?)

(b) Will arrangements be made to ensure that participants who have difficulty understanding English can comprehend the information provided about the research project?

YES  NO (If YES, what arrangements have been made? If NO, give reasons.)

### 3.2 PLAIN LANGUAGE STATEMENT (IF APPLICABLE)

CONFIRM THAT THE PLAIN LANGUAGE STATEMENT WILL:

YES NOT APPLICABLE

1. be printed on University of Melbourne letterhead
2. include clear identification of the University, the Department(s) involved, the project title, the Principal and Other Researchers (including contact details), and the study level if it is a student research project.
3. provide details of the purpose of the research project
4. provide details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-taping of events), and estimated time commitment
5. provide details of any risks involved and the procedures in place to minimise these.
6. advise that the project has received clearance by the HREC
7. (if the sample size is small), confirm that this may have implications for protecting the identity of the participants
8. include a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health (if relevant)
9. state that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied
10. provide advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see \*\* below)
11. provide advice as to whether or not data is to be destroyed after a minimum period (if relevant)
12. provide in the footer, the project HREC number, date and version of the PLS
13. provide advice that if participants have any concerns about the conduct of this research project that they can contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739

[\*\*Re 10 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state these limitations]

#### **PLEASE ATTACH A COPY OF THE PLAIN LANGUAGE STATEMENT TO YOUR APPLICATION**

### **3.3 OBTAINING CONSENT**

#### **(a) How will each participant's consent be established?**

**By signing and returning a Consent Form – see 3.4  
below**

**By returning an anonymous survey**

**Via a verbal agreement**

**Via a person with lawful authority to consent (eg.**

**Via a recorded agreement for interview**

**parent, doctor) – see 3.3(b) below**

**Other (Please describe in no more than 50 words):**

#### **(b) If participants are unable to give informed consent, explain who will consent on their behalf and how such consent will be obtained.**

### **3.4 CONSENT FORM (IF APPLICABLE)**

#### **CONFIRM THAT THE CONSENT FORM WILL:**

1. be printed on University of Melbourne letterhead
2. include the title of the project and names of researchers
3. state that the project is for research purposes
4. state that involvement in the project is voluntary and that participants are free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied
5. outline particular requirements of participants including, for

**YES**

**NOT APPLICABLE**

- example, whether interviews are to be audio and/or video-taped
6. include arrangements to protect the confidentiality of data
  7. include advice that there are legal limitations to data confidentiality (see below)\*\*
  8. (if the sample size is small) confirm that this may have implications for protecting the identity of the participants
  9. (once signed and returned) be retained by the researcher

[\*\*Re 7 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state and explain these limitations]

#### **PLEASE ATTACH A COPY OF THE CONSENT FORM TO YOUR APPLICATION**

#### **4. PRIVACY AND CONFIDENTIALITY**

[Section 18 of the National Statement describes 'Privacy' as "...a complex concept that stems from a core idea that individuals have a sphere of life from which they should be able to exclude any intrusion." A major application of the concept of privacy is information privacy: the interest of a person in controlling access to and use of any information personal to that person. 'Confidentiality', a narrower more specific term than 'privacy' refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another.

At the Commonwealth level, the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the *Privacy Act 1988*. Sections 95 and 95A of the Act are of particular relevance to researchers. There is regulation at State and Territory level in the form of legislation related to privacy generally or the administration of agencies, or administrative codes of practice. In Victoria, the *Health Records Act 2001* regulates health information handled by the Victorian public sector and private sector, while the Information Privacy Act 2000 regulates the collection and handling of non-health-related personal information. Section 18.1 of the National Statement states that an HREC must be satisfied that a research proposal conforms to all relevant Commonwealth, State or Territory privacy legislation or codes of practice]

##### **4.1 ACCESSING PERSONAL INFORMATION**

[Personal Information' includes names, addresses, or information/opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information/opinion. It also includes Health Information (e.g. health opinions, organ donation or genetic information) and Sensitive Information (e.g. political views, sexual preferences, criminal records)]

*Is there a requirement for the researchers to obtain Personal Information (either identifiable or potentially identifiable) about individuals without their consent?*

- |  | <b>YES</b>               | <b>NO</b>                |
|--|--------------------------|--------------------------|
| a) from Commonwealth departments or agencies?                      | <input type="checkbox"/> | <input type="checkbox"/> |
| b) from State departments or agencies?                             | <input type="checkbox"/> | <input type="checkbox"/> |
| c) from Other Third Parties, such as non-government organisations? | <input type="checkbox"/> | <input type="checkbox"/> |

*If you answered YES to (a), (b) or (c), you will need to complete [Module P](#) and attach it to this application*

#### **4.2 REPORTING PROJECT OUTCOMES**

(a) *Will the project outcomes be made public at the end of the project?*

- |                              |                             |   |
|------------------------------|-----------------------------|---|
| <input type="checkbox"/> YES | <input type="checkbox"/> NO | (If YES, give details of how the results will be made public (eg in journal articles book, conference paper, the media, working paper or other). If NO, explain why not.) |
|------------------------------|-----------------------------|---|

(b) *Will a report of the project outcomes be made available to participants at the end of the project?*

- |                              |                             |   |
|------------------------------|-----------------------------|---|
| <input type="checkbox"/> YES | <input type="checkbox"/> NO | (If Yes, give details of the type of report and how it will be made available. If No, explain why not.) |
|------------------------------|-----------------------------|---|

#### **4.3 WILL THE RESEARCH INVOLVE:**

- complete anonymity of participants (i.e., researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification)?
- de-identified samples or data (i.e., an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the

**YES**

**NO**

- sample of information relates)?
- potentially identifiable samples or data (i.e., a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)?
  - participants having the option of being identified in any publication arising from the research?
  - participants being referred to by pseudonym in any publication arising from the research?
  - any other method of protecting the privacy of participants? Please describe:

*Note that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the Plain Language Statement.*

## 5 DATA STORAGE, SECURITY AND DISPOSAL

### 5.1 DATA STORAGE

*Does data storage comply with the University policy? [University of Melbourne Policy on the Management of Research Data and Records is available at: <http://www.unimelb.edu.au/records/research.html> The Joint NHMRC/AVCC Statement and Guidelines on Research Practice is available at: <http://www.nhmrc.gov.au/funding/policy/researchprac.htm> ]*

- YES       NO      *(If NO, please explain.)*

### 5.2 DATA SECURITY

**(a) Will the Principal Researcher be responsible for security of data collected?**

- YES       NO      *(If NO, please provide further details. You may also use this space to explain any differences between arrangements in the field, and on return to campus.)*

**(b) Will data be kept in locked facilities in the Department through which the project is being conducted?**

- YES       NO      *(If NO, please explain how and where data will be held, including any arrangements for data security during fieldwork.)*

**(c) Which of the following methods will be used to ensure confidentiality of data?  
(select all options that are relevant)**

- data and codes and all identifying information to be kept in separate locked filing cabinets
- access to computer files to be available by password only
- access by named researcher(s) only
- other (please describe)

**(d) Will others besides the researchers listed in sections 0.3 and 0.4 have access to the raw data?**

- YES       NO      *(If YES, please explain who and for what purpose?  
What is their connection to the project?)*

### 5.3 DATA RETENTION AND DISPOSAL

[Research data and records should be maintained for as long as they are of continuing value to the researcher and as long as recordkeeping requirements such as patent requirements, legislative and other regulatory requirements exist. The minimum retention period for research data and records is five years after publication, or public release, of the work of the research as stated in the University of Melbourne [Code of Conduct for Research](#). If the project involves clinical trial(s), the data should be kept for a minimum of 15 years (refer to Section 12.1 of the National Statement for further details)]

*Specify how long materials (e.g. files, audiotapes, questionnaires, videotapes, photographs) collected during the study will be retained after the study and how they will ultimately be disposed of.*

## **6. POTENTIAL CONFLICT OF INTEREST**

### **6.1 POTENTIAL CONFLICT OF INTEREST**

*Is there any affiliation or financial interest for researchers in this research or its outcomes or any circumstances which might represent a perceived, potential or actual conflict of interest?*

YES       NO      (If YES, give brief details?)

[If you have declared a potential conflict of interest, you should include an appropriate comment on the Plain Language Statement and Consent Form]

### **6.2 COMPLIANCE WITH THE CODE OF CONDUCT FOR RESEARCH**

[University researchers must disclose and manage Conflict of Interest in accord with the provisions of the University's Code of Conduct for Research. See <http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html>]

*Is the Conflict of Interest noted above in section 6.1 being managed in accordance with the Code of Conduct?*

YES       NO       Not Applicable

## **7. DECLARATION BY RESEARCHERS**

*The information contained herein is, to the best of our knowledge and belief, accurate.*

*We have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University's Code of Conduct for Research and any other condition laid down by the University of Melbourne's Human Research Ethics Committee or its Sub-Committees. We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants. We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.*

*If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.*

*We, the researcher(s) agree:*

- To only start this research project after obtaining final approval from the Human Research Ethics Committee (HREC);
- To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
- To provide additional information as requested by the HREC;
- To provide progress reports to the HREC as requested, including annual and final reports;
- To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
- To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
- To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;
- To agree to an audit if requested by the HREC;
- To only use data and any tissue samples collected for the study for which approval has been given;

*We have read the NH&MRC National Statement on Ethical Conduct in Research Involving Humans and agree to comply with its provisions.*

**All researchers associated with this project must sign**

Researchers' Name (please PRINT)	Signature	Date


## 8. DECLARATION BY DEPARTMENTAL HUMAN ETHICS ADVISORY GROUP (HEAG)

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

The HEAG has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommends approval of the project. The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a principal researcher for this project, the declaration should be signed by another authorised member of the HEAG]

Comments/Provisos:

Name of HEAG Chair (in BLOCK LETTERS)	
Signature	
Date	

## 9. DECLARATION BY HEAD OF DEPARTMENT

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

I have reviewed this project and consider the methodological, technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommend approval of the project. I consider that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]

This project has the approval and support of this Department/School/Centre.

Name of Head (in BLOCK LETTERS)	
Signature	
Date	

## 10 WHEN COMPLETE

When this form has been completed and finalised it should be attached to the coversheet section of the application completed in Themis Research and then submitted to the nominated Human Ethics Advisory Group for review.

**INTENTIONALLY BLANK**

# Creating a Standard Project Human Ethics Application

A Standard Project application is to be completed for all individual research projects unless they are eligible for consideration as a project involving minimal risk or are part of an existing HREC approved program application. A Standard Project application requires HEAG review and HESC approval.

## Creating a Standard Project Application

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the **Create** button in the Create New Documents section.

<a href="#">Human Ethics Home Page - Researcher Worklist</a>	
<a href="#">Create New Documents</a>	
<b>Ethics Application (including transfers and registrations):</b>	<a href="#">Create</a>

The Project Type screen will display.

## Define the Project Type

- 1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

**Note:** you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

- 2 Click on the **Next** button.

The Research Checklist screen will display.

## Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

**Important:** you must select at least one item from the Available Checklist Item list before progressing (choose **None of the above** if applicable). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

- 1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 2 Click on the arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the arrow to remove an item from the Selected Checklist Items list, if required.

- 3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

- 4 Click on the **Next** button.

The Application Type screen will display.

## Select the Application Type

- 1** Click on the appropriate radio button (**Standard Project**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

- 2** Click on the **Next** button.

The Application Message screen will display.

## Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.

Step 4 - Application Message			
<input type="button" value="Cancel"/> <input type="button" value="Save As Draft"/> <input type="button" value="Back"/> <input type="button" value="Step 4 of 15"/> <input type="button" value="Next"/>			
Ethics Application ID	Status	Application Type	Approval Category
0600146.1	Draft	Project Application	HESC
<b>Based on the responses provided this project is eligible for submission as a Project Application.</b>			

- 1** Click on the **Next** button.

The Project Details screen will display.

## Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

### 1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	Select the appropriate HEAG from the drop-down list	
HESC	This field will default based on the HEAG selected above	
Project Title	Enter the title of your project	
Brief description of project	Enter a brief description of the project	The description, no more than 100 words, should outline the broad aims and key questions of the project.
Project From date	Use the drop-down list to select the month and year the project is expected to start	
Project To date	Use the drop-down list to select the month and year the project is expected to end	
Start date for data collection phase	Enter the proposed start date for the data collection phase of the project	<b>Important:</b> data collection may not commence until formal approval for the project has been granted and the date entered in this field should allow for a reasonable period of review of your application.

### 2 Click on the **Next** button.

The Participating Researcher screen will display.

## Enter the Participating Researchers

The Project Details screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details.

### 1 Click on the **Add Researcher** button.

The Search Researchers screen will display.



Select Name	Department/Organisation
No data exists.	
<input type="button" value="Select"/>	

### 2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

### 3 Enter the surname of the researcher for which you are searching in the bottom field.

### 4 Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to **Creating an External Researcher in Human Ethics** information sheet).

Select Name	Department/Organisation
<input checked="" type="radio"/> BALL, MS CRYSTAL	018-University Systems Project
<input type="button" value="Select"/>	

### 5 Click on the radio button in the Select column to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

### Enter the Researcher Details

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

#### 6 Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 7.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. <b>Note:</b> the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	<b>Note:</b> these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. <b>Note:</b> you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

#### 7 Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select Researcher Role	Researcher Type	Researcher Name	Department/Organisation
<input checked="" type="radio"/> Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project
<a href="#">Add Researcher</a>	<a href="#">Delete Researcher</a>	<a href="#">Update Researcher</a>	

#### 8 Follow **steps 1 to 7** above to enter additional researchers if required.

**Note:** for any project there must be one and only one Responsible Researcher named against the project.

#### 9 Once you have added all the required researchers, click on the **Next** button to continue.

The Additional Documentation Required screen will display.

## Access Additional Documentation

The Additional Documentation Required screen will display any forms that you must complete and attach to your ethics application prior to submission. The forms are available on the Research Office web site but you will be able to download them via the hyperlink/s on this screen. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

- 1** **Important:** Click on the **Save As Draft** button before proceeding to download any additional documentation.

A confirmation message will display advising that the application has been saved.

- 2** Click on the hyperlink for the form you wish to download.

<b>Application Form</b>
<ul style="list-style-type: none"> <li>• Standard Project</li> </ul>

The link will access the relevant document from the Research Office web site and open it in a new browser window. In most cases the document will open at an instruction sheet, and you will need to scroll down from this page to view the body of the form.

- 3** Save the document to your PC/local server for later completion and attachment to Themis.
- 4** Close the browser window and reactivate your Themis session.
- 5** Complete **steps 2 to 4** above for all required documents.
- 6** Once you have accessed all the required documents, click on the **Next** button to continue.  
The Attachments screen will display.

## Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

### Add an electronic attachment

- 1** Click on the **Add Attachment** button in the Attachment table.

The Add Attachment screen will display.

- 2** Complete the attachment details.

Field	Action	Comments
Add	Field will default to <b>Desktop File/Text/URL</b> , do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Interview, Miscellaneous, Plain Language Statement, and Test.</b> <b>Note:</b> you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	<b>If selecting File:</b> click on the <b>Browse</b> button to locate and select the document you wish to attach. <b>If selecting URL:</b> type the full internet address you wish to reference. <b>If selecting Text:</b> enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

If you wish to add multiple attachments, go to task # 3. Otherwise go to task #4.

- 3** Click on the **Add Another** button and repeat **step 2** for each new attachment.

- 4** Once you have added all your attachments click on the **Apply** button.

You will receive a confirmation that the attachment has been added but not saved.

- 5** Click on the **Save As Draft** button to save the attachment.

## Register a document to be provided in hard copy only

**1** Click on the **Add Another Row** button in the Supporting Documents table.

The Add Attachment screen will display.

**2** Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Evidence of Approval, Interview, Other, Plain Language Statement, and Questionnaire/Survey.</b>
Description	Enter a brief description of the document you will be submitting	

**3** Repeat **steps 1 and 2** for each document you wish to register.

**4** Once you have registered all your attachments click on the **Save As Draft** button.

You will receive a confirmation that the application has been saved.

**5** Once you have attached all the required documents, click on the **Next** button to continue.

The Application Review screen will display.

## Review the Application

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

*If validation errors are identified*

Application Review					
Data validation errors have been identified in this application. You cannot proceed to the submission page until the errors specified in the table below have been corrected.					
<b>Data Validation Error</b> Multiple electronic attachments of type 'Application' have been attached to this application	<table border="1"> <tr> <td><b>Application Step</b></td> <td><b>Go To Page</b></td> </tr> <tr> <td>Step 15</td> <td></td> </tr> </table>	<b>Application Step</b>	<b>Go To Page</b>	Step 15	
<b>Application Step</b>	<b>Go To Page</b>				
Step 15					

**1** Click on the associated  icon in the Go To Page column.

This will link you directly to the appropriate page.

**2** Update the information as required and click on the **Save As Draft** button to commit your changes.

**3** Use the drop down list () at the bottom of the screen to return to the review page.

**4** Repeat **steps 1 to 3** above for each of the validation errors.

**5** Click on the **Next** button.

The Submission screen will display.

## Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

**1** Read the submission confirmation statement.

**2** Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).

**Important:** if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

**3** Click on the **Submit Application** button.

A Confirmation of Submission screen will display.

**Note:** all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

## Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

- 1** Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

- 2** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).

- 3** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

- 4** Click on the **Output** icon to open the application in the web browser screen.

- 5** Select **File > Print** from the web browser Toolbar to print the application.

- 6** Ensure the application is signed by all responsible researchers.

- 7** Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

## Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	<p>For any project there must be a Responsible Researcher named against the project.</p> <p><b>Note:</b> there may only be one person with this role per application and only a member of staff may be named.</p> <p>In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects).</p> <p>Only the person named as Responsible Researcher, and the creator, will have access to update an application.</p>
Student Researcher	<p>There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.</p>
Co-researcher	<p>There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).</p>
Associated Personnel	<p>There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.</p>



**THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE**

**APPLICATION FOR APPROVAL OF A PROJECT  
INVOLVING HUMAN PARTICIPANTS**

**PROJECT REFERENCE DETAILS**

Enter the Ethics ID number assigned by Themis Research to this ethics application.


Enter the title of the Project as recorded in Themis Research

Enter the name of the Responsible Researcher as recorded in Themis Research

**1. PROJECT DETAILS**

1.1 **EXECUTIVE SUMMARY IN PLAIN ENGLISH:** Provide a brief summary of the project outlining the broad aims, background, key questions, research design/approach, the participants in the study and what they will be asked to do, and the importance or relevance of the project. [This description must be in everyday language, free from jargon, technical terms or discipline-specific phrases. (No more than 300 words).]

1.2 **AIMS OF AND JUSTIFICATION FOR THE RESEARCH:** State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Also provide a brief description of current research/literature review, a justification as to why this research should proceed and an explanation of any expected benefits to the community. [No more than 500 words]

1.3 **METHOD** Provide an outline of the proposed method, including details of the recruitment strategy and data collection techniques, the tasks participants will be asked to do, the estimated time commitment involved, and how data will be analysed. [No more than 500 words]

1.4 **USE OF INDEPENDENT CONTRACTORS** Will parts of this project be carried out by independent contractors? (e.g. interviewing, questionnaire design and analysis, sample testing, etc)

YES       NO

If YES, confirm that the independent contractor will be engaged on the basis of relevant qualifications and experience and will receive from the Responsible Researcher, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it. [The responsibility for effective oversight and proper conduct of the project remains with the Responsible Researcher]

**1.5 MONITORING**

(a) How will researchers monitor the conduct of the project to ensure that it complies with the protocols set out in this application, the University's human ethics guidelines and the National Statement on Ethical Conduct in Research Involving Humans? [Address, in particular, cases where several people are

involved in recruiting, interviewing or administering procedures, or when the research is being carried out at some distance from the Principal Researcher (i.e. interstate or overseas)]

- (b)** For student research projects how will the student be supervised to ensure they comply with the protocols? If the student is working overseas, provide additional details of any local supervision arrangements.

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## **2. PARTICIPANT DETAILS**

**2.1 DOES THE RESEARCH SPECIFICALLY TARGET:** [Tick as many as applicable]

- a. students or staff of this University
  - b. adults (over the age of 18 years and competent to give consent)
  - c. children/legal minors (anyone under the age of 18 years)
  - d. the elderly
  - e. people from non-English speaking backgrounds
  - f. pensioners or welfare recipients
  - g. anyone intellectually or mentally impaired who cannot provide consent
  - h. anyone who has a physical disability
  - i. patients or clients of professionals
  - j. anyone who is a prisoner or parolee
  - k. a ward of the state
  - l. any other person whose capacity to give informed consent may be compromised
  - m. Aboriginal and/or Torres Strait Islander people and/or communities
  - n. other collectives where a leader or council of elders may need to give consent

NO

## **2.2 NUMBER, AGE RANGE AND SOURCE OF PARTICIPANTS**

*Provide number, age range and source of participants.*

**2.3 JUSTIFICATION OF PARTICIPANT NUMBERS** [The quality and validity of research is an essential condition of its ethical acceptability (refer National Statement page 5)] *Where applicable, provide a justification of sample size (including details of statistical power of the sample, where appropriate), explaining how this sample size will allow the aims of the study to be achieved.*

## **2.4 PARTICIPANT RECRUITMENT**

(a) Please indicate the method of recruitment by ticking the appropriate boxes. Tick all that apply.

<b>Mail out - <u>see below</u></b>	<input type="checkbox"/> <b>Email - <u>see below</u></b>	<input type="checkbox"/> <b>Telephone</b>	<input type="checkbox"/>
<b>Advertisement - <u>see below</u></b>	<input type="checkbox"/> <b>Recruitment carried out by third party (eg. employer, doctor) - <u>see below</u></b>	<input type="checkbox"/> <b>Recruitment carried out by researcher/s</b>	<input type="checkbox"/>
<b>Contact details obtained from public documents (eg. phone book)</b>	<input type="checkbox"/> <b>Contact details obtained from private sources (eg. employee list, membership database) - <u>see below</u></b>	<input type="checkbox"/> <b>Personal contacts</b>	<input type="checkbox"/>
<b>Participants from a previous study</b>	<input type="checkbox"/> <b>Snowball (participants suggest other potential participants)</b>	<input type="checkbox"/> <b>Other (Please explain in no more than 50 words):</b>	<input type="checkbox"/>

- If using a **mail out** or **email** who will be distributing it?
  - If using an **advertisement**:

Yes  No  NA  If "No," please explain (no more than 50 words):

- If recruitment is to be conducted by a **third party**, (eg employer, doctor) have you attached an approval letter?

- requesting their assistance? [yes, no or not applicable]  
Yes  No  NA  If "No" please explain (no more than 50 words):

- confirming their willingness to assist?  
Yes  No  NA  If "No" please explain (no more than 50 words):

- that has been drafted for the third party to send to potential participants?  
Yes  No  NA  If "No" please explain (no more than 50 words):

- If contact details are to be obtained from **private sources**, have you attached an approval letter?  
Yes  No  If "No" please explain (no more than 50 words):

(b) Describe how, by whom, where potential participants are to be identified or selected for this research.

(c) Describe how, by whom, where potential participants are to be approached or invited to take part in this research.

## 2.5 DEPENDENT RELATIONSHIPS

[The issue of research involving persons in dependent or unequal relationships (e.g. teacher/student, doctor/patient, student/lecturer, client/counsellor, warder/prisoner, and employer/employee) is discussed in Section 7 of the National Statement. Such a relationship may compromise a participant's ability to give consent which is free from any form of pressure (real or implied)]. Are any of the participants in a dependent relationship with any of the researchers, particularly those involved in recruiting for or conducting the project?

YES  NO (If YES, explain the dependent relationship and the steps to be taken by the researchers to ensure that participation is purely voluntary and not influenced by the relationship in any way.)

## 2.6 PAYMENT OR INCENTIVES OFFERED TO PARTICIPANTS

Do you propose to pay, reimburse or reward participants?

YES  NO (If YES, how, how much and for what purpose? Please justify the approach)

## 2.7 DECEPTION OR CONCEALMENT

[Deception and concealment is discussed in Section 17 of the National Statement. Essentially the practice is not considered ethical unless there are compelling reasons given for its use] Will the true purpose of the research, or the collection of data itself, be concealed from participants or will participants in any way be deceived?

YES  NO

If you answered YES, provide a clear justification. [You will also need to provide participants with details of the deception in a debriefing (refer 3.4) and give them the opportunity to withdraw their data if they wish to do so.]

## 3. RISK AND RISK MANAGEMENT

### 3.1 STUDY PROFILE –DOES THE RESEARCH INVOLVE THE FOLLOWING:

[Tick as many as apply. Provide details in methodology –section 1.5 and attach information where indicated]

- |  | YES                      | NO                       |
|--|--------------------------|--------------------------|
| • use of questionnaires designed by the researcher ( <b>attach a copy</b> )      | <input type="checkbox"/> | <input type="checkbox"/> |
| • use of standard survey instruments ( <b>attach a copy</b> )                    | <input type="checkbox"/> | <input type="checkbox"/> |
| • use of on-line surveys ( <b>attach printout of screen information</b> )        | <input type="checkbox"/> | <input type="checkbox"/> |
| • use of interviews ( <b>attach the list of interview questions</b> )            | <input type="checkbox"/> | <input type="checkbox"/> |
| • use of focus groups ( <b>attach the list of focus group topics/questions</b> ) | <input type="checkbox"/> | <input type="checkbox"/> |
| • observation of participants without their knowledge                            | <input type="checkbox"/> | <input type="checkbox"/> |
| • covert observation   | <input type="checkbox"/> | <input type="checkbox"/> |

- |   |                          |                                     |
|---|--------------------------|-------------------------------------|
| • audio-taping interviewees or events   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • video-taping interviewees or events   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • access to personal and/or confidential data (including student, patient or client data) without the participant's specific consent  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • administration of any stimuli, tasks, investigations or procedures which may be experienced by participants as physically or mentally painful, stressful or unpleasant during or after the research process | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • performance of any acts which might diminish the self-esteem of participants or cause them to experience embarrassment, regret or depression  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • research about participants involved in illegal activities  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • research conducted in an overseas setting   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • administration of any substance or agent  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • use of non-treatment or placebo control conditions  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • collection of body tissues or fluid samples   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| • collection and/or testing of DNA samples  | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

### 3.2 POTENTIAL RISKS TO PARTICIPANTS

*Identify, as far as possible, all potential risks to participants (e.g. physical, psychological, social, legal or economic etc.), associated with the project and the setting (e.g. overseas) in which the project is conducted. It may be useful to consider the study profile above and your response to participant details in section 2*

### 3.3 MANAGING POTENTIAL RISKS

*Describe what measures you have in place to minimize these potential risks to participants and to ensure that support is available if needed. [Depending on risks, participants may need additional support (e.g. external counseling) during or after the study]*

### 3.4 DEBRIEFING (if applicable)

*What debriefing will participants receive following the study and when? (Attach a copy of any written material or statement to be used in such a debriefing, if applicable). [Participants may need to talk about the experience of being involved in the study with the researchers, as well as learn more about the aims of the research]*

### 3.5 BENEFITS COMPARED TO POTENTIAL RISKS

*Outline the benefits of the study to the community (and participants, if applicable), relative to the potential risks to participants*

### 3.6 MANAGING ADVERSE / UNEXPECTED OUTCOMES

*Describe what measures you have in place in the event that participants experience adverse effects arising from their involvement in the project (e.g. adverse drug reaction, revelation of illegal activity, or unexpected distress due to questioning)*

### 3.7 POTENTIAL RISKS TO RESEARCHERS

*Will there be any significant risks to researchers associated with the project and the setting (e.g. overseas) in which the project is conducted. (e.g. personal safety, health, emotional well being)? [Refer to the University's [Environmental Health & Safety Manual](#) for more information]*

  YES     NO    *(If YES, how will such risks be addressed)*

## 4. INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT

Before research is undertaken, the informed and voluntary consent of participants (and other properly interested parties) is generally required (refer sections 1.7 - 1.12 of the National Statement for more details). Information needs to be provided to participants at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. Such information is often provided in a written **Plain Language Statement**. Each participant's consent needs to be clearly established (e.g. by using a signed **Consent Form**, returning an anonymous survey or recording an agreement for interview).

#### 4.1 PROVIDING INFORMATION FOR PARTICIPANTS

(a) Will you be providing participants with information in a written Plain Language Statement?

YES       NO

(If NO, provide details of the protocol you will use to explain the research project to participants and invite their participation?)

(b) Will arrangements be made to ensure that participants who have difficulty understanding English can comprehend the information provided about the research project?

YES       NO

(If YES, what arrangements have been made? If NO, give reasons.)

#### 4.2 PLAIN LANGUAGE STATEMENT (IF APPLICABLE)

CONFIRM THAT THE PLAIN LANGUAGE STATEMENT WILL:

- | 1.  | be printed on University of Melbourne letterhead   | <input type="checkbox"/> | <input type="checkbox"/> |
|-----|--|--------------------------|--------------------------|
| 2.  | include clear identification of the University, the Department(s) involved, the project title, the Principal and Other Researchers (including contact details), and the study level if it is a student research project.             | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.  | provide details of the purpose of the research project   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.  | provide details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-taping of events), and estimated time commitment  | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.  | provide details of any risks involved and the procedures in place to minimise these.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.  | advise that the project has received clearance by the HREC   | <input type="checkbox"/> | <input type="checkbox"/> |
| 7.  | (if the sample size is small), confirm that this may have implications for protecting the identity of the participants   | <input type="checkbox"/> | <input type="checkbox"/> |
| 8.  | include a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health (if relevant) | <input type="checkbox"/> | <input type="checkbox"/> |
| 9.  | state that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied  | <input type="checkbox"/> |                          |
| 10. | provide advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see ** below)   | <input type="checkbox"/> |                          |
| 11. | provide advice as to whether or not data is to be destroyed after a minimum period (if relevant)   | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. | provide in the footer, the project HREC number, date and version of the PLS  | <input type="checkbox"/> |                          |
| 13. | provide advice that if participants have any concerns about the conduct of this research project that they can contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739       | <input type="checkbox"/> |                          |

YES

NOT APPLICABLE

[\*\*Re 10 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state these limitations]

**PLEASE ATTACH A COPY OF THE PLAIN LANGUAGE STATEMENT TO YOUR APPLICATION**

#### 4.3 OBTAINING CONSENT

**(a) How will each participant's consent be established?**

- |  |                          |  |                          |
|--|--------------------------|--|--------------------------|
| <b>By signing and returning a Consent Form – see 4.4 below</b> | <input type="checkbox"/> | <b>By returning an anonymous survey</b>  | <input type="checkbox"/> |
| <b>Via a verbal agreement</b>                                  | <input type="checkbox"/> | <b>Via a person with lawful authority to consent (eg. parent, doctor) – see 4.3(b) below</b> | <input type="checkbox"/> |
| <b>Via a recorded agreement for interview</b>                  | <input type="checkbox"/> | <b>Other (Please describe in no more than 50 words):</b>                                     | <input type="checkbox"/> |

**(b) If participants are unable to give informed consent, explain who will consent on their behalf and how such consent will be obtained.**

**4.4 CONSENT FORM (IF APPLICABLE)**

**CONFIRM THAT THE CONSENT FORM WILL:**

- |  |                                     |   |
|--|-------------------------------------|---|
| 1. be printed on University of Melbourne letterhead  | <input type="checkbox"/> YES        | <input type="checkbox"/> NOT APPLICABLE |
| 2. include the title of the project and names of researchers   | <input type="checkbox"/>            | <input type="checkbox"/>                |
| 3. state that the project is for research purposes   | <input type="checkbox"/>            | <input type="checkbox"/>                |
| 4. state that involvement in the project is voluntary and that participants are free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied | <input type="checkbox"/>            | <input type="checkbox"/>                |
| 5. outline particular requirements of participants including, for example, whether interviews are to be audio and/or video-taped   | <input type="checkbox"/>            | <input type="checkbox"/>                |
| 6. include arrangements to protect the confidentiality of data   | <input checked="" type="checkbox"/> | <input type="checkbox"/>                |
| 7. include advice that there are legal limitations to data confidentiality (see below)**   | <input type="checkbox"/>            | <input type="checkbox"/>                |
| 8. (if the sample size is small) confirm that this may have implications for protecting the identity of the participants   | <input type="checkbox"/>            | <input type="checkbox"/>                |
| 9. (once signed and returned) be retained by the researcher  | <input type="checkbox"/>            | <input type="checkbox"/>                |

[\*\*Re 7 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state and explain these limitations]

**PLEASE ATTACH A COPY OF THE CONSENT FORM TO YOUR APPLICATION**

**5. PRIVACY AND CONFIDENTIALITY**

[Section 18 of the National Statement describes 'Privacy' as "...a complex concept that stems from a core idea that individuals have a sphere of life from which they should be able to exclude any intrusion." A major application of the concept of privacy is information privacy: the interest of a person in controlling access to and use of any information personal to that person. 'Confidentiality', a narrower more specific term than 'privacy' refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another.]

At the Commonwealth level, the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the *Privacy Act 1988*. Sections 95 and 95A of the Act are of particular relevance to researchers. There is regulation at State and Territory level in the form of legislation related to privacy generally or the administration of agencies, or administrative codes of practice. In Victoria, the *Health Records Act 2001* regulates health information handled by the Victorian public sector and private sector, while the Information Privacy Act 2000 regulates the collection and handling of non-health-related personal information. Section 18.1 of the National Statement states that an HREC must be satisfied that a research proposal conforms to all relevant Commonwealth, State or Territory privacy legislation or codes of practice]

**5.1 ACCESSING PERSONAL INFORMATION**

[Personal Information' includes names, addresses, or information/opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information/opinion. It also includes Health Information (e.g. health opinions, organ donation or genetic information) and Sensitive Information (e.g. political views, sexual preferences, criminal records)]

*Is there a requirement for the researchers to obtain Personal Information (either identifiable or potentially identifiable) about individuals without their consent?*

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| a) from Commonwealth departments or agencies?                      | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| b) from State departments or agencies?                             | <input type="checkbox"/>     | <input type="checkbox"/>    |
| c) from Other Third Parties, such as non-government organisations? | <input type="checkbox"/>     | <input type="checkbox"/>    |

*If you answered YES to (a), (b) or (c), you will need to complete [Module P](#) and attach it to this application*

## 5.2 REPORTING PROJECT OUTCOMES

(a) *Will the project outcomes be made public at the end of the project?*

YES       NO      *(If YES, give details of how the results will be made public (eg in journal articles book, conference paper, the media, working paper or other). If NO, explain why not.)*

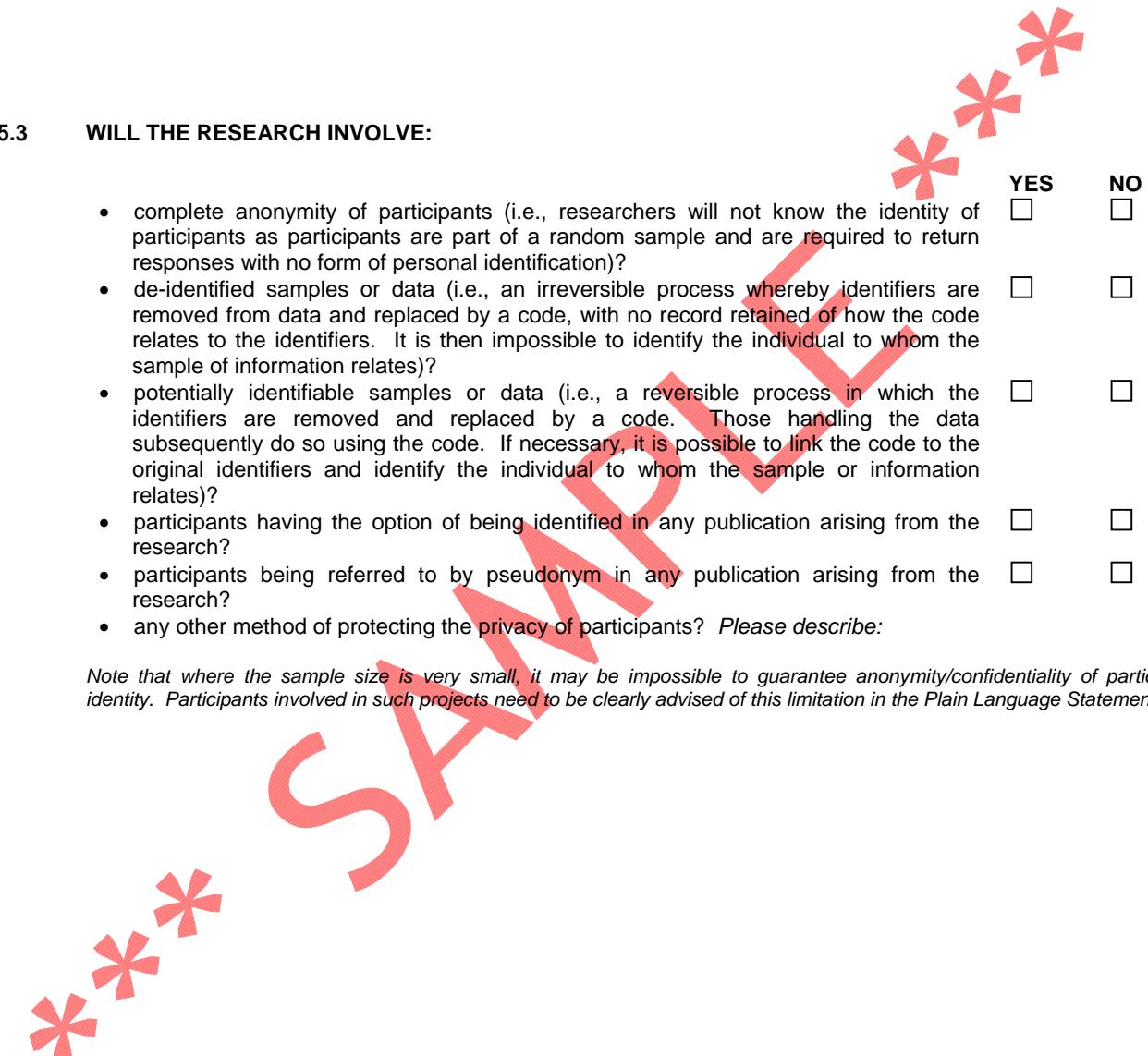
(b) *Will a report of the project outcomes be made available to participants at the end of the project?*

YES       NO      *(If Yes, give details of the type of report and how it will be made available. If No, explain why not.)*

## 5.3 WILL THE RESEARCH INVOLVE:

- complete anonymity of participants (i.e., researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification)?  YES       NO
- de-identified samples or data (i.e., an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates)?  YES       NO
- potentially identifiable samples or data (i.e., a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)?  YES       NO
- participants having the option of being identified in any publication arising from the research?  YES       NO
- participants being referred to by pseudonym in any publication arising from the research?  YES       NO
- any other method of protecting the privacy of participants? *Please describe:*

*Note that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the Plain Language Statement.*



## **6. DATA STORAGE, SECURITY AND DISPOSAL**

### **6.1 DATA STORAGE**

Does data storage comply with the University policy? [University of Melbourne Policy on the Management of Research Data and Records is available at: <http://www.unimelb.edu.au/records/research.html> The Joint NHMRC/AVCC Statement and Guidelines on Research Practice is available at: <http://www.nhmrc.gov.au/funding/policy/researchprac.htm> ]

YES       NO      (If NO, please explain.)

### **6.2 DATA SECURITY**

(a) Will the Principal Researcher be responsible for security of data collected?

YES       NO      (If NO, please provide further details. You may also use this space to explain any differences between arrangements in the field, and on return to campus.)

(b) Will data be kept in locked facilities in the Department through which the project is being conducted?

YES       NO      (If NO, please explain how and where data will be held, including any arrangements for data security during fieldwork.)

(c) Which of the following methods will be used to ensure confidentiality of data?  
(select all options that are relevant)

- data and codes and all identifying information to be kept in separate locked filing cabinets
- access to computer files to be available by password only
- access by named researcher(s) only
- other (please describe)

(d) Will others besides the researchers associated with this project have access to the raw data?

YES       NO      (If YES, please explain who and for what purpose?  
What is their connection to the project?)

### **6.3 DATA RETENTION AND DISPOSAL**

[Research data and records should be maintained for as long as they are of continuing value to the researcher and as long as recordkeeping requirements such as patent requirements, legislative and other regulatory requirements exist. The minimum retention period for research data and records is five years after publication, or public release, of the work of the research as stated in the University of Melbourne [Code of Conduct for Research](#). If the project involves clinical trial(s), the data should be kept for a minimum of 15 years (refer to Section 12.1 of the National Statement for further details)]

Specify how long materials (e.g. files, audiotapes, questionnaires, videotapes, photographs) collected during the study will be retained after the study and how they will ultimately be disposed of.

## **7. POTENTIAL CONFLICT OF INTEREST**

### **7.1 POTENTIAL CONFLICT OF INTEREST**

Is there any affiliation or financial interest for researchers in this research or its outcomes or any circumstances which might represent a perceived, potential or actual conflict of interest?

YES       NO      (If YES, give brief details?)

[If you have declared a potential conflict of interest, you should include an appropriate comment on the Plain Language Statement and Consent Form]

## 7.2 COMPLIANCE WITH THE CODE OF CONDUCT FOR RESEARCH

[University researchers must disclose and manage Conflict of Interest in accord with the provisions of the University's *Code of Conduct for Research*. See <http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html> ]

*Is the Conflict of Interest noted above in section 8.1 being managed in accordance with the Code of Conduct?*

YES       NO       Not Applicable

## 8. DECLARATION BY RESEARCHERS

*The information contained herein is, to the best of our knowledge and belief, accurate.*

*We have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University's *Code of Conduct for Research* and any other condition laid down by the University of Melbourne's Human Research Ethics Committee or its Sub-Committees. We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants. We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.*

*If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.*

*We, the researcher(s) agree:*

- To only start this research project after obtaining final approval from the Human Research Ethics Committee (HREC);
- To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
- To provide additional information as requested by the HREC;
- To provide progress reports to the HREC as requested, including annual and final reports;
- To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
- To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
- To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;
- To agree to an audit if requested by the HREC;
- To only use data and any tissue samples collected for the study for which approval has been given;

*We have read the NH&MRC National Statement on Ethical Conduct in Research Involving Humans and agree to comply with its provisions.*

*All researchers associated with this project must sign*

Researchers' Name (please PRINT)	Signature	Date

## **9. DECLARATION BY DEPARTMENTAL HUMAN ETHICS ADVISORY GROUP (HEAG)**

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

The HEAG has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommends approval of the project. The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a principal researcher for this project, the declaration should be signed by another authorised member of the HEAG]

Comments/Provisos:

Name of HEAG Chair (in BLOCK LETTERS)	
Signature	
Date	

## **10. DECLARATION BY HEAD OF DEPARTMENT**

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

I have reviewed this project and consider the methodological, technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommend approval of the project. I consider that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]

This project has the approval and support of this Department/School/Centre.

Name of Head (in BLOCK LETTERS)	
Signature	
Date	

## **11. WHEN COMPLETE**

When this form has been completed and finalised it should be attached to the coversheet section of the application completed in Themis Research and then submitted to the nominated Human Ethics Advisory Group for review.

**INTENTIONALLY BLANK**

# Creating a Program Human Ethics Application

A Program application is to be completed where a group of researchers (or a whole department) wish to seek approval for a program of research within which a series of related individual research projects will be undertaken. A Program application requires HEAG review and HESC approval. Related individual projects can be approved by a HEAG (for further information on creating a Project refer to the **Creating a Project Within A Program Human Ethics Application** information sheet).

## Creating a Program Application

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the **Create** button in the Create New Documents section.

<a href="#">Human Ethics Home Page - Researcher Worklist</a>	
<a href="#">Create New Documents</a>	
Ethics Application (including transfers and registrations): <a href="#">Create</a>	

The Project Type screen will display.

## Define the Project Type

- 1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

**Note:** you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

- 2 Click on the **Next** button.

The Research Checklist screen will display.

## Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

**Important:** you must select at least one item from the Available Checklist Item list before progressing (choose **None of the above** if applicable). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

- 1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 2 Click on the arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the arrow to remove an item from the Selected Checklist Items list, if required.

- 3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

- 4 Click on the **Next** button.

The Application Type screen will display.

## Select the Application Type

- 1** Click on the appropriate radio button (**Program**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

- 2** Click on the **Next** button.

You will need to complete the Program checklist before progressing through to the Application Message screen.

## Complete the Program Checklist

The Program Checklist requires you to confirm you are submitting an ethics application for a broad program.

*Please confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be undertaken as part of the program.*

- 1** Click on the **Yes** or **No** radio button.

**Note:** if you answer **No** it means the project is not eligible for submission as a Program. You will be returned to the Project Type screen and will need to choose an alternate project type.

- 2** Click on the **Next** button.

The Application Message screen will display.

## Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.

Step 5 - Application Message			
<input type="button" value="Cancel"/> <input type="button" value="Save As Draft"/> <input type="button" value="Back"/> <input type="button" value="Step 5 of 15"/> <input type="button" value="Next"/>			
Ethics Application ID	Status	Application Type	Approval Category
0600148.1	Draft	Program Application	HESC
Based on the responses provided this project is eligible for submission as a Program Application.			

- 1** Click on the **Next** button.

The Project Details screen will display.

## Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

### 1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	Select the appropriate HEAG from the drop-down list	
Other Participating HEAGs	Click on the <b>Add Another HEAG</b> button, then select the appropriate HEAG from the drop-down list	This field is optional and should be used if the Program is to cover research projects considered by more than one HEAG.
HESC	This field will default based on the Responsible HEAG selected above	
Program Category	Tick the appropriate checkbox/s to select the category/s that apply to the program application	
Degrees for which research may be undertaken	Tick the appropriate checkbox/s to select the degree/s for which research may be undertaken	
Project Title	Enter the title of your program	
Brief description of project	Enter a brief description of the program	The description, no more than 100 words, should outline the broad aims and key questions of the program.
Overview of anticipated staff/student involvement	Enter an overview of staff and students likely to be involved in Projects within the program	<b>Note:</b> you should not include specific details of researchers that are to be named in the Program Application.
Program From date	Use the drop-down list to select the month and year the program is expected to start	The proposed start date should allow for a reasonable period of review of the program application.
Program To date	Use the drop-down list to select the month and year the program is expected to end	

### 2 Click on the **Next** button.

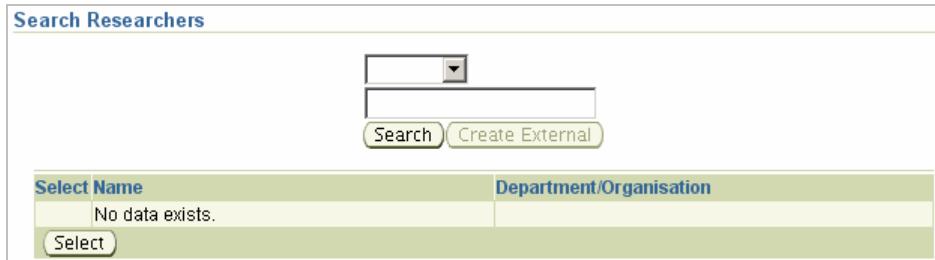
The Participating Researcher screen will display.

## Enter the Participating Researchers

The Project Details screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details.

### 1 Click on the **Add Researcher** button.

The Search Researchers screen will display.



Select Name	Department/Organisation
No data exists.	
<input type="button" value="Select"/>	

### 2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

### 3 Enter the surname of the researcher for which you are searching in the bottom field.

**4** Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to [Creating an External Researcher in Human Ethics](#)).

Select Name	Department/Organisation
<input checked="" type="radio"/> BALL, MS CRYSTAL	018-University Systems Project
<b>Select</b>	

**5** Click on the radio button in the Select column to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

*Enter the Researcher Details*

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

**6** Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 7.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. <b>Note:</b> the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	<b>Note:</b> these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. <b>Note:</b> you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

**7** Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select Researcher Role	Researcher Type	Researcher Name	Department/Organisation
<input checked="" type="radio"/> Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project
<b>Add Researcher</b> <b>Delete Researcher</b> <b>Update Researcher</b>			

**8** Follow **steps 1 to 7** above to enter additional researchers if required.

**Note:** for any project there must be one and only one Responsible Researcher named against the project.

**9** Once you have added all the required researchers, click on the **Next** button to continue.

The Additional Documentation Required screen will display.

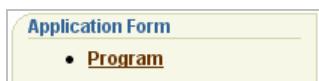
## Access Additional Documentation

The Additional Documentation Required screen will display any forms that you must complete and attach to your ethics application prior to submission. The forms are available on the Research Office web site but you will be able to download them via the hyperlink/s on this screen. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

- 1** **Important:** Click on the **Save As Draft** button before proceeding to download any additional documentation.

A confirmation message will display advising that the application has been saved.

- 2** Click on the hyperlink for the form you wish to download.



The link will access the relevant document from the Research Office web site and open it in a new browser window. In most cases the document will open at an instruction sheet, and you will need to scroll down from this page to view the body of the form.

- 3** Save the document to your PC/local server for later completion and attachment to Themis.
- 4** Close the browser window and reactivate your Themis session.
- 5** Complete **steps 2 to 4** above for all required documents.
- 6** Once you have accessed all the required documents, click on the **Next** button to continue.

The Attachments screen will display.

## Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

### Add an electronic attachment

- 1** Click on the **Add Attachment** button in the Attachment table.

The Add Attachment screen will display.

- 2** Complete the attachment details.

Field	Action	Comments
Add	Field will default to <b>Desktop File/Text/URL</b> , do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Interview, Miscellaneous, Plain Language Statement, and Test.</b> <b>Note:</b> you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	<b>If selecting File:</b> click on the <b>Browse</b> button to locate and select the document you wish to attach. <b>If selecting URL:</b> type the full internet address you wish to reference. <b>If selecting Text:</b> enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

If you wish to add multiple attachments, go to task # 3. Otherwise go to task #4.

- 3** Click on the **Add Another** button and repeat **step 2** for each new attachment.

- 4** Once you have added all your attachments click on the **Apply** button.

You will receive a confirmation that the attachment has been added but not saved.

- 5** Click on the **Save As Draft** button to save the attachment.

## Register a document to be provided in hard copy only

**1** Click on the **Add Another Row** button in the Supporting Documents table.

The Add Attachment screen will display.

**2** Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Evidence of Approval, Interview, Other, Plain Language Statement, and Questionnaire/Survey.</b>
Description	Enter a brief description of the document you will be submitting	

**3** Repeat **steps 1 and 2** for each document you wish to register.

**4** Once you have registered all your attachments click on the **Save As Draft** button.

You will receive a confirmation that the application has been saved.

**5** Once you have attached all the required documents, click on the **Next** button to continue.

The Application Review screen will display.

## Review the Application

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

*If validation errors are identified*

Application Review					
Data validation errors have been identified in this application. You cannot proceed to the submission page until the errors specified in the table below have been corrected.					
<b>Data Validation Error</b> Multiple electronic attachments of type 'Application' have been attached to this application	<table border="1"> <tr> <td><b>Application Step</b></td> <td><b>Go To Page</b></td> </tr> <tr> <td>Step 15</td> <td></td> </tr> </table>	<b>Application Step</b>	<b>Go To Page</b>	Step 15	
<b>Application Step</b>	<b>Go To Page</b>				
Step 15					

**1** Click on the associated icon in the Go To Page column.

This will link you directly to the appropriate page.

**2** Update the information as required and click on the **Save As Draft** button to commit your changes.

**3** Use the drop down list ( at the bottom of the screen to return to the review page.

**4** Repeat **steps 1 to 3** above for each of the validation errors.

**5** Click on the **Next** button.

The Submission screen will display.

## Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

**1** Read the submission confirmation statement.

**2** Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).

**Important:** if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

**3** Click on the **Submit Application** button.

A Confirmation of Submission screen will display.

**Note:** all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

## Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

**1** Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

**2** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).

**3** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

**4** Click on the **Output** icon to open the application in the web browser screen.

**5** Select **File > Print** from the web browser Toolbar to print the application.

**6** Ensure the application is signed by all responsible researchers.

**7** Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

## Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	<p>For any project there must be a Responsible Researcher named against the project.</p> <p><b>Note:</b> there may only be one person with this role per application and only a member of staff may be named.</p> <p>In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects).</p> <p>Only the person named as Responsible Researcher, and the creator, will have access to update an application.</p>
Student Researcher	<p>There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.</p>
Co-researcher	<p>There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).</p>
Associated Personnel	<p>There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.</p>



**THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE**

**PROGRAM APPLICATION**

THE UNIVERSITY OF  
MELBOURNE

**PROGRAM REFERENCE DETAILS**

Enter the Ethics ID number assigned by Themis Research to this ethics application.


Enter the title of the Program as recorded in Themis Research

Enter the name of the Responsible Researcher as recorded in Themis Research

**1. PROGRAM DETAILS**

1.1 **EXECUTIVE SUMMARY IN PLAIN ENGLISH:** *Provide a brief summary of the Program of research, including what participants will be required to do. [This description must be in everyday language, free from jargon, technical terms or discipline-specific phrases. (No more than 300 words).]*

1.2 **AIMS OF AND JUSTIFICATION FOR THE RESEARCH:** *State the aims and significance of the Program. Also please provide a brief description of current research, a justification as to why this research should proceed and an explanation of any expected benefits to the community. [No more than 600 words]*

1.3 **PROGRAM DESCRIPTION:** *Please provide a detailed description of the proposed Program, including:*

- the research parameters;
- the major research questions;
- the level to which the projects within the Program will be identical;
- proposed methodology;
- an explanation of what participants will be required to do;
- any procedure which is beyond already established and accepted techniques.

*[The description should normally be no more than two pages long and should be intelligible to someone who is not an expert in the field]*

1.4 **USE OF INDEPENDENT CONTRACTORS** *Will parts of this Program of research be carried out by independent contractors? (e.g. interviewing, questionnaire design and analysis, sample testing, etc)*

YES       NO

*If YES, confirm that the independent contractor will be engaged on the basis of relevant qualifications and experience and will receive from the first named Principal Researcher, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it. [The responsibility for effective oversight and proper conduct of the Program remains with the Principal Researcher(s)]*

**1.5 MONITORING**

(a) *How will researchers monitor the conduct of the Program to ensure that it complies with the protocols set out in this application, the University's human ethics guidelines and the National Statement on Ethical Conduct in Research Involving Humans? [Address, in particular, cases where several people are*

involved in recruiting, interviewing or administering procedures, or when the research is being carried out at some distance from the Principal Researcher (i.e. interstate or overseas)]

- (b)** For student research projects associated with this Program how will the student be supervised to ensure they comply with the protocols? If the student is working overseas, provide additional details of any local supervision arrangements.

## **2. PARTICIPANT DETAILS**

**2.1      DOES THE RESEARCH SPECIFICALLY TARGET:** [Tick as many as applicable]

- a. students or staff of this University
  - b. adults (over the age of 18 years and competent to give consent)
  - c. children/legal minors (anyone under the age of 18 years)
  - d. the elderly
  - e. people from non-English speaking backgrounds
  - f. pensioners or welfare recipients
  - g. anyone intellectually or mentally impaired who cannot provide consent
  - h. anyone who has a physical disability
  - i. patients or clients of professionals
  - j. anyone who is a prisoner or parolee
  - k. a ward of the state
  - l. any other person whose capacity to give informed consent may be compromised
  - m. Aboriginal and/or Torres Strait Islander people and/or communities
  - n. other collectives where a leader or council of elders may need to give consent

YES     NO

## 2.2 NUMBER, AGE RANGE AND SOURCE OF PARTICIPANTS

*Provide number, age range and source of participants.*

**2.3 JUSTIFICATION OF PARTICIPANT NUMBERS** [The quality and validity of research is an essential condition of its ethical acceptability (refer National Statement page 5)] Where applicable, provide a justification of sample size (including details of statistical power of the sample, where appropriate), explaining how this sample size will allow the aims of the study to be achieved.

## **2.4 PARTICIPANT RECRUITMENT**

- (a) Please indicate the method of recruitment by ticking the appropriate boxes. Tick all that apply.

**Mail out - see below**

Email- see below

Telephone

1

## **Advertisement - see below**

Recruitment carried out by third party

Recruitment carried out by researcher/s

1

**Contact details obtained from  
public documents (eg. phone  
book)**

Contact details obtained from private sources (eg. employee list, membership lists, etc.)

**Personal contacts**

□

**Participants from a previous study**

database) – see below  
**Snowball** (participants suggest other potential participants)

Other (Please explain in no more than 50 words):

- If using a **mail out** or **email** who will be distributing it?
  - If using an **advertisement**:
    - explain where will it be placed? [e.g. on waiting room wall, in newspaper, in newsletter]
    - have you attached a copy?

Yes  No  NA  If "No" please explain (no more than 50 words):

- If recruitment is to be conducted by a **third party**, (eg employer, doctor) have you attached an approval letter?

- requesting their assistance? [yes, no or not applicable]

Yes  No  NA  If "No" please explain (no more than 50 words):

- confirming their willingness to assist?  
Yes  No  NA  If "No" please explain (no more than 50 words):

- that has been drafted for the third party to send to potential participants?  
Yes  No  NA  If "No" please explain (no more than 50 words):

- If contact details are to be obtained from **private sources**, have you attached an approval letter?  
Yes  No  If "No" please explain (no more than 50 words):

(b) Describe how, by whom, where potential participants are to be identified or selected for this research.

(c) Describe how, by whom, where potential participants are to be approached or invited to take part in this research.

## 2.5 DEPENDENT RELATIONSHIPS

[The issue of research involving persons in dependent or unequal relationships (e.g. teacher/student, doctor/patient, student/lecturer, client/counsellor, warder/prisoner, and employer/employee) is discussed in Section 7 of the National Statement. Such a relationship may compromise a participant's ability to give consent which is free from any form of pressure (real or implied)]. Are any of the participants in a dependent relationship with any of the researchers, particularly those involved in recruiting for or conducting the Program of research?

YES  NO (If YES, explain the dependent relationship and the steps to be taken by the researchers to ensure that participation is purely voluntary and not influenced by the relationship in any way.)

## 2.6 PAYMENT OR INCENTIVES OFFERED TO PARTICIPANTS

Do you propose to pay, reimburse or reward participants?

YES  NO (If YES, how, how much and for what purpose? Please justify the approach)

## 2.7 DECEPTION OR CONCEALMENT

[Deception and concealment is discussed in Section 17 of the National Statement. Essentially the practice is not considered ethical unless there are compelling reasons given for its use] Will the true purpose of the research, or the collection of data itself, be concealed from participants or will participants in any way be deceived?

YES  NO

If you answered YES, provide a clear justification. [You will also need to provide participants with details of the deception in a debriefing (refer 3.4) and give them the opportunity to withdraw their data if they wish to do so.]

## 3. RISK AND RISK MANAGEMENT

### 3.1 STUDY PROFILE –DOES THE RESEARCH INVOLVE THE FOLLOWING:

[Tick as many as apply. Provide details in the Program description –section 1.7 and attach information where indicated]

	YES	NO
• use of questionnaires designed by the researcher ( <b>attach a copy</b> )	<input type="checkbox"/>	<input type="checkbox"/>
• use of standard survey instruments ( <b>attach a copy</b> )	<input type="checkbox"/>	<input type="checkbox"/>
• use of on-line surveys ( <b>attach printout of screen information</b> )	<input type="checkbox"/>	<input type="checkbox"/>
• use of interviews ( <b>attach the list of interview questions</b> )	<input type="checkbox"/>	<input type="checkbox"/>
• use of focus groups ( <b>attach the list of focus group topics/questions</b> )	<input type="checkbox"/>	<input type="checkbox"/>
• observation of participants without their knowledge	<input type="checkbox"/>	<input type="checkbox"/>
• covert observation	<input type="checkbox"/>	<input type="checkbox"/>
• audio-taping interviewees or events	<input type="checkbox"/>	<input type="checkbox"/>
• video-taping interviewees or events	<input type="checkbox"/>	<input type="checkbox"/>
• access to personal and/or confidential data (including student, patient or client data)	<input type="checkbox"/>	<input type="checkbox"/>

- without the participant's specific consent
- administration of any stimuli, tasks, investigations or procedures which may be experienced by participants as physically or mentally painful, stressful or unpleasant during or after the research process
  - performance of any acts which might diminish the self-esteem of participants or cause them to experience embarrassment, regret or depression
  - research about participants involved in illegal activities
  - research conducted in an overseas setting
  - administration of any substance or agent
  - use of non-treatment or placebo control conditions
  - collection of body tissues or fluid samples
  - collection and/or testing of DNA samples

### **3.2 POTENTIAL RISKS TO PARTICIPANTS**

*Identify, as far as possible, all potential risks to participants (e.g. physical, psychological, social, legal or economic etc.), associated with the Program and the setting (e.g. overseas) in which the study is conducted. It may be useful to consider the study profile above and your response to participant details in section 2*

### **3.3 MANAGING POTENTIAL RISKS**

*Describe what measures you have in place to minimize these potential risks to participants and to ensure that support is available if needed. [Depending on risks, participants may need additional support (e.g. external counseling) during or after the study]*

### **3.4 DEBRIEFING (if applicable)**

*What debriefing will participants receive following the study and when? (Attach a copy of any written material or statement to be used in such a debriefing, if applicable). [Participants may need to talk about the experience of being involved in the study with the researchers, as well as learn more about the aims of the research]*

### **3.5 BENEFITS COMPARED TO POTENTIAL RISKS**

*Outline the benefits of the study to the community (and participants, if applicable), relative to the potential risks to participants*

### **3.6 MANAGING ADVERSE / UNEXPECTED OUTCOMES**

*Describe what measures you have in place in the event that participants experience adverse effects arising from their involvement in the study (e.g. adverse drug reaction, revelation of illegal activity, or unexpected distress due to questioning)*

### **3.7 POTENTIAL RISKS TO RESEARCHERS**

*Will there be any significant risks to researchers associated with the study and the setting (e.g. overseas) in which the any of the projects associated with this Program is conducted. (e.g. personal safety, health, emotional well being)? [Refer to the University's [Environmental Health & Safety Manual](#) for more information]*

YES

NO

(If YES, how will such risks be addressed)

## 4. INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT

Before research is undertaken, the informed and voluntary consent of participants (and other properly interested parties) is generally required (refer sections 1.7 - 1.12 of the National Statement for more details). Information needs to be provided to participants at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. Such information is often provided in a written **Plain Language Statement**. Each participant's consent needs to be clearly established (e.g. by using a signed **Consent Form**, returning an anonymous survey or recording an agreement for interview).

### 4.1 PROVIDING INFORMATION FOR PARTICIPANTS

- (a) *Will participants be provided with information about any of the projects within this Program in a written Plain Language Statement (PLS)?*

YES       NO

*(If YES, please attach a copy of the type of PLS that will be provided. If NO, provide details of the type of protocol that will be used to explain any of the projects within this Program to participants and invite their participation?)*

- (b) *Will arrangements be made to ensure that participants who have difficulty understanding English can comprehend the information provided about any of the projects within this Program?*

YES       NO

*(If YES, what arrangements have been made? If NO, give reasons.)*

### 4.2 OBTAINING CONSENT

- (a) *How will each participant's consent be established for any of the projects within this Program?*

By signing and returning a Consent Form – see 4.2(b)

By returning an anonymous survey

Via a verbal agreement

Via a person with lawful authority to consent (eg. parent, doctor) – see 4.2(c) below

Via a recorded agreement for interview

Other (Please describe in no more than 50 words):

- (b) *Please attach a copy of the type of consent form that will be used.*

- (c) *If participants are unable to give informed consent, explain who will consent on their behalf and how such consent will be obtained.*

## 5. PRIVACY AND CONFIDENTIALITY

[Section 18 of the National Statement describes 'Privacy' as "...a complex concept that stems from a core idea that individuals have a sphere of life from which they should be able to exclude any intrusion." A major application of the concept of privacy is information privacy: the interest of a person in controlling access to and use of any information personal to that person. 'Confidentiality', a narrower more specific term than 'privacy' refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another.]

At the Commonwealth level, the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the *Privacy Act 1988*. Sections 95 and 95A of the Act are of particular relevance to researchers. There is regulation at State and Territory level in the form of legislation related to privacy generally or the administration of agencies, or administrative codes of practice. In Victoria, the *Health Records Act 2001* regulates health information handled by the Victorian public sector and private sector, while the *Information Privacy Act 2000* regulates the collection and handling of non-health-related personal information. Section 18.1 of the National Statement states that an HREC must be satisfied that a research proposal conforms to all relevant Commonwealth, State or Territory privacy legislation or codes of practice]

### 5.1 ACCESSING PERSONAL INFORMATION

[Personal Information' includes names, addresses, or information/opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information/opinion. It also includes Health Information (e.g. health opinions, organ donation or genetic information) and Sensitive Information (e.g. political views, sexual preferences, criminal records)]

*Is there a requirement for the researchers to obtain Personal Information (either identifiable or potentially identifiable) about individuals without their consent?*

- a) from Commonwealth departments or agencies?
- b) from State departments or agencies?
- c) from Other Third Parties, such as non-government organisations?

YES	<input type="checkbox"/>	<input type="checkbox"/>
NO	<input type="checkbox"/>	<input type="checkbox"/>

*If you answered YES to (a), (b) or (c), you will need to complete [Module P](#) and attach it to this application*

### 5.2 REPORTING PROGRAM OUTCOMES

(a) *Will the Program outcomes be made public at the end of the research?*

YES       NO

*(If YES, give details of how the results will be made public (eg in journal articles book, conference paper, the media, working paper or other). If NO, explain why not.)*

(b) *Will a report of the Program outcomes be made available to participants at the end of the research?*

YES       NO

*(If Yes, give details of the type of report and how it will be made available. If No, explain why not.)*

### 5.3 WILL THE RESEARCH INVOLVE:

- complete anonymity of participants (i.e., researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification)?
- de-identified samples or data (i.e., an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates)?
- potentially identifiable samples or data (i.e., a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)?
- participants having the option of being identified in any publication arising from the research?
- participants being referred to by pseudonym in any publication arising from the research?
- any other method of protecting the privacy of participants? Please describe:

YES	<input type="checkbox"/>	<input type="checkbox"/>
NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	<input type="checkbox"/>	<input type="checkbox"/>
NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	<input type="checkbox"/>	<input type="checkbox"/>
NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	<input type="checkbox"/>	<input type="checkbox"/>
NO	<input type="checkbox"/>	<input type="checkbox"/>

*Note that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such research need to be clearly advised of this limitation in the Plain Language Statement.*

## **6. DATA STORAGE, SECURITY AND DISPOSAL**

### **6.1 DATA STORAGE**

Does data storage comply with the University policy? [University of Melbourne Policy on the Management of Research Data and Records is available at: <http://www.unimelb.edu.au/records/research.html> The Joint NHMRC/AVCC Statement and Guidelines on Research Practice is available at: <http://www.nhmrc.gov.au/funding/policy/researchprac.htm> ]

YES       NO      (If NO, please explain.)

### **6.2 DATA SECURITY**

(a) Will the Principal Researcher be responsible for security of data collected?

YES       NO      (If NO, please provide further details. You may also use this space to explain any differences between arrangements in the field, and on return to campus.)

(b) Will data be kept in locked facilities in the Department through which the Program is being conducted?

YES       NO      (If NO, please explain how and where data will be held, including any arrangements for data security during fieldwork.)

(c) Which of the following methods will be used to ensure confidentiality of data? (select all options that are relevant)

- data and codes and all identifying information to be kept in separate locked filing cabinets
- access to computer files to be available by password only
- access by named researcher(s) only
- other (please describe)

(d) Will others besides the researchers listed in sections 0.3 and 0.4 have access to the raw data?

YES       NO      (If YES, please explain who and for what purpose? What is their connection to the Program?)

### **6.3 DATA RETENTION AND DISPOSAL**

[Research data and records should be maintained for as long as they are of continuing value to the researcher and as long as recordkeeping requirements such as patent requirements, legislative and other regulatory requirements exist. The minimum retention period for research data and records is five years after publication, or public release, of the work of the research as stated in the University of Melbourne [Code of Conduct for Research](#). If the research involves clinical trial(s), the data should be kept for a minimum of 15 years (refer to Section 12.1 of the National Statement for further details)]

Specify how long materials (e.g. files, audiotapes, questionnaires, videotapes, photographs) collected during the study will be retained after the study and how they will ultimately be disposed of.

## **7. POTENTIAL CONFLICT OF INTEREST**

### **7.1 POTENTIAL CONFLICT OF INTEREST**

*Is there any affiliation or financial interest for researchers in this research or its outcomes or any circumstances which might represent a perceived, potential or actual conflict of interest?*

YES       NO      (If YES, give brief details?)

[If you have declared a potential conflict of interest, you should include an appropriate comment on the Plain Language Statement and Consent Form]

### **7.2 COMPLIANCE WITH THE CODE OF CONDUCT FOR RESEARCH**

[University researchers must disclose and manage Conflict of Interest in accord with the provisions of the University's Code of Conduct for Research. See <http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html>]

*Is the Conflict of Interest noted above in section 8.1 being managed in accordance with the Code of Conduct?*

YES       NO       Not Applicable

## **8. DECLARATION BY RESEARCHERS**

*The information contained herein is, to the best of our knowledge and belief, accurate.*

*We have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University's Code of Conduct for Research and any other condition laid down by the University of Melbourne's Human Research Ethics Committee or its Sub-Committees. We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants. We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.*

*If approval is granted, the Program and its associated projects will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.*

*We, the researcher(s) agree:*

- *To only start this research after obtaining final approval for the Program from the Human Research Ethics Committee (HREC) and final approval for individual projects belonging to this Program from the departmental Human Ethics Advisory Group (HEAG);*
- *To only carry out this research where adequate funding is available to enable the research to be carried out according to good research practice and in an ethical manner;*
- *To provide additional information as requested by the HREC;*
- *To provide progress reports to the HREC as requested, including annual and final reports;*
- *To maintain the confidentiality of all data collected from or about research participants, and maintain security procedures for the protection of privacy;*
- *To notify the HREC in writing immediately if any change to the Program is proposed and await approval before proceeding with the proposed change;*
- *To notify the HEAG in writing immediately if any change to any project belonging to this Program is proposed and await approval before proceeding with the proposed change;*
- *To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;*
- *To agree to an audit if requested by the HREC;*
- *To only use data and any tissue samples collected for the study for which approval has been given;*

*We have read the NH&MRC National Statement on Ethical Conduct in Research Involving Humans and agree to comply with its provisions.*

**All researchers listed the application must sign**

Researchers' Name (please PRINT)	Signature	Date

#### **9. DECLARATION BY DEPARTMENTAL HUMAN ETHICS ADVISORY GROUP (HEAG)**

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

*The HEAG has reviewed this Program and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommends approval of the Program. The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a principal researcher for this Program, the declaration should be signed by another authorised member of the HEAG]*

Comments/Provisos:

Name of HEAG Chair (in BLOCK LETTERS)	
Signature	
Date	

#### **10. DECLARATION BY HEAD OF DEPARTMENT**

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

*I have reviewed this Program and consider the methodological, technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommend approval of the Program. I consider that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the Head of Department is also a principal researcher for this Program, the declaration should be signed by another authorised member of the Department]*

*This Program has the approval and support of this Department/School/Centre.*

Name of Head (in BLOCK LETTERS)	
Signature	
Date	

#### **10 WHEN COMPLETE**

**When this form has been completed and finalised it should be attached to the coversheet section of the application completed in Themis Research and then submitted to the nominated Human Ethics Advisory Group for review.**

A Project Within a Program application is to be completed for an individual research project which is part of an HREC approved Program of research. If you are unsure whether your research fits within this category, you may select the Project Within a Program option and complete the related checklist to determine whether you can proceed. A Project Within a Program application can be approved by a HEAG. For further information on creating a Program refer to the **Creating a Program Human Ethics Application** information sheet.

## Creating a Project Within a Program Application

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the **Create** button in the Create New Documents section.

<a href="#">Human Ethics Home Page - Researcher Worklist</a>	
<a href="#">Create New Documents</a>	
Ethics Application (including transfers and registrations): <a href="#">Create</a>	

The Project Type screen will display.

### Define the Project Type

- 1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

**Note:** you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

- 2 Click on the **Next** button.

The Research Checklist screen will display.

### Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

**Important:** you must select at least one item from the Available Checklist Item list before progressing (choose **None of the above** if applicable). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

- 1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 2 Click on the  arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the  arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the  arrow to remove an item from the Selected Checklist Items list, if required.

- 3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

- 4 Click on the **Next** button.

The Application Type screen will display.

## Select the Application Type

- 1** Click on the appropriate radio button (**Project Within A Program**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

- 2** Click on the **Next** button.

You will need to complete additional Project information before progressing through to the Application Message screen.

## Complete Project Within A Program Information

The Project Within A Program screen requires you to enter additional information regarding the ethics application you are submitting.

### Responsible HEAG

- 1** Select the HEAG responsible for administering the research project from the drop-down list.

### Program Details

You will need to indicate the Program/s in which your project application belongs.

- 1** Click on the **Add Program** button.

The Search and Select: Add Program screen will display.

- 2** Select the information on which you would like to perform your search.

You may search by Program ID, Program Title, Responsible Researcher or Responsible HEAG.

- 3** Enter the value for which you would like to search and click on the **Go** button.

The Programs matching your search criteria will display.

Results			
<a href="#">Select All</a>   <a href="#">Select None</a>			
Select Program ID	Program Title	Responsible Researcher	Responsible HEAG
<input checked="" type="checkbox"/> 0600148.1	Mystery and the Occult	BALL, MS CRYSTAL	University Systems Project

- 4** Tick the Select checkbox for the appropriate program and click on the **Select** button.

The Search and Select screen will close and the program selected will populate in the Program Details section.

- 5** Click on the **Show** link to display additional information regarding the Program selected.

Add Program					
Details	Program Id	Program Name	Responsible Researcher	Responsible HEAG	Delete
<a href="#">Show</a>	0600148.1	Mystery and the Occult	BALL, MS CRYSTAL	University Systems Project	

- 6** Repeat **steps 1 to 5** above for each Program to which you wish to link the Project.

### Confirm that you have read the approved Program application

- 1** Tick the checkbox confirming you have read the associated program application.

- 2** Click on the **Next** button.

The Application Message screen will display.

## Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.

Step 5 - Application Message			
<input type="button" value="Cancel"/> <input type="button" value="Save As Draft"/> <input type="button" value="Back"/> <input type="button" value="Step 5 of 12"/> <input type="button" value="Next"/>			
<b>Ethics Application ID</b> 0600151.1	<b>Status</b> Draft	<b>Application Type</b> Project Within Program	<b>Approval Category</b> HEAG
Based on the responses provided this project will be submitted for review by the responsible HEAG as a Project within Program Application.			

- 1 Click on the **Next** button.

The Project Details screen will display.

## Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

- 1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	This field will default from the HEAG selected in the Project Within a Program screen above	
HESC	This field will default based on the Responsible HEAG above	
Project Title	Enter the title of your project	
Brief description of project	Enter a brief description of the project	The description, no more than 100 words, should outline the broad aims and key questions of the project.
Project From date	Use the drop-down list to select the month and year the project is expected to start	
Project To date	Use the drop-down list to select the month and year the project is expected to end	
Start date for data collection phase	Enter the proposed start date for the data collection phase of the project	<b>Important:</b> data collection may not commence until formal approval for the project has been granted and the date entered in this field should allow for a reasonable period of review of your application.

- 2 Click on the **Next** button.

The Participating Researcher screen will display.

## Enter the Participating Researchers

The Project Details screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details.

- 1 Click on the **Add Researcher** button.

The Search Researchers screen will display.

Search Researchers	
<input type="button" value="▼"/> <input type="text"/> <input type="button" value="Search"/> <input type="button" value="Create External"/>	

- 2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

**3** Enter the surname of the researcher for which you are searching in the bottom field.

**4** Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to **Creating an External Researcher in human Ethics** information sheet).

Select Name	Department/Organisation
<input type="radio"/> BALL, MS CRYSTAL	018-University Systems Project
<b>Select</b>	

**5** Click on the radio button to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

### *Enter the Researcher Details*

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

**6** Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 8.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. <b>Note:</b> the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	<b>Note:</b> these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. <b>Note:</b> you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

**7** Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select Researcher Role	Researcher Type	Researcher Name	Department/Organisation
<input type="radio"/> Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project
<b>Add Researcher</b>	<b>Delete Researcher</b>	<b>Update Researcher</b>	

- 8** Follow **steps 1 to 7** above to enter additional researchers if required.

**Note:** for any project there must be one and only one Responsible Researcher named against the project.

- 9** Once you have added all the required researchers, click on the **Next** button to continue.

The Additional Documentation Required screen will display.

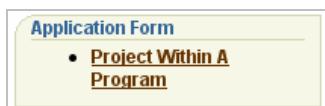
### Access Additional Documentation

The Additional Documentation Required screen will display any forms that you must complete and attach to your ethics application prior to submission. The forms are available on the Research Office web site but you will be able to download them via the hyperlink/s on this screen. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

- 1** **Important:** Click on the **Save As Draft** button before proceeding to download any additional documentation.

A confirmation message will display advising that the application has been saved.

- 2** Click on the hyperlink for the form you wish to download.



The link will access the relevant document from the Research Office web site and open it in a new browser window. In most cases the document will open at an instruction sheet, and you will need to scroll down from this page to view the body of the form.

- 3** Save the document to your PC/local server for later completion and attachment to Themis.

- 4** Close the browser window and reactivate your Themis session.

- 5** Complete **steps 2 to 4** above for all required documents.

- 6** Once you have accessed all the required documents, click on the **Next** button to continue.

The Attachments screen will display.

### Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

#### Add an electronic attachment

- 1** Click on the **Add Attachment** button in the Attachment table.

The Add Attachment screen will display.

- 2** Complete the attachment details.

Field	Action	Comments
Add	Field will default to <b>Desktop File/Text/URL</b> , do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Interview, Miscellaneous, Plain Language Statement, and Test.</b> <b>Note:</b> you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	<b>If selecting File:</b> click on the <b>Browse</b> button to locate and select the document you wish to attach. <b>If selecting URL:</b> type the full internet address you wish to reference. <b>If selecting Text:</b> enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

- 3** Click on the **Add Another** button and repeat **step 2** for each new attachment.
- 4** Once you have added all your attachments click on the **Apply** button.  
You will receive a confirmation that the attachment has been added but not saved.
- 5** Click on the **Save As Draft** button to save the attachment.

#### *Register a document to be provided in hard copy only*

- 1** Click on the **Add Another Row** button in the Supporting Documents table.  
The Add Attachment screen will display.
- 2** Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module</b> , <b>Advertisement</b> , <b>Application</b> , <b>Consent Form</b> , <b>Debriefing Statement</b> , <b>Evidence of Approval</b> , <b>Interview</b> , <b>Other</b> , <b>Plain Language Statement</b> , and <b>Questionnaire/Survey</b> .
Description	Enter a brief description of the document you will be submitting	

- 3** Repeat **steps 1 and 2** for each document you wish to register.
- 4** Once you have registered all your attachments click on the **Save As Draft** button.  
You will receive a confirmation that the application has been saved.
- 5** Once you have attached all the required documents, click on the **Next** button to continue.  
The Application Review screen will display.

#### **Review the Application**

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

##### *If validation errors are identified*

Application Review					
Data validation errors have been identified in this application. You cannot proceed to the submission page until the errors specified in the table below have been corrected.					
<b>Data Validation Error</b> Multiple electronic attachments of type 'Application' have been attached to this application	<table border="1" style="float: right; border-collapse: collapse;"> <tr> <td style="padding: 2px;"><b>Application Step</b></td> <td style="padding: 2px;"><b>Go To Page</b></td> </tr> <tr> <td style="padding: 2px;">Step 15</td> <td style="padding: 2px;"></td> </tr> </table>	<b>Application Step</b>	<b>Go To Page</b>	Step 15	
<b>Application Step</b>	<b>Go To Page</b>				
Step 15					

- 1** Click on the associated  icon in the Go To Page column.  
This will link you directly to the appropriate page.
- 2** Update the information as required and click on the **Save As Draft** button to commit your changes.
- 3** Use the drop down list () at the bottom of the screen to return to the review page.
- 4** Repeat **steps 1 to 3** above for each of the validation errors.
- 5** Click on the **Next** button.  
The Submission screen will display.

## Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

- 1** Read the submission confirmation statement.
- 2** Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).

**Important:** if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

- 3** Click on the **Submit Application** button.

A Confirmation of Submission screen will display.

**Note:** all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

## Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

- 1** Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

- 2** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).

- 3** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

- 4** Click on the **Output** icon to open the application in the web browser screen.

- 5** Select **File > Print** from the web browser Toolbar to print the application.

- 6** Ensure the application is signed by all responsible researchers.

- 7** Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

## Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	<p>For any project there must be a Responsible Researcher named against the project.</p> <p><b>Note:</b> there may only be one person with this role per application and only a member of staff may be named.</p> <p>In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects).</p> <p>Only the person named as Responsible Researcher, and the creator, will have access to update an application.</p>
Student Researcher	<p>There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.</p>
Co-researcher	<p>There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).</p>
Associated Personnel	<p>There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.</p>



**THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE**

**PROJECT WITHIN PROGRAM APPLICATION**

THE UNIVERSITY OF  
MELBOURNE

**PROGRAM REFERENCE DETAILS**

Enter the Ethics ID number assigned by Themis Research to this ethics application.


Enter the title of the Program as recorded in Themis Research

Enter the name of the Responsible Researcher as recorded in Themis Research

**1. PROJECT DETAILS**

- 1.1 EXECUTIVE SUMMARY IN PLAIN ENGLISH:** Provide a brief outline of the project in everyday language. Include a description of how the Project relates to the approved Program, along with a summary of the proposed methodology, an explanation of what participants will be required to do specifically in this project and a description of any procedure which is beyond already established and accepted techniques. Please provide a description of the participant population, including anticipated number and age-range, along with information as to how participants are to be recruited. If the Project does not require use of a plain language statement or consent form, please provide additional details about how the informed consent of participants will be obtained and documented. [No more than 500 words]

- 1.2 ALIGNMENT WITH APPROVED PROGRAM OF RESEARCH:** Please confirm that the Project shares the following elements in common with the approved Program:

	YES	NO
a) theoretical structure	<input type="checkbox"/>	<input type="checkbox"/>
b) as per the identified category indicated on the Approved Program	<input type="checkbox"/>	<input type="checkbox"/>
- <b>EITHER</b> an integrated research question	<input type="checkbox"/>	<input type="checkbox"/>
- <b>OR</b> cohesive methodological approach	<input type="checkbox"/>	<input type="checkbox"/>
c) researchers (at least one of the principal researchers nominated in the Program must be associated with the Project-within-Program application)	<input type="checkbox"/>	<input type="checkbox"/>
d) participant population	<input type="checkbox"/>	<input type="checkbox"/>
e) methodology	<input type="checkbox"/>	<input type="checkbox"/>
f) risk/inconvenience to participants	<input type="checkbox"/>	<input type="checkbox"/>
g) risks to researchers	<input type="checkbox"/>	<input type="checkbox"/>
h) arrangements to document informed consent	<input type="checkbox"/>	<input type="checkbox"/>
i) arrangements to preserve confidentiality	<input type="checkbox"/>	<input type="checkbox"/>

[If you have responded "no" to any of the above elements please discuss this issue with the HEAG. If a Project-within-Program Application differs substantively from the approved Program in any of the above areas it will be necessary to either submit an application for an amendment to the Program or treat the application as an individual Project (unrelated to the Program) and, instead, complete a Form 1 Project application for consideration by the relevant HESC]

## **2. PLAIN LANGUAGE STATEMENT (IF APPLICABLE)**

### **CONFIRM THAT THE PLAIN LANGUAGE STATEMENT WILL:**

- |   | YES                      | NOT APPLICABLE           |
|---|--------------------------|--------------------------|
| 1. be printed on University of Melbourne letterhead   | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. include clear identification of the University, the Department(s) involved, the project title, the Principal and Other Researchers (including contact details), and the study level if it is a student research project.             | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. provide details of the purpose of the research project   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. provide details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-taping of events), and estimated time commitment  | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. provide details of any risks involved and the procedures in place to minimise these.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. advise that the project has received clearance by the HREC   | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. (if the sample size is small), confirm that this may have implications for protecting the identity of the participants   | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. include a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health (if relevant) | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. state that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied  | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. provide advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see ** below)  | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. provide advice as to whether or not data is to be destroyed after a minimum period (if relevant)  | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. provide in the footer, the project HREC number, date and version of the PLS   | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. provide advice that if participants have any concerns about the conduct of this research project that they can contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739      | <input type="checkbox"/> | <input type="checkbox"/> |

[\*\*Re 10 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state these limitations]

**PLEASE ATTACH A COPY OF THE PLAIN LANGUAGE STATEMENT TO YOUR APPLICATION**

## **3. CONSENT FORM (IF APPLICABLE)**

### **CONFIRM THAT THE CONSENT FORM WILL:**

- |  | YES                      | NOT APPLICABLE           |
|--|--------------------------|--------------------------|
| 1. be printed on University of Melbourne letterhead  | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. include the title of the project and names of researchers   | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. state that the project is for research purposes   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. state that involvement in the project is voluntary and that participants are free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. outline particular requirements of participants including, for example, whether interviews are to be audio and/or video-taped   | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. include arrangements to protect the confidentiality of data   | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. include advice that there are legal limitations to data confidentiality (see below)**   | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. (if the sample size is small) confirm that this may have implications for protecting the identity of the participants   | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. (once signed and returned) be retained by the researcher  | <input type="checkbox"/> | <input type="checkbox"/> |

[\*\*Re 7 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state and explain these limitations]

**PLEASE ATTACH A COPY OF THE CONSENT FORM TO YOUR APPLICATION**

#### **4. DECLARATION BY RESEARCHERS**

*The information contained herein is, to the best of our knowledge and belief, accurate.*

*We have obtained and read a copy of the approved Program on which this project is based and agree to carry out the project in strict accordance with the protocol outlined in that Program. We have the appropriate qualifications, experience and facilities to conduct the research and to deal with any emergencies and contingencies related to the research that may arise.*

*We, the researcher(s) agree:*

- To only start this research project after obtaining final approval from the departmental Human Ethics Advisory Group (HEAG);
  - To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
  - To provide additional information as requested by the HEAG or HREC;
  - To provide progress reports to the HREC as requested, including annual and final reports;
  - To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
  - To notify the HEAG in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
  - To notify the HREC in writing immediately if any adverse event occurs after approval has been obtained;
  - To agree to an audit if requested by the HREC;
  - To only use data and any tissue samples collected for the study for which approval has been given;

*We have read the NH&MRC National Statement on Ethical Conduct in Research Involving Humans and agree to comply with its provisions.*

**All researchers listed in the application must sign**

## 5. DECLARATION BY DEPARTMENTAL HUMAN ETHICS ADVISORY GROUP (HEAG)

DATE APPLICATION RECEIVED: / /

*HEAG NO:*

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

## CHECKLIST

Has the HEAG reviewed the related Program Application?

YES NO

10 of 10

Is the HEAG satisfied that this project fits within the approved program? (If not, please ensure that either an amendment to the Program is submitted to the HESC or the researchers submit a separate Form 1 Project application)

10 of 10

10

Are there any minor differences between the Project and Program applications?

10 / 10

If yes:

□ □

- have these been addressed in the Project application?
- do any of these differences need HESC approval?

10 / 10

10

Have the following documents been attachments if applicable:								
	YES	NO	N/A		YES	NO	N/A	
- evidence of external approvals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	- debriefing statement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- recruitment advertisement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	- plain language statement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- questionnaire	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	- consent form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- list of interview questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					

#### COMMENTS FOR INFORMATION/ACTION OF HESC:

The HEAG has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommends approval of the project. The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a principal researcher for this project, the declaration should be signed by another authorised member of the HEAG]

Comments/Provisos:

Name of HEAG Chair (in BLOCK LETTERS)	
Signature	
Date	

#### 6. DECLARATION BY HEAD OF DEPARTMENT

DATE APPLICATION RECEIVED: / /

HEAG NO:

TECHNICAL REVIEW COMPLETED

ETHICAL REVIEW COMPLETED

I have reviewed this project and consider the methodological, technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommend approval of the project. I consider that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]

This project has the approval and support of this Department/School/Centre.

Name of Head (in BLOCK LETTERS)	
Signature	
Date	

#### 11. WHEN COMPLETE

When this form has been completed and finalised it should be attached to the coversheet section of the application completed in Themis Research and then submitted to the nominated Human Ethics Advisory Group for review.

# Creating a Transfer of Human Ethics Clearance Application



A Transfer of Ethics Clearance is to be completed where a researcher needs to transfer an ethics clearance obtained from an HREC at another institution to a University of Melbourne HREC as the Primary HREC (and as such, the University of Melbourne will become responsible for the research). For example, where a researcher has moved from another university to take up a position at the University of Melbourne and will be continuing past research projects which have been granted ethics clearance.

## Creating a Transfer Application

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the **Create** button in the Create New Documents section.

Human Ethics Home Page - Researcher Worklist	
<a href="#">Create New Documents</a>	
Ethics Application (including transfers and registrations): <a href="#">Create</a>	

The Project Type screen will display.

## Define the Project Type

- 1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

**Note:** you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

- 2 Click on the **Next** button.

The Research Checklist screen will display.

## Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

**Important:** you must select at least one item from the Available Checklist Item list before progressing (**note:** for a Transfer application, you must select **Already has or requires other ethics approval** as a minimum before submitting your application). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

- 1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 2 Click on the arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the arrow to remove an item from the Selected Checklist Items list, if required.

- 3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

- 4 Click on the **Next** button.

The Application Type screen will display.

## Select the Application Type

- 1** Click on the appropriate radio button (**Transfer of Ethics Clearance**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

- 2** Click on the **Next** button.

The Application Message screen will display.

## Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.

Step 4 - Application Message			
<input type="button" value="Cancel"/> <input type="button" value="Save As Draft"/> <input type="button" value="Back"/> <input type="button" value="Step 4 of 14"/> <input type="button" value="Next"/>			
Ethics Application ID	Status	Application Type	Approval Category
0600182.1	Draft	Transfer	HESC
<b>Based on the response provided the project is eligible for submission as an application for Transfer of External Ethics Clearance.</b>			

- 1** Click on the **Next** button.

The Project Details screen will display.

## Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

### 1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	Select the appropriate HEAG from the drop-down list	
HESC	This field will default based on the HEAG selected above	
Project Title	Enter the title of your project	
Brief description of project	Enter a brief description of the project	The description, no more than 100 words, should outline the broad aims and key questions of the project.
Project From date	Use the drop-down list to select the month and year the project started	
Project To date	Use the drop-down list to select the month and year the project is expected to end	
Start date for data collection phase	Enter the date the data collection phase of the project commenced	

### 2 Click on the **Next** button.

The Participating Researcher screen will display.

## Enter the Participating Researchers

The Project Details screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details.

### 1 Click on the **Add Researcher** button.

The Search Researchers screen will display.



Select Name	Department/Organisation
No data exists.	
<input type="button" value="Select"/>	

### 2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

### 3 Enter the surname of the researcher for which you are searching in the bottom field.

### 4 Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to **Creating an External Researcher in Human Ethics** information sheet).

Select Name	Department/Organisation
<input checked="" type="radio"/> BALL, MS CRYSTAL	018-University Systems Project
<input type="button" value="Select"/>	

### 5 Click on the radio button to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

### Enter the Researcher Details

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

#### 6 Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 10.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. <b>Note:</b> the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	<b>Note:</b> these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. <b>Note:</b> you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

#### 7 Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select Researcher Role	Researcher Type	Researcher Name	Department/Organisation
<input checked="" type="radio"/> Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project
<a href="#">Add Researcher</a>	<a href="#">Delete Researcher</a>	<a href="#">Update Researcher</a>	

#### 8 Follow **steps 1 to 7** above to enter additional researchers if required.

**Note:** for any project there must be one and only one Responsible Researcher named against the project.

#### 9 Once you have added all the required researchers, click on the **Next** button to continue.

The Location of Research screen will display.

## Specify the Location of the Research

The Location of Research screen allows you to indicate where the research will be undertaken. **Note:** where the research is being undertaken at locations additional to or other than the University of Melbourne additional approvals and/or ethics clearances may be required.

- 1** Tick the checkbox/s for the location/s where your research is to be undertaken.

**Important:** where research is undertaken overseas, you will need to contact the Risk Management Office to ensure compliance with University procedures.

- 2** Tick the checkbox/s for the category of location/s at which your research is to be undertaken.

**If you have selected Other category go to task #3. Otherwise go to task #4.**

- 3** Specify the details of the other external location.

- 4** Click on the **Next** button.

The Other Approvals Required screen will display.

## Specify the Other Non-Ethics Approval Required

The Other Approvals screen enables you to record any non-ethics approvals you require from external bodies.

**Important:** you must forward a copy of any approvals already received to the HEAG (either by hard copy or electronic copy attached to this application - refer below for further information on attaching documents) for review with your application.

*Have you determined whether approvals from external bodies will be required?*

- 1** Click on the appropriate radio button to select whether external approvals will be required.

**Note:** if you indicate external approvals are required, you will need to complete additional fields.

**If external approvals are required, go to task #2. Otherwise go to task #6.**

*Have you identified the organisations/individuals from whom approval needs to be sought?*

- 2** Select the appropriate response (**Yes** or **Yet to be Determined**) from the drop-down list.

**Note:** if you indicate that organisations/individuals have been identified, you will need to complete additional fields in the Other Approvals Required table that displays.

**If the organisations/individuals have been identified, go to task #3. Otherwise go to task #6.**

## Details of Other Approvals Required

- 3** Click on the **Add Approvals** button.

The Approval details table will display.

- 4** Complete the approval details.

**Note:** if the fields outlined below do not display, click on the **Show** link to expand the row.

Field	Action	Comments
Approval Required From	Enter the organisation or individual from whom approval is required	
Approval Status	Select the status of the approval request from the drop-down list	Values available are: <b>Approved, Rejected, Under Review, Yet to be Sought, Requested By Reviewing Committee.</b>
Number of sites approval covers	Where research is being undertaken at multiple sites, indicate the number of sites the specified approval covers	<b>Note:</b> if applicable, you may enter text (e.g.: all).
Approval Number (if applicable)	Enter the approval number, if applicable	
Date approval granted	Enter the date the approval was granted, if applicable	Enter the date in format: DD-MMM-YYYY (e.g.: 20-Jun-2006) or use the <b>Pick a Date Calendar</b> to select the appropriate date.

Other approval details continued

Field	Action	Comments
Special conditions of approval	Select <b>Yes</b> or <b>No</b> from the drop-down list to indicate whether special conditions have been attached to the approval	
Comments	Enter any comments or special conditions relating to the specified approval, if required	

- 5 Click on the **Add Approval** button and complete **step 4** above for all approvals required.
- 6 Use the Comments field to record any overall comments relating to non-ethics approvals required for your research project.
- 7 Click on the **Next** button.

The Other Ethics Clearances screen will display.

### Specify the Other Ethics Clearances Required

The Other Ethics Clearances screen enables you to record details of all Australian HRECs to which the project has been, or will, be submitted.

**Important:** you must forward a copy of any approvals already received to the HEAG (either by hard copy or electronic copy attached to this application - refer below for further information on attaching documents) for review with your application.

#### Details of Ethics Clearance

- 1 Click on the **Add Ethics Clearance** button.

The Clearance details table will display.

- 2 Complete the clearance details.

**Note:** if the fields outlined below do not display, click on the **Show** link to expand the row.

Field	Action	Comments
Name of HREC	Enter the name of the HREC from whom clearance is sought	
Status of ethics application	Select the status of the clearance request from the drop-down list	Values available are: <b>Approved</b> , <b>Rejected</b> , <b>Pending</b> , <b>Not yet Applied</b> .
Australian sites/s covered by application to HREC	Where research is being undertaken at multiple sites, indicate the sites covered by this clearance application	<b>Note:</b> if applicable, you may enter text (e.g.: all)
Registration number assigned by the institution	Enter the registration number assigned to the clearance	
Date clearance granted	Enter the date the clearance was granted, if applicable	Enter the date in format: DD-MMM-YYYY (e.g.: 20-Jun-2006) or use the <b>Pick a Date Calendar</b> to select the appropriate date.
Period of approval - from Period of approval - to	Enter the start and end date of the clearance granted	Enter the date in format: DD-MMM-YYYY (e.g.: 20-Jun-2006) or use the <b>Pick a Date Calendar</b> to select the appropriate date.
Special conditions	Select <b>Yes</b> or <b>No</b> from the drop-down list to indicate whether special conditions have been attached to the clearance	
Comments	Enter any comments or special conditions relating to the specified clearance	

- 3 Click on the **Add Ethics Clearance** button and complete **step 2** above for all clearances required.

*Of the HRECs the application was submitted to, indicate which had prime responsibility for monitoring the research*

- 4 Select the appropriate HREC from the drop-down list.

This list will contain all the HRECs that you indicated in the table above.

*Of the HRECs the application was/will be submitted to, indicate which will have prime responsibility for monitoring the research*

**5 Select the University of Melbourne from the drop-down list.**

**Note:** for an application to transfer ethics clearance obtained from an HREC at another institution to the University of Melbourne you must list the University of Melbourne as the responsible HREC.

**6 Enter the reason for the transfer of clearance in the Comments field.**

**7 Click on the Next button.**

The Additional Documentation screen will display.

### Access Additional Documentation

The Additional Documentation Required screen will display a list of the documentation that you must attach to your ethics application prior to submission. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

#### Attachments Required

Please attach to this application copies of the:

- project approval letter (as provided by the Primary Approving HREC);
- other project approval letters (provided from other HRECs if applicable);
- approved protocol (as approved by the Primary Approving HREC);
- all relevant correspondence including details of amendments requested and special conditions to be met;
- copies of information material being provided to participants - including plain language statements and consent forms. Ensure that the participant information material is on University of Melbourne letterhead, includes University contact details and details of University of Melbourne supervisor/s.

**1 Click on the Next button.**

The Attachments screen will display.

### Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

#### Add an electronic attachment

**1 Click on the Add Attachment button in the Attachment table.**

The Add Attachment screen will display.

**2 Complete the attachment details.**

Field	Action	Comments
Add	Field will default to <b>Desktop File/Text/URL</b> , do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Interview, Miscellaneous, Plain Language Statement, and Test.</b>  <b>Note:</b> you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	<b>If selecting File:</b> click on the <b>Browse</b> button to locate and select the document you wish to attach.  <b>If selecting URL:</b> type the full internet address you wish to reference.  <b>If selecting Text:</b> enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

If you wish to add multiple attachments, go to task # 3. Otherwise go to task #4.

- 3 Click on the **Add Another** button and repeat **step 2** for each new attachment.
- 4 Once you have added all your attachments click on the **Apply** button.  
You will receive a confirmation that the attachment has been added but not saved.
- 5 Click on the **Save As Draft** button to save the attachment.

*Register a document to be provided in hard copy only*

- 1 Click on the **Add Another Row** button in the Supporting Documents table.  
The Add Attachment screen will display.
- 2 Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module</b> , <b>Advertisement</b> , <b>Application</b> , <b>Consent Form</b> , <b>Debriefing Statement</b> , <b>Evidence of Approval</b> , <b>Interview</b> , <b>Other</b> , <b>Plain Language Statement</b> , and <b>Questionnaire/Survey</b> .
Description	Enter a brief description of the document you will be submitting	

- 3 Repeat **steps 1 and 2** for each document you wish to register.
- 4 Once you have registered all your attachments click on the **Save As Draft** button.  
You will receive a confirmation that the application has been saved.
- 5 Once you have attached all the required documents, click on the **Next** button to continue.  
The Application Review screen will display.

## Review the Application

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

*If validation errors are identified*

Application Review					
Data validation errors have been identified in this application. You cannot proceed to the submission page until the errors specified in the table below have been corrected.					
<b>Data Validation Error</b> Multiple electronic attachments of type 'Application' have been attached to this application	<table border="1"> <thead> <tr> <th>Application Step</th> <th>Go To Page</th> </tr> </thead> <tbody> <tr> <td>Step 15</td> <td></td> </tr> </tbody> </table>	Application Step	Go To Page	Step 15	
Application Step	Go To Page				
Step 15					

- 1 Click on the associated icon in the Go To Page column.  
This will link you directly to the appropriate page.
- 2 Update the information as required and click on the **Save As Draft** button to commit your changes.
- 3 Use the drop down list ( ) at the bottom of the screen to return to the review page.
- 4 Repeat **steps 1 to 3** above for each of the validation errors.
- 5 Click on the **Next** button.  
The Submission screen will display.

## Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

- 1** Read the submission confirmation statement.
- 2** Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).

**Important:** if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

- 3** Click on the **Submit Application** button.

A Confirmation of Submission screen will display.

**Note:** all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

## Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

- 1** Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

- 2** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).

- 3** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

- 4** Click on the **Output** icon to open the application in the web browser screen.

- 5** Select **File > Print** from the web browser Toolbar to print the application.

- 6** Ensure the application is signed by all responsible researchers.

- 7** Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

## Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	<p>For any project there must be a Responsible Researcher named against the project.</p> <p><b>Note:</b> there may only be one person with this role per application and only a member of staff may be named.</p> <p>In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects).</p> <p>Only the person named as Responsible Researcher, and the creator, will have access to update an application.</p>
Student Researcher	There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.
Co-researcher	There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).
Associated Personnel	There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.



THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF  
MELBOURNE

## TRANSFER FORM FOR PROJECTS APPROVED BY AN EXTERNAL HREC

### 1. ADMINISTRATION DETAILS

DATE OF SUBMISSION:	ETHICS ID:		
APPLICATION TYPE:	Transfer		
RESPONSIBLE HEAG:	Melbourne Graduate School of Education	HESC:	Humanities and Applied Sciences
ADMINISTERING DEPARTMENT:	Melbourne Graduate School of Education	ADMINISTERING CENTRE: (if applicable)	

### 2. PROJECT DETAILS

Title:

Brief Description:

**Primary HREC Name:**

*That is the HREC which primarily approved the project*

**HREC Reference No:**

**Project Approval Period:**

From:

To:

### 3. PERSON DETAILS

Role	Name	Person Type	Department/ Organisation	Phone/ Alternate Phone	Email/ Alternate Email

#### 4. ADDITIONAL QUESTIONS

4.1 **AIMS OF AND JUSTIFICATION FOR THE RESEARCH:** State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Also provide a brief description of current research/literature review, a justification as to why this research should proceed and an explanation of any expected benefits to the community. [No more than 500 words]

4.2 **METHOD** Provide an outline of the proposed method, including details of the recruitment strategy and data collection techniques, the tasks participants will be asked to do, the estimated time commitment involved, and how data will be analysed. [No more than 500 words]

4.3 **USE OF INDEPENDENT CONTRACTORS** Will parts of this project be carried out by independent contractors? (e.g. interviewing, questionnaire design and analysis, sample testing, etc)

- YES    NO If YES, confirm that the independent contractor will be engaged on the basis of relevant qualifications and experience and will receive from the Responsible Researcher, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it. [The responsibility for effective oversight and proper conduct of the project remains with the Responsible Researcher]

#### 4.4 MONITORING

- (a) How will researchers monitor the conduct of the project to ensure that it complies with the protocols set out in this application, the University's human ethics guidelines and the National Statement on Ethical Conduct in Human Research? [Address, in particular, cases where several people are involved in recruiting, interviewing or administering procedures, or when the research is being carried out at some distance from the Principal Researcher (i.e. interstate or overseas)]
- (b) For student research projects how will the student be supervised to ensure they comply with the protocols? If the student is working overseas, provide additional details of any local supervision arrangements.

4.5 **FUNDING DETAILS:** Is this project being funded?

- YES    NO If YES, provide details including the source of the funding/grant, its duration and registration number, if known.

#### 5. ATTACHMENTS

Copies of the following need to be attached:

	YES	NO	NOT APPLICABLE
• A copy of the project approval letter. That is the ethics clearance letter from the Primary HREC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• A copy of the approved protocol. That is the full project application approved by the Primary HREC, complete with plain language statements, consent forms, other associated documentation and any amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• A copy of any other project approval letter(s). That is any ethics clearance letter(s) from other HREC(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **6. DECLARATION BY RESEARCHERS**

The information contained herein is, to the best of our knowledge and belief, accurate.

We have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University's Code of Conduct for Research and any other condition laid down by the University of Melbourne's Human Research Ethics Committee or its Sub-Committees. We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants. We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.

If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

We, the researcher(s) agree:

- To only start this research project after obtaining final approval from the Human Research Ethics Committee (HREC);
- To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
- To provide additional information as requested by the HREC;
- To provide progress reports to the HREC as requested, including annual and final reports;
- To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
- To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
- To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;
- To agree to an audit if requested by the HREC;
- To only use data and any tissue samples collected for the study for which approval has been given;

We have read the National Statement on Ethical Conduct in Human Research and agree to comply with its provisions.

**All researchers associated with this project must sign**

Researchers' Name (please PRINT)	Signature	Date

## **7. DECLARATION BY DEPARTMENTAL HUMAN ETHICS ADVISORY GROUP (HEAG)**

DATE APPLICATION RECEIVED:

/ /

HEAG NO:

*The HEAG has considered this project, including the role and contribution of University of Melbourne staff, students and supervisors.*  
[Note: If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]

*Please tick ONE of the following*

The HEAG recommends that the project be transferred to the University of Melbourne.

The HEAG recommends that the project be transferred to the University of Melbourne subject to the following conditions [see Comments/Provisos below].

**Comments/Provisos:**

Name of HEAG Chair (in BLOCK LETTERS)	
Signature	
Date	

## **8. DECLARATION BY HEAD OF DEPARTMENT**

DATE APPLICATION RECEIVED:

/ /

HEAG NO:

*This project has the approval and support of this Department/School/Centre. [Note: If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]*

Name of Head (in BLOCK LETTERS)	
Signature	
Date	

## **9. WHEN COMPLETE**

**When this form has been completed and finalised it should be attached to the coversheet section of the application completed in Themis Research and then submitted to the nominated Human Ethics Advisory Group for review.**

# Creating a Registration of External Ethics Clearance



A Registration of External Ethics Clearance is to be completed where a researcher needs to register an ethics clearance obtained from a HREC at another institution and where the approving institution will remain the responsible HREC. For example, where a researcher is a student of the University of Melbourne but their research is being undertaken in one of the teaching hospitals and as such they are required to apply for ethics clearance through the hospital. While the approving HREC will remain responsible for the research, the researcher will need to register the details of the clearance with the University of Melbourne.

## Creating a Registration of External Ethics Clearance

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the **Create** button in the Create New Documents section.

Human Ethics Home Page - Researcher Worklist	
Create New Documents	
Ethics Application (including transfers and registrations): <input type="button" value="Create"/>	

The Project Type screen will display.

### Define the Project Type

- 1 Tick the appropriate checkbox(s) to identify the type of project for which you are applying.

**Note:** you may select multiple project types, if appropriate.

Project Type	Additional information required
Staff Research Project	No additional information is required on this screen for this option.
Practical Class	You must provide the name of the class in the field that displays below.
Funded Consultancy	No additional information is required on this screen for this option.
Supervised Student Research Project	You must select the appropriate tertiary level/s (e.g.: Doctorate, PhD, Advanced Medical Science, etc.) using the checkboxes in the table that displays below.
Other	You must specify the nature of the application in the field that displays below.

- 2 Click on the **Next** button.

The Research Checklist screen will display.

### Complete the Research Checklist

The information entered in the checklist will determine: the application types available; additional questions to be completed online; and additional modules to be completed offline and attached to the application.

**Important:** you must select at least one item from the Available Checklist Item list before progressing (**note:** for a Registration application, you must select **Already has or requires other ethics approval** as a minimum before submitting your application). If you do not select any checklist item a warning message will display when you try and progress to the next screen.

- 1 Highlight the item you wish to add from the Available Checklist Items list (on the left).

**Note:** the description for the selected item will display in the field under the table.

- 2 Click on the arrow to move the highlighted item to the Selected Checklist Items list (on the right).

To add all available items to the Selected Checklist Items list at once, click on the arrow, or use the **Move All** hyper-link (remember to remove the **None of the above** item before progressing).

Click on the arrow to remove an item from the Selected Checklist Items list, if required.

- 3 Click on the **Save as Draft** button.

While you may save the record at any stage of the application process, it is recommended that you save regularly to ensure you do not lose information if your session times out.

- 4 Click on the **Next** button.

The Application Type screen will display.

## Select the Application Type

- 1** Click on the appropriate radio button (**Registration of External Ethics Clearance**) to identify the application type.

The following step in the process will vary depending on the application type selected here.

Application Type	Process
Minimal Risk	You must complete further checklists before proceeding to the Application Message screen.
Standard Project	You may proceed directly to the Application Message screen.
Program	You must confirm that you are seeking approval for a broad program of research within which individual projects can be identified to be part of the program before progressing to the Application Message screen.
Project Within a Program	You must specify the HEAG and the program (or add the program) and confirm that you have read the approved program application before proceeding to the Application Message screen.
Transfer of Ethics Clearance	You may proceed directly to the Application Message screen.
Registration of External Ethics Clearance	You may proceed directly to the Application Message screen.

- 2** Click on the **Next** button.

The Application Message screen will display.

## Application Message Screen

Once Themis collates and evaluates all the information you entered in the relevant checklists and project type screens, the Application Message screen will display a message of eligibility for the Human Ethics application project type.

Step 4 - Application Message			
<input type="button" value="Cancel"/> <input type="button" value="Save As Draft"/> <input type="button" value="Back"/> Step 4 of 14 <input type="button" value="Next"/>			
Ethics Application ID	Status	Application Type	Approval Category
0600183.1	Draft	Registration	HESC
Based on the response provided the project is eligible for submission as an application for Registration of an External Ethics Clearance.			

- 1** Click on the **Next** button.

The Project Details screen will display.

## Enter the Project Details

The Project Details screen allows you to identify the responsible HEAG and enter information relating to your application (i.e.: project title, description and dates).

### 1 Enter the Project Details.

Field	Action	Comments
Responsible HEAG	Select the appropriate HEAG from the drop-down list	
HESC	This field will default based on the HEAG selected above	
Project Title	Enter the title of your project	
Brief description of project	Enter a brief description of the project	The description, no more than 100 words, should outline the broad aims and key questions of the project.
Project From date	Use the drop-down list to select the month and year the project started	
Project To date	Use the drop-down list to select the month and year the project is expected to end	
Start date for data collection phase	Enter the date the data collection phase of the project commenced	

### 2 Click on the **Next** button.

The Participating Researcher screen will display.

## Enter the Participating Researchers

The Project Details screen allows you to record the researchers associated with your project, the role they will take in the research, as well as their contact, qualification and relevant training details. **Note:** when submitting a registration it is not essential to add details of all external researchers associated with the project. You only need to include details of the principal external researchers.

### 1 Click on the **Add Researcher** button.

The Search Researchers screen will display.



Select Name	Department/Organisation
No data exists.	
<input type="button" value="Select"/>	

### 2 Select the category of researcher for which to search from the drop-down list in the top field.

- Select **Staff** if the researcher is a member of staff at the University of Melbourne.
- Select **Student** if the researcher is a student at the University of Melbourne.
- Select **External** if the researcher belongs to an external organisation or is retired.

### 3 Enter the surname of the researcher for which you are searching in the bottom field.

### 4 Click on the **Search** button.

A list of researchers matching your search criteria will display in the table below. **Note:** if no data is returned for an External researcher you may create an external person record (refer to **Creating an External Researcher in Human Ethics** information sheet).



Select Name	Department/Organisation
<input checked="" type="radio"/> BALL, MS CRYSTAL	018-University Systems Project
<input type="button" value="Select"/>	

### 5 Click on the radio button in the Select column to select the appropriate researcher then click on the **Select** button.

The Researcher Details screen will display.

### Enter the Researcher Details

You must complete the information in the Researcher Details screen for each researcher you add to your ethics application.

#### 6 Enter the researcher details.

Field	Action	Comments
Name	Field will default from the Themis record	
Phone Number	Field will default from the Themis record	
Researcher Role	Select the appropriate role from the drop-down list	For further information on the available roles refer to the table on page 10.
Researcher Type	Field will default from the Themis record	
Department	Field will default from the Themis record	
Centre (if applicable)	Use the Search and Select function to retrieve the appropriate Centre	This field should be left blank if the researcher does not belong to a Centre. <b>Note:</b> the list of available Centres only includes formal University Centres created under Regulation 6.1.R7.
Contact Details fields	Enter alternate contact details if required	<b>Note:</b> these contact details will be stored against the ethics application and will not be available on the person's Themis HR record.
HR Validated Qualifications	This field will display any qualifications that a staff member has entered via Themis Self Service	
Additional Qualifications	Enter any additional qualifications, not displayed above	
Experience and Skills relevant to the project	Enter any experience the researcher has that is relevant to the project	This field is mandatory. In particular, you should describe any experience the researcher or supporting staff has in conducting research of this type and in dealing with any emergencies, unexpected outcomes or contingencies that may arise.
Additional training required	Enter any additional training required to carry out this research	This field is optional. <b>Note:</b> you should include details on how training identified will be provided.
Ethics training already undertaken	Enter details of any ethics training the researcher has undertaken that will benefit this research	This field is mandatory for student researchers.

#### 7 Click on the **Save and Continue** button.

The Participating Researcher screen will display, and the researcher you have added will display in the researcher table.

Select Researcher Role	Researcher Type	Researcher Name	Department/Organisation
<input checked="" type="radio"/> Responsible Researcher	Staff	Ball, Ms Crystal	University Systems Project
<a href="#">Add Researcher</a>	<a href="#">Delete Researcher</a>	<a href="#">Update Researcher</a>	

#### 8 Repeat **steps 1 to 7** above to enter additional researchers if required.

**Note:** for any project there must be one and only one Responsible Researcher named against the project.

#### 9 Once you have added all the required researchers, click on the **Next** button to continue.

The Additional Documentation Required screen will display.

## Specify the Location of the Research

The Location of Research screen allows you to indicate where the research will be undertaken. **Note:** where the research is being undertaken at locations additional to or other than the University of Melbourne additional approvals and/or ethics clearances may be required.

- 1** Tick the checkbox/s for the location/s where your research is to be undertaken.

**Important:** where research is undertaken overseas, you will need to contact the Risk Management Office to ensure compliance with University procedures.

- 2** Tick the checkbox/s for the category of location/s at which your research is to be undertaken.

**If you have selected Other category go to task #3. Otherwise go to task #4.**

- 3** Specify the details of the other external location.

- 4** Click on the **Next** button.

The Other Approvals Required screen will display.

## Specify the Other Non-Ethics Approval Required

The Other Approvals screen enables you to record any non-ethics approvals you require from external bodies.

**Important:** you must forward a copy of any approvals already received to the HEAG (either by hard copy or electronic copy attached to this application - refer below for further information on attaching documents) for review with your application.

*Have you determined whether approvals from external bodies will be required?*

- 1** Click on the appropriate radio button to select whether external approvals will be required.

**Note:** if you indicate external approvals are required, you will need to complete additional fields.

**If external approvals are required, go to task #2. Otherwise go to task #6.**

*Have you identified the organisations/individuals from whom approval needs to be sought?*

- 2** Select the appropriate response (**Yes** or **Yet to be Determined**) from the drop-down list.

**Note:** if you indicate that organisations/individuals have been identified, you will need to complete additional fields in the Other Approvals Required table that displays.

**If the organisations/individuals have been identified, go to task #3. Otherwise go to task #6.**

## Details of Other Approvals Required

- 3** Click on the **Add Approvals** button.

The Approval details table will display.

- 4** Complete the approval details.

**Note:** if the fields outlined below do not display, click on the **Show** link to expand the row.

Field	Action	Comments
Approval Required From	Enter the organisation or individual from whom approval is required	
Approval Status	Select the status of the approval request from the drop-down list	Values available are: <b>Approved, Rejected, Under Review, Yet to be Sought, Requested By Reviewing Committee.</b>
Number of sites approval covers	Where research is being undertaken at multiple sites, indicate the number of sites the specified approval covers	<b>Note:</b> if applicable, you may enter text (e.g.: all).
Approval Number (if applicable)	Enter the approval number, if applicable	
Date approval granted	Enter the date the approval was granted, if applicable	Enter the date in format: DD-MMM-YYYY (e.g.: 20-Jun-2006) or use the <b>Pick a Date Calendar</b> to select the appropriate date.

Other approval details continued

Field	Action	Comments
Special conditions of approval	Select <b>Yes</b> or <b>No</b> from the drop-down list to indicate whether special conditions have been attached to the approval	
Comments	Enter any comments or special conditions relating to the specified approval, if required	

- 5 Click on the **Add Approval** button and complete **step 4** above for all approvals required.
- 6 Use the Comments field to record any overall comments relating to non-ethics approvals required for your research project.
- 7 Click on the **Next** button.

The Other Ethics Clearances screen will display.

### Specify the Other Ethics Clearances Required

The Other Ethics Clearances screen enables you to record details of all Australian HRECs to which the project has been, or will, be submitted.

**Important:** you must forward a copy of any approvals already received to the HEAG (either by hard copy or electronic copy attached to this application - refer below for further information on attaching documents) for review with your application.

#### Details of Ethics Clearance

- 1 Click on the **Add Ethics Clearance** button.

The Clearance details table will display.

- 2 Complete the clearance details.

**Note:** if the fields outlined below do not display, click on the **Show** link to expand the row.

Field	Action	Comments
Name of HREC	Enter the name of the HREC from whom clearance is sought	
Status of ethics application	Select the status of the clearance request from the drop-down list	Values available are: <b>Approved</b> , <b>Rejected</b> , <b>Pending</b> , <b>Not yet Applied</b> .
Australian sites/s covered by application to HREC	Where research is being undertaken at multiple sites, indicate the sites covered by this clearance application	<b>Note:</b> if applicable, you may enter text (e.g.: all)
Registration number assigned by the institution	Enter the registration number assigned to the clearance	
Date clearance granted	Enter the date the clearance was granted, if applicable	Enter the date in format: DD-MMM-YYYY (e.g.: 20-Jun-2006) or use the <b>Pick a Date Calendar</b> to select the appropriate date.
Period of approval - from Period of approval - to	Enter the start and end date of the clearance granted	Enter the date in format: DD-MMM-YYYY (e.g.: 20-Jun-2006) or use the <b>Pick a Date Calendar</b> to select the appropriate date.
Special conditions	Select <b>Yes</b> or <b>No</b> from the drop-down list to indicate whether special conditions have been attached to the clearance	
Comments	Enter any comments or special conditions relating to the specified clearance	

- 3 Click on the **Add Ethics Clearance** button and complete **step 2** above for all clearances required.

*Of the HRECs the application was/will be submitted to, indicate which will have prime responsibility for monitoring the research*

**5 Select the responsible HREC from the drop-down list.**

This list will contain all the HRECs that you indicated in the table above.

**Note:** for the following categories of research you must list the University of Melbourne as the responsible HREC:

- The research is externally funded and the University of Melbourne is responsible for all legal liabilities associated with the research
- The research is non-funded but involves participation in a drug trial for which the drug company is not responsible for legal liabilities

**6 Click on the **Next** button.**

The Additional Documentation screen will display.

### Access Additional Documentation

The Additional Documentation Required screen will display a list of the documentation that you must attach to your ethics application prior to submission. Refer to the **Human Ethics - Table of Research Checklist Items** document for a complete list of documentation required for each application type.

Attachments Required
<p>Please attach to this application:</p> <ul style="list-style-type: none"> <li>• project approval letter (as provided by the Primary Approving HREC);</li> <li>• other project approval letters (provided from other HRECs if applicable);</li> <li>• approved protocol (as approved by the Primary Approving HREC, complete with plain language statements, consent forms and details of any amendments requested and approved);</li> </ul>

**1 Click on the **Next** button.**

The Attachments screen will display.

### Attach Required Documentation

The Attachments screen allows you to attach any relevant documents to your Human Ethics application (including: the full application, consent forms, plain language statements and additional statements). This screen also allows you to log details of any documentation that can only be provided in hard copy.

#### Add an electronic attachment

**1 Click on the **Add Attachment** button in the Attachment table.**

The Add Attachment screen will display.

**2 Complete the attachment details.**

Field	Action	Comments
Add	Field will default to <b>Desktop File/Text/URL</b> , do not change	
Description	Enter a brief description of the attachment	This field is mandatory.
Category	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module, Advertisement, Application, Consent Form, Debriefing Statement, Interview, Miscellaneous, Plain Language Statement, and Test.</b>  <b>Note:</b> you must include an attachment in the Application category before you will be able to submit the ethics application for review.
Type	Click on the radio button to select the appropriate attachment type	<b>If selecting File:</b> click on the <b>Browse</b> button to locate and select the document you wish to attach. <b>If selecting URL:</b> type the full internet address you wish to reference. <b>If selecting Text:</b> enter a simple text message in the field provided. If desired you may enter a name for the text attachment in the field below.

If you wish to add multiple attachments, go to task # 3. Otherwise go to task #4.

- 3 Click on the **Add Another** button and repeat **step 2** for each new attachment.
- 4 Once you have added all your attachments click on the **Apply** button.  
You will receive a confirmation that the attachment has been added but not saved.
- 5 Click on the **Save As Draft** button to save the attachment.

*Register a document to be provided in hard copy only*

- 1 Click on the **Add Another Row** button in the Supporting Documents table.  
The Add Attachment screen will display.
- 2 Complete the document details.

Field	Action	Comments
Attachment Type	Select the category of the attachment from the drop-down list	Categories available are: <b>Additional Module</b> , <b>Advertisement</b> , <b>Application</b> , <b>Consent Form</b> , <b>Debriefing Statement</b> , <b>Evidence of Approval</b> , <b>Interview</b> , <b>Other</b> , <b>Plain Language Statement</b> , and <b>Questionnaire/Survey</b> .
Description	Enter a brief description of the document you will be submitting	

- 3 Follow **steps 1 to 7** above to enter additional researchers if required.
- 4 Once you have registered all your attachments click on the **Save As Draft** button.  
You will receive a confirmation that the application has been saved.
- 5 Once you have attached all the required documents, click on the **Next** button to continue.  
The Application Review screen will display.

## Review the Application

The Application Review screen will identify any validation errors or omissions (e.g.: either not including an Application type attachment or identifying multiple Application type attachments) in relation to your ethics application.

*If validation errors are identified*

Application Review					
Data validation errors have been identified in this application. You cannot proceed to the submission page until the errors specified in the table below have been corrected.					
<b>Data Validation Error</b> Multiple electronic attachments of type 'Application' have been attached to this application	<table border="1"> <thead> <tr> <th>Application Step</th> <th>Go To Page</th> </tr> </thead> <tbody> <tr> <td>Step 15</td> <td></td> </tr> </tbody> </table>	Application Step	Go To Page	Step 15	
Application Step	Go To Page				
Step 15					

- 1 Click on the associated icon in the Go To Page column.  
This will link you directly to the appropriate page.
- 2 Update the information as required and click on the **Save As Draft** button to commit your changes.
- 3 Use the drop down list ( ) at the bottom of the screen to return to the review page.
- 4 Repeat the steps above for each of the validation errors.
- 5 Click on the **Next** button.  
The Submission screen will display.

## Submit the Application

Once you have reviewed your application and corrected any validation errors, you may submit your application for review by the nominated HEAG.

- 1** Read the submission confirmation statement.
- 2** Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the application until you tick this box (i.e.: the **Submit Application** button will not be active).

**Important:** if someone other than the responsible researcher submits the application, additional checkboxes will display and must be answered before you will be able to submit the application.

- 3** Click on the **Submit Application** button.

A Confirmation of Submission screen will display.

**Note:** all researchers named on the application will receive an email to confirm the application has been submitted for review and the application will display in the **Current Applications** section of the Human Ethics Worklist, with a status of Submitted. Any of the named researchers (with access to Themis) will be able to view the application and track its status via their Worklist.

## Print the Application

Once you have submitted your application in Themis, you will need to print a copy of the application summary report and submit it with any the required number of copies of your supporting documentation to the nominated HEAG. **Note:** for details instructions refer to the **Printing a Human Ethics application and related attachments** information sheet.

- 1** Click on the **Reporting** tab located on the top right of the screen.

The Submit Report screen will display.

- 2** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc).
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).

- 3** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number. Click **OK** to close this message. The Requests monitoring screen will display.

- 4** Click on the **Output** icon to open the application in the web browser screen.

- 5** Select **File > Print** from the web browser Toolbar to print the application.

- 6** Ensure the application is signed by all responsible researchers.

- 7** Submit the paper copies of your application and any attachments to the HEAG Administrator.

The paper copy you submit to the HEAG Administrator must contain the following documents:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)

## Definition of Researcher Roles

Researcher Role	Researcher Role Definition
Responsible Researcher	<p>For any project there must be a Responsible Researcher named against the project.</p> <p><b>Note:</b> there may only be one person with this role per application and only a member of staff may be named.</p> <p>In the case of Student Projects, please note the Responsible Researcher would be the student supervisor (even in the case of PhD projects).</p> <p>Only the person named as Responsible Researcher, and the creator, will have access to update an application.</p>
Student Researcher	<p>There can be multiple student researchers associated with a project. It is recognised that for many projects, the Student Researcher is the person who is actually conducting the research and may be submitting the application.</p>
Co-researcher	<p>There can be multiple Co-researchers associated with a project. These would normally be persons in the role of co-supervisor of a student project, or other contributing researchers (staff or external).</p>
Associated Personnel	<p>There can be multiple associated personnel with a project. This role would only be assigned to a person who is not considered a researcher on the project.</p>



THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF  
MELBOURNE

## REGISTRATION FORM FOR PROJECTS APPROVED BY AN EXTERNAL HREC

### 1. ADMINISTRATION DETAILS

DATE OF SUBMISSION:	ETHICS ID:		
APPLICATION TYPE:	Registration		
RESPONSIBLE HEAG:	Melbourne Graduate School of Education	HESC:	Humanities and Applied Sciences
ADMINISTERING DEPARTMENT:	Melbourne Graduate School of Education	ADMINISTERING CENTRE: (if applicable)	

### 2. PROJECT DETAILS

Title:

Brief Description:

**Primary HREC Name:**

*That is the HREC with primary responsibility for the project.*

**HREC Reference No:**

**Project Approval Period:**

From:

To:

### 3. RESEARCHER(S) DETAILS

Role	Name	Person Type	Department/ Organisation	Phone/ Alternate Phone	Email/ Alternate Email

#### 4. ADDITIONAL QUESTIONS

4.1 **AIMS OF AND JUSTIFICATION FOR THE RESEARCH:** State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Also provide a brief description of current research/literature review, a justification as to why this research should proceed and an explanation of any expected benefits to the community. [No more than 500 words]

4.2 **METHOD:** Provide an outline of the proposed method, including details of the recruitment strategy and data collection techniques, the tasks participants will be asked to do, the estimated time commitment involved, and how data will be analysed. [No more than 500 words]

4.3 **USE OF INDEPENDENT CONTRACTORS:** Will parts of this project be carried out by independent contractors? (e.g. interviewing, questionnaire design and analysis, sample testing, etc)

- YES    NO If YES, confirm that the independent contractor will be engaged on the basis of relevant qualifications and experience and will receive from the Responsible Researcher, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it. [The responsibility for effective oversight and proper conduct of the project remains with the Responsible Researcher]

#### 4.4 MONITORING

- (a) How will researchers monitor the conduct of the project to ensure that it complies with the protocols set out in this application, the University's human ethics guidelines and the National Statement on Ethical Conduct in Human Research? [Address, in particular, cases where several people are involved in recruiting, interviewing or administering procedures, or when the research is being carried out at some distance from the Principal Researcher (i.e. interstate or overseas)]
- (b) For student research projects how will the student be supervised to ensure they comply with the protocols? If the student is working overseas, provide additional details of any local supervision arrangements.

4.5 **FUNDING DETAILS:** Is this project being funded?

- YES    NO If YES, provide details including the source of the funding/grant, its duration and registration number, if known.

#### 5. ATTACHMENTS

Copies of the following need to be attached:

	YES	NO	NOT APPLICABLE
• A copy of the project approval letter. That is the ethics clearance letter from the Primary HREC.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• A copy of the approved protocol. That is the full project application approved by the Primary HREC, complete with plain language statements, consent forms, other associated documentation and any amendments.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• A copy of any other project approval letter(s). That is any ethics clearance letter(s) from other HREC(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **6. DECLARATION BY RESEARCHERS**

The information contained herein is, to the best of our knowledge and belief, accurate.

We have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University's Code of Conduct for Research and any other condition laid down by the University of Melbourne's Human Research Ethics Committee or its Sub-Committees. We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants. We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.

If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

We, the researcher(s) agree:

- To only start this research project after obtaining final approval from the Human Research Ethics Committee (HREC);
- To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
- To provide additional information as requested by the HREC;
- To provide progress reports to the HREC as requested, including annual and final reports;
- To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
- To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
- To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;
- To agree to an audit if requested by the HREC;
- To only use data and any tissue samples collected for the study for which approval has been given;

We have read the National Statement on Ethical Conduct in Human Research and agree to comply with its provisions.

**All researchers associated with this project must sign**

Researchers' Name (please PRINT)	Signature	Date

## **7. DECLARATION BY DEPARTMENTAL HUMAN ETHICS ADVISORY GROUP (HEAG)**

DATE APPLICATION RECEIVED:

/ /

HEAG NO:

*The HEAG has considered this project, including the role and contribution of University of Melbourne staff, students and supervisors.*  
[Note: If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]

*Please tick ONE of the following*

The HEAG recommends that the project be registered with the University of Melbourne.

The HEAG recommends that the project be registered with the University of Melbourne subject to the following conditions [see Comments/Provisos below].

**Comments/Provisos:**

Name of HEAG Chair (in BLOCK LETTERS)	
Signature	
Date	

## **8. DECLARATION BY HEAD OF DEPARTMENT**

DATE APPLICATION RECEIVED:

/ /

HEAG NO:

*This project has the approval and support of this Department/School/Centre. [Note: If the Head of Department is also a principal researcher for this project, the declaration should be signed by another authorised member of the Department]*

Name of Head (in BLOCK LETTERS)	
Signature	
Date	

## **9. WHEN COMPLETE**

**When this form has been completed and finalised it should be attached to the coversheet section of the application completed in Themis Research and then submitted to the nominated Human Ethics Advisory Group for review.**

# Printing an ethics application summary & related attachments



The printed version of an ethics application includes:

- the application summary (data entered directly into Themis)
- the completed application form (the document electronically attached via Themis)
- other attachments (either electronically attached via Themis or being provided in hard copy only - including plain language statements, consent forms, etc)
- a request for amendment summary (data entered directly into Themis)

## Printing the application summary

A copy of the Human Ethics application summary may be printed via the reports screen (this is the version that you should submit to the HEAG or HESC for formal review).

**1** Log on to Themis using the appropriate responsibility.

**Note:** you will be able to access this feature via either the **UOM Research Self Service** or **UOM RMS Human Ethics Department** responsibilities.

**2** Select the **Reporting** function listed under the Reporting section.

The Submit Report screen will display.

**Submit Report**

**Report**

\* Report Name: UOM RMS HE AP Project - Application Summary  
✓ TIP Select a report to display the parameter fields

Description:   
✓ TIP The Description entered can be used later to search for this request

**Parameters**

\* Application Version:

**Output Layout**

Format: PDF

**3** Enter your report specifications.

Field	Action	Comments
Report Name	Select <b>UOM RMS HE AP XXX - Application Summary</b> from the drop-down list	<b>Note:</b> replace <b>XXX</b> with the application type you wish to print (e.g.: Project Application, Project Application, Request for Transfer, etc). If you are printing a Request for Amendment, select <b>UOM RMS Amendment Form Generator</b> .
Description	Enter a description for the report, if desired	<b>Note:</b> this field is optional, but entering a description may help you identify the report later.
Application Version	Enter the application version number of the application you wish to print, or use the <b>Torch</b> to select from the list of values	<b>Note:</b> you will only be able to select from the ethics applications on which you are named as a researcher or for which you are responsible as a HEAG administrator.
Format	Select the desired report format from the drop-down list	This field will default to <b>PDF</b> , but if you would like the output in a form that you may edit, select <b>RTF</b> (word).
Scheduling Recurrence	This field will default to <b>Never repeat</b> and should not need to be changed	
Scheduling Start Date	This field will default to <b>As soon as possible</b> and should not need to be changed	
Notifications	This function is not currently being used and should be left blank	

**4** Click on the **Submit** button.

A message will display advising that your report has been scheduled, and indicating the request ID number.

**Information**

Your request for Testing has been scheduled. The Request ID is 5155166

- 5** Click **OK** to close this message.  
The Requests monitoring screen will display.

Requests							
View		Last 24 hours	Go				
Status	Name	Phase	Scheduled Date	Details	Output	Request ID	Republish
✓	UOM RMS HE AP Project - Application Summary	Pending	10-Aug-2007 10:01:34			7237151	

This screen will default to display all the reports you have generated in the last 24 hours. To display an alternate set, select the value from the **View** drop-down list and click on the **Go** button.

- **Details** icon will display the report parameters you specified
- **Output** icon will display the report in the format you specified in the parameters
- **Republish** icon will enable you to re-submit the report without having to re-enter the parameter details

- 6** Click on the **Refresh** button to update the request Phase.

**Note:** the Output column will remain blank until the application has completed. Once the application has been successfully run, an icon will display.

- 7** Click on the **Output** icon to open the application in the web browser screen.

**Note:** if you selected **RTF** as the application output format you may receive a dialog box asking whether you wish to **Open** or **Save** the report.

<b>THE UNIVERSITY OF MELBOURNE HUMAN RESEARCH ETHICS COMMITTEE</b>  <b>APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN PARTICIPANTS</b>	 <b>THE UNIVERSITY OF MELBOURNE</b>		
<b>A. ADMINISTRATION DETAILS</b>			
APPLICATION TYPE:	Project Application	ETHICS ID:	0716194
RESPONSIBLE HEAG:	Information Systems	HESC:	Humanities and Applied Sciences
ADMINISTERING DEPARTMENT:	830 - Enterprise Applications	ADMINISTERING CENTRE: (if applicable)	
<b>B. PROJECT DETAILS</b>			
Title:	The Daggi '80s		
Project Type:	Staff Research Project		
Research Involves:	None Selected		
Brief Description:	A look at the people, the fashion, movies and music of the 1980s		
Proposed Duration of whole Research Project:	From: SEP-2007	To: NOV-2009	
Proposed Date to Commence Data Collection:	01-SEP-07		
<b>C. PERSON DETAILS</b>			
Role	Full Name	Person Type	Department Name
Responsible	Hodgkin Ms Rebecca	Staff	830 - Enterprise Applications

- 8** Select **File > Print** from the web browser Toolbar to print the application.

**Note:** the application will print to your standard printer, not your Themis printer (if different).

- 9** Click on the browser **Back** button to return to the Request Monitor screen.

**Important:** do not close the output window as you will close and exit out of your current Themis session.

- 10** Click on the **Ethics** tab located on the top right of the screen to return to your Ethics Workbench.

## Printing the attachments (including the completed application form)

You may print the attachments for an ethics application via the application summary screen.

- 1 Log on to Themis using the appropriate responsibility.

**Note:** you will be able to access this feature via either the **UOM Research Self Service** or **UOM RMS Human Ethics Department** responsibilities.

- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.

The Human Ethics Workbench screen will display.

- 3 Locate the application in the **Current Applications** section or perform a search for a current application.

Refer to the **Searching for Applications in the Human Ethics Workbench** information sheet for further information.

- 4 Navigate to the Application Summary screen.

In the Workbench: click on the **View** icon for the appropriate ethics record. The Ethics Overview screen will display.

In the Ethics Overview: click on the **View** icon for the appropriate record version. The Application Summary screen will display.

						Printable Page
Available Pages	Ethics Application ID	Approval Category	Responsible HEAG	HESC	Status	
Project Details	0600106.1	HEAG	YOUR HEAG			Draft
• <a href="#">Application Summary</a>	Title: <b>The Daggy '80s</b>					
• <a href="#">Full Application Details</a>	Application Type: <b>Project Application</b>					
• <a href="#">Update Application</a>	Project Type: <b>Staff Research Project</b>					
	Description: <b>A look at the people, the fashion, movies and music of the 1980s</b>					
	Proposed duration of the WHOLE research Project: <b>SEP-2006</b> To: <b>OCT-2009</b>					
	Proposed Start Date for Data Collection of the project: <b>25-Sep-2006</b>					
Application Management	<b>Selected Minimum Risk Checklist Items</b>					
• <a href="#">Document Review</a>	Risks to the researchers					
• <a href="#">Status History</a>	<b>Selected Research Checklist Items</b>					
• <a href="#">Correspondence</a>	None of the above					
Associated Personnel						
	Name	Role	Type	Department/Organisation		
	Mortyme, Dr Juan	Responsible Researcher	Staff	University Systems Project		
	Sight, Prof Heinz	Co researcher	External	Society of Australian Fashion		
<a href="#">Return to Ethics Record</a>						

- 5 Scroll down to the Attachments table and locate the attachment you wish to print.

Attached Electronic Documents								
File Name	Type	Description	Category	Last Updated By	Last Updated	Usage	Update	Delete
<a href="#">ethicscover.doc</a>	File	the usual	Application	RHODGKIN	25-Sep-2006	One-Time		

- 6 Click on the **File Name** link to open the attachment.

The document will open in a new screen (your Themis session will still be open), in the appropriate application for specified format (e.g.: as a Word, Excel, Adobe PDF, etc document).

- 7 Print the document as you would normally in the application (e.g.: **File > Print**) then close the document.

- 8 Return to your Themis session and repeat steps 6 and 7 above for each document you wish to print.

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# Updating a Human Ethics Application via the Workbench

Sometimes an application may require updating after it has been submitted (e.g.: updates to the registry information for clinical trials, updating additional ethics or non-ethics clearances, and location of research). The Human Ethics Workbench allows a researcher access to these screens in order to update details where required.

## To update application details

- 1 Log on to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.

The Human Ethics Home Page will display. **Note:** once you submit your application, it will no longer display in the Items Requiring Action section, but will display in the Current Applications section. If the application you require does not display, you may retrieve it using the Search function (for details on how to search for an application, refer to the **Searching for an Application in the Human Ethics Workbench** information sheet).

- 3 Locate the appropriate ethics application and click on the associated **View** icon.

Ethics Id	Application Type	Responsible Researcher	Title	Status	<b>View</b>
0600180.1	Project Application	HODGKIN, MS REBECCA ANNE	Beer Goggles	Draft	

The Ethics Record Overview screen for the selected record will display. **Note:** if your ethics application record has multiple versions, you will be able to access these past versions from this overview page.

- 4 Locate the application version you wish to access and click on the **View** icon.

Application Versions							
Version Name	System Status	Operational Status	Status Set By	Last Update	Last Updated By	<b>View</b>	<b>Update</b>
0600180.1	Initiated	Draft	Drink, Ms Anita	21-JUL-2006	Drink, Ms Anita		

A summary of the selected ethics application will display.

- 5 Use the links in the **Available Pages** menu on the left of the screen to access the Additional Question screen. You will be able to update the **Clinical Trials**, **Location of Research**, **Other Approvals** and/or **Ethics Clearance** screens.

## Updating the Clinical Trials information

- 1 Click on the **Clinical Trials** hyper link in the Available Pages menu.

The Clinical Trials screen will display. **Note:** any information you entered during the application submission will display.

- 2 Update the information as required.

For further details regarding this screen refer to the **Completing the Clinical Trials Screen** information sheet.

- 3 Click on the **Save** button.

A message advising that the changes have been saved will display.

## Updating the Research Location information

- 1 Click on the **Location of Research** hyper link in the Available Pages menu.

The Research Location screen will display. **Note:** any information you entered during the application submission will display.

- 2 Update the information as required.

For further details regarding this screen refer to the **Completing the Location of Research Screen** information sheet.

- 3 Click on the **Save** button.

A message advising that the changes have been saved will display.

## Updating the Ethics Clearance information

- 1 Click on the **Ethics Clearances** hyper link in the Available Pages menu.

The Ethics Clearances screen will display. **Note:** any information you entered during the application submission will display.

- 2 Update the information as required.

For further details regarding this screen refer to the **Completing the Other Ethics Clearance Screen** information sheet.

- 3 Click on the **Save** button.

A message advising that the changes have been saved will display.

## Updating the Other (Non-Ethics) Approvals information

- 1 Click on the **Other Approvals** hyper link in the Available Pages menu.

The Other Approvals screen will display. **Note:** any information you entered during the application submission will display.

- 2 Update the information as required.

For further details regarding this screen refer to the **Completing the Other (Non-Ethics) Approvals Screen** information sheet.

- 3 Click on the **Save** button.

A message advising that the changes have been saved will display.

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# Request for amendment of a Human Ethics application



If you wish to make changes to an ethics application after it has been approved by the relevant HEAG or HESC, you will need to submit a request for amendment. A request for amendment must progress through the same approval process as the original ethics application before the changes will be incorporated as part of the approved ethics protocol. **Note:** any researcher named on the original ethics application may submit a request for amendment.

## Creating a Request for Amendment

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page - Researcher Worklist screen will display.
- 3 Click on the Ethics Application Amendment: **Create** button in the Create New Documents section.

Human Ethics Home Page - Researcher Worklist	
<a href="#">Create New Documents</a>	
Ethics Application (including transfers and registrations): <a href="#">Create</a>	
Ethics Application Amendment: <a href="#">Create</a>	

The Request for Amendment screen will display ethics applications on which you are named.

<a href="#">Request For Amendment</a>																									
The applications below are current applications on which you are named as a researcher and which have been approved by the relevant ethics committee. To initiate a request for amendment locate the relevant application and select the "create" icon.																									
If the "create" icon is disabled it means that there is already a Request for Amendment being prepared by another named researcher, or one is currently under review by the HEAG or HESC. It is only possible to have ONE Request for Amendment in preparation or under review at any one time. A second Request for Amendment can only be created once the initial one has either been approved or rejected. Alternatively, the Request for Amendment currently in draft or under review can be updated to include the details of the additional amendments required.																									
Please contact your HEAG Administrator if you have any queries relating to incorporating additional requests within a current Request for Amendment.																									
<a href="#">Refine Search</a>																									
<table border="1"><thead><tr><th>Ethics Id</th><th>Application Type</th><th>Title</th><th>Responsible Researcher</th><th>Status</th><th>Create</th></tr></thead><tbody><tr><td>0600280.1</td><td>Project Application</td><td>My life as a hamster</td><td>RODENT, MS IMA</td><td>Approved HEAG</td><td></td></tr><tr><td>0600380.2</td><td>Minimal Risk</td><td>The best things about pizza</td><td>RONI, DR PEPE</td><td>Approved HEAG</td><td></td></tr><tr><td>0600440.1</td><td>Minimal Risk</td><td>What is it about Greek food?</td><td>KOPITA, PROF SPANI</td><td>Approved HEAG</td><td></td></tr></tbody></table>		Ethics Id	Application Type	Title	Responsible Researcher	Status	Create	0600280.1	Project Application	My life as a hamster	RODENT, MS IMA	Approved HEAG		0600380.2	Minimal Risk	The best things about pizza	RONI, DR PEPE	Approved HEAG		0600440.1	Minimal Risk	What is it about Greek food?	KOPITA, PROF SPANI	Approved HEAG	
Ethics Id	Application Type	Title	Responsible Researcher	Status	Create																				
0600280.1	Project Application	My life as a hamster	RODENT, MS IMA	Approved HEAG																					
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0600440.1	Minimal Risk	What is it about Greek food?	KOPITA, PROF SPANI	Approved HEAG																					
<a href="#">Return To Workbench</a>																									

**Note:** the **Create** icon will be inactive (i.e.: greyed out ) if a Request for Amendment is currently in progress (i.e.: another named researcher is preparing a request) or currently under review by the HEAG or HESC.

- 4 Click on the **Create** () icon for the project you would like to request amendment.
- The Request for Amendment details screen for the selected ethics application record will display.

<a href="#">Request For Amendment</a>											
<a href="#">Save</a> <a href="#">Back</a> <a href="#">Next</a>											
<table border="1"><thead><tr><th>Ethics ID</th><th>Status</th><th>Application Type</th><th>Title</th><th>Approval Category</th></tr></thead><tbody><tr><td>0600380.3</td><td>Draft</td><td>Minimal Risk</td><td>The best things about pizza</td><td>HEAG</td></tr></tbody></table>		Ethics ID	Status	Application Type	Title	Approval Category	0600380.3	Draft	Minimal Risk	The best things about pizza	HEAG
Ethics ID	Status	Application Type	Title	Approval Category							
0600380.3	Draft	Minimal Risk	The best things about pizza	HEAG							
<a href="#">General Instructions</a>											
<b>Nature of and Reasons for Amendment</b>											
Please provide details of the changes you propose to make to the project and explain why they are necessary. Please justify any increase in sample size. Note that if there are any changes to the details previously completed in the online section of the application, you can modify these by continuing to select NEXT throughout the online application that follows. Modification to details of researchers can be made via the Researcher Details screen. Any attachments that have been amended can be replaced/attached via the Attachment Screen.											
<input type="text"/>											
<b>Impact on Documentation</b>											
Indicate whether the proposed changes to the research will require any modification to documentation related to the ethics application (e.g., changes to consent forms, plain language statements or other documents). Indicate below which documents will be modified, or what new documentation is required, and ensure that you include updated versions of current attachments or add new attachments via the Attachments screen.											
<input type="text"/>											
<b>Possible inconveniences or Risks to Participants</b>											

**5** Enter the details of your request for amendment.

**Note:** all fields must be completed before you will be able to progress to and update the application.

Field	Action	Comments
Nature of and reasons for amendment	Enter details of the changes you propose to make and an explanation of why they are necessary	
Impact on documentation	Indicate whether the changes will require modification to documentation relating to the project and include details of which attachments will be updated or what new attachments will be added.	
Possible inconveniences or risks to participants	Enter any inconveniences or possible risks that the changes may create for participants	
Actions to be taken by researcher to reduce risk	Enter any additional actions and/or support that you need to provide as a result of the changes	
Expected date of implementation of amendment to research	Enter the date you expect to implement the proposed amendment	<b>Note:</b> ensure you allow sufficient time for review of your request.
Possible affect on funding arrangements	Enter details any effects the changes will have on funding arrangements, if applicable	
Possible implications for compliance with legislative requirements	Enter details of any effect the changes will have on compliance with legislative requirements, if applicable	

**6** Click on the **Next** button to progress to the ethics application.

**Note:** this is a copy of the original ethics application with the same Ethics Application ID as the original. However the Application ID will have a new version number (e.g.: 0600380.3) and the status will be Draft.

Ethics ID	Status
0600380.3	Draft

**7** Progress through the ethics application and update details as required.

**8** Attach any new and/or modified documents.

For example: application, consent form, plain language statement, etc.

**9** Click on the **Submit Application** button.

A message will display confirming your request for amendment has been submitted to the nominated HEAG for review.

An electronic version of this Request for Amendment has been submitted to the nominated HEAG. (The Administrator of the HEAG will receive an email alert advising that the amendment has been submitted). However, to facilitate the review process you will also need to provide the HEAG Administrator with ONE paper copy of:

- A summary of information you have entered in Themis (to print a copy of this summary, select the Reporting tab at the top right of this page, choose REQUEST FOR AMENDMENT from the list of available reports, enter the ethics ID number, select SUBMIT. Via the reports monitor screen, select the OUTPUT icon to view the report and then choose to print it to your standard printer.)
- Any new or modified attachments that you have entered into Themis as part of this Request for Amendment
- Any additional supporting documentation that is only available in hard copy

Your request for amendment will display in the Current Applications section of your workbench.

**Note:** the Ethics Id will indicate a new version number for the application.

CURRENT APPLICATIONS						
<a href="#">Refine Search</a>						
Ethics Id	Application Type	Responsible Researcher	Title	Status	View	
0600440.1	Minimal Risk	KOPITA, PROF SPANI	What is it about Greek food?	Approved HEAG		
0602181.1	Project Application	NORING, DR CONSTANCE	Life in the undergrowth - an exploration of the hours after a big night out	Lodged		
0600380.3	Minimal Risk	RONI, DR PEPE	The best things about pizza	Lodged		

**10** Print a copy of the Request for Amendment and any revised/new attachments.

Refer to **Printing a Human Ethics application and related attachments** information sheet for further details.

**11** Ensure the Request for Amendment is signed by the responsible researcher.

**12** Submit the paper copies of your Request for Amendment and any attachments to the HEAG Administrator.



THE UNIVERSITY OF MELBOURNE  
HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF  
MELBOURNE

## REQUEST FOR AMENDMENT

### 1. ADMINISTRATION DETAILS

DATE OF SUBMISSION:

ETHICS ID:

APPLICATION TYPE:

RESPONSIBLE HEAG:

Melbourne Graduate School of  
Education

HESC:

Humanities and Applied Sciences

ADMINISTERING  
DEPARTMENT:

Melbourne Graduate School of  
Education

ADMINISTERING  
CENTRE:  
(if applicable)

### 2. PROJECT DETAILS

Title:

Brief Description:

Project Approval Period:

From:

To:

### 3. PERSON DETAILS

Role	Name	Person Type	Department / Organisation	/ Phone / Alternate Phone	Email / Alternate Email

#### **4. REQUEST FOR AMENDMENT DETAILS**

**4.1 Nature of and reason for amendment**

**4.2 Impact on documentation**

**4.3 Possible inconvenience or risks to participants**

**4.4 Actions to be taken by researchers to reduce risks**

**4.5 Expected date of implementation of amendment to research**

**4.6 Possible affect on funding arrangements**

**4.7 Possible implications for compliance with legislative requirements**

#### **5. ATTACHMENTS**

Copies of the following need to be attached:

- (a) copies of amended surveys, questionnaires or interview questions
- (b) copies of the amended advertisement, plain language statement, and consent form
- (c) any permission or approval letters required as a result of the proposed changes

## 6. SIGNATURES

### RESPONSIBLE RESEARCHERS

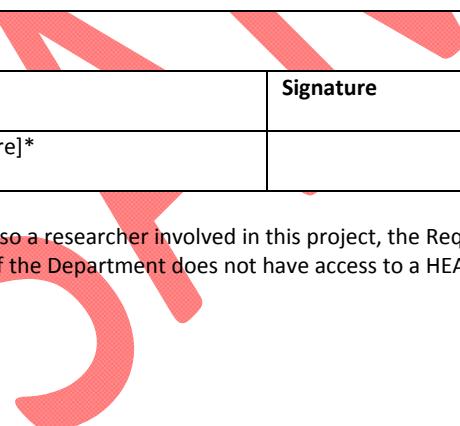
Name	Signature	Date

### HEAG/DEPARTMENT USE ONLY

*Please tick ONE of the following*

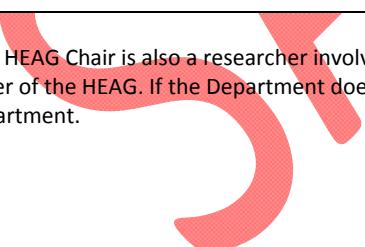
The HEAG/Head of Department recommends the amendment for approval by the HESC	
The HEAG approves this amendment as the project was previously approved as a minimal risk project or as a project-within program and the amendment presents no additional risks.	

**Comments/Provisos:**



	Signature	Date
[insert ethics chair here]*		

\* If the HEAG Chair is also a researcher involved in this project, the Request for Amendment should be signed by another authorised member of the HEAG. If the Department does not have access to a HEAG the Request for Amendment should be signed by the Head of Department.



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# Completing a Human Ethics Annual Report

Any human ethics application that has been approved or ratified by the HESC (in a system status of finalised) has annual reporting obligations. You will receive an email notification advising that an annual report is due and any application with a report due will display in the Annual Reports Due section of the Responsible Researcher's Human Ethics Workbench.

## Completing an annual report

- 1 Log in to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.

The Human Ethics Home Page - Researcher Worklist screen will display. The Annual Reports Due section will display a list of applications with a report due. **Note:** Co-researchers and students may lodge an annual report by accessing the record via the Current Application section and clicking on the **Update** button in the Ethics Record Overview screen.

Annual Reports Due				
Ethics Id	Application Type	Responsible Researcher	Title	Update
0600380.3	Minimal Risk	RONI, DR PEPE	The best things about pizza	

- 3 Locate the required application and click on the **Update** icon.

The Annual Report Details screen will display. This screen is the first in a series of steps required to complete the annual report process. **Note:** this screen is view only - if you wish to update any details on this screen you will need to send an email to the relevant HESC Administrator.

Step 1 - Annual Report Details					
Cancel Save Step 1 ▾ Next					
Ethics Application ID	Approval Category	Application Type	Maximum Expiry Date	Annual Report Number	Year
0600380.3	HEAG	Minimal Risk	22-Sep-2011	1	2008
<b>Project Title</b>					
The best things about pizza					
<b>Researcher/Department details</b>					
If any changes have been made to the researchers associated with the research as outlined below (including the Department with which they are associated, or their contact details), note that you will need to submit a separate Request for Amendment.					
Researcher Role	Researcher Type	Researcher Name	Department/Organisation		
Responsible Researcher	Staff	Roni, Dr Pepe	018 - University Systems Project		
Co researcher	External	Aido, Professor Tom	Pizza Hut Pty Ltd		

- 4 Click on the **Next** button.

The Annual Report Project Status screen will display.

## Specify the status of the project

The Annual Report Project Status screen allows you to indicate the current status of the research project and provide any details regarding the progress of the project. **Note:** it is recommended that, while completing your annual report, you save regularly to ensure you do not lose information if your session times out.

Step 2 - Annual Report Project Status					
Cancel Save Back Step 2 ▾ Next					
<b>Status of project</b>					
Please indicate the current status of the project: <span style="border: 1px solid black; padding: 2px;">Continuing - data collection not yet complete</span>					
<b>Estimated completion date</b>					
Please indicate the anticipated completion date: <span style="border: 1px solid black; padding: 2px;">28-Feb-2007</span>					
<b>Project Progress</b>					
Please give a BRIEF statement of progress in the project to date or please explain why project was abandoned or, in the case of a completed project the outcome of the research.					

- 1 Enter the status details for the project.

Field	Action	Comments
Current status of project	Select the appropriate status from the drop-down list	If you select a status of <b>Not yet commenced</b> or <b>Continuing - Data collection not yet complete</b> you will need to indicate an anticipated completion date for the project.
Estimated completion date	Enter the anticipated completion date for the project	<b>Note:</b> this field will only display if you select <b>Not yet commenced</b> or <b>Continuing - Data collection not yet complete</b> in the status field above.
Project progress	Enter a brief statement regarding the project process to date, or reasons the project was abandoned	

**2 Click on the **Next** button.**

The Last Twelve Months screen will display.

**Indicate the progress of the research conducted over the last 12 months**

The Last Twelve Months screen enables you to answer a number of specific questions regarding the progress of the research conducted over the preceding 12 months.

Step 3 - The Last Twelve Months	
<input type="button" value="Cancel"/> <input type="button" value="Save"/> <input type="button" value="Back"/> <input type="button" value="Step 3"/> <input type="button" value="Next"/>	
<p>Please answer all of the following questions relating to the research that has been conducted over the last twelve months.</p>	
<p>Have all conditions of approval required by the HEAG and Human Ethics Sub-Committee been met?</p>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Have there been any changes to procedures or direction of the approved protocol (including the source, number and manner of recruiting participants)?</p>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Have there been any changes to the consent procedures or documentation that were approved in the original protocol since your last report?</p>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Has the project been monitored as detailed in the approved protocol?</p>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Has data been stored securely, as detailed in the original protocol?</p>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Have there been any incidents/unforeseen problems during the project, including:</p> <ul style="list-style-type: none"> <li>• Data security problems</li> <li>• Adverse effects on participants</li> <li>• Unforeseen problems of an ethical nature</li> <li>• Withdrawal of participants from the project which has had a significant impact on the research (either because of the proportion of participants that have withdrawn, or because of the reason for their withdrawal)</li> </ul>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Have any complaints been made about the conduct of the project?</p>	
<p><input type="radio"/> Yes <input type="radio"/> No</p>	
<p>How will your research findings be disseminated? (e.g., conference papers, publications?)</p>	

*Have all conditions of approval required by the HEAG and Human Ethics Sub-Committee been met?*

**1 Click on the appropriate radio button to indicate whether the conditions of approval have been met.**

**Note:** if you select **No** you will need to complete additional information that will display below.

- Enter the details of the conditions that have not been met and reasons why.

*Have there been any changes to procedures or direction of the approved protocol?*

**2 Click on the appropriate radio button to indicate whether the approved procedures or direction have changed.**

**Note:** if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the procedures or direction that have changed.
- Indicate whether approval has been sought for these changes by selecting Yes or No from the drop-down list.

*Have there been any changes to the consent procedures or documentation that were approved in the original protocol?*

**3 Click on the appropriate radio button to indicate whether the consent procedures or documentation have changed.**

**Note:** if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the consent procedures and/or documentation that have changed.

*Has the project been monitored as detailed in the approved protocol?*

**4 Click on the appropriate radio button to indicate whether monitoring has been performed as detailed in the protocol.**

**Note:** if you select **No** you will need to complete additional information that will display below.

- Enter the details of the monitoring that has been performed and why it was not conducted as outlined in the approved protocol.

*Has data been stored securely, as detailed in the original protocol?*

**5 Click on the appropriate radio button to indicate whether the data has been stored as detailed in the protocol.**

**Note:** if you select **No** you will need to complete additional information that will display below.

- Enter the details of the data storage undertaken and why it has not met the approved protocol.

*Have there been any incidents/unforeseen problems during the project?*

**6 Click on the appropriate radio button to indicate whether there have been any incidents/unforeseen problems.**

**Note:** if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the incidents/problems.

*Have any complaints been made about the conduct of the project?*

**7** Click on the appropriate radio button to indicate whether there have been any complaints regarding conduct.

**Note:** if you select **Yes** you will need to complete additional information that will display below.

- Enter the details of the complaints and the action taken by researchers.

*How will your research findings be disseminated?*

**8** Enter the details of the methods by which the research finding will be disseminated.

**9** Click on the **Next** button.

The Continuing Projects screen will display.

**Complete the continuing project details**

This screen enables you to confirm that the correct process details are in place for continuing projects. **Note:** this screen need only be completed if you select a project status of **Not yet commenced** or **Continuing - data collection not yet complete**.

Step 4 - Continuing Projects	
<input type="button" value="Cancel"/> <input type="button" value="Save"/> <input type="button" value="Back"/> <input type="button" value="Step 4"/> <input type="button" value="Next"/>	
<p>Do you propose to make any amendments to the project including SIGNIFICANT changes to the plain language statement(s) and consent form(s) that will need approval for use in the coming year?</p> <p><input type="radio"/> Yes   <input type="radio"/> Not required   <input type="radio"/> Yet to be determined</p> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p>If 'YES' you will need to submit a Request for Amendment to your HEAG before new work can proceed. This can be done by completing and submitting your request via Themis Research.</p> </div> <p>Have you reviewed (and updated where necessary) all current advertisements, plain language statements and consent forms to be used in the coming year? (e.g., dates, names and contact details of researchers, etc.)</p> <p><input type="checkbox"/> Yes, relevant document have been updated/are current</p> <p>Can you please confirm that the relevant contact details for the HREC are included in documentation to be provided to participants</p> <p><input type="checkbox"/> Yes, relevant documents include current contact details for the approving HREC</p> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p>Note that it is a requirement of approval that participants be provided with contact details for the approving HREC. These details should be included in any plain language statements or other documentation provided to participants. (Note that the relevant contact number for the Executive Officer, HREC, at the University of Melbourne is 8344 2073.)</p> </div> <p>Please confirm that all people or groups (for example, coresearchers, research assistants, schools, hospitals, organisations) involved in recruitment been instructed in the informed consent procedures approved by the approving HEAG/HESC?</p> <p><input type="radio"/> Yes, people/groups involved in recruitment have been instructed in informed consent procedures  <input type="radio"/> Not Applicable</p>	

*Do you propose to make any amendments to the project that will need approval for use in the coming year?*

**1** Click on the appropriate radio button to indicate whether amendments requiring approval will be made.

**Note:** if you select **Yes** you will need to submit a Request for Amendment to your HEAG before any new work may proceed. For further details refer to the **Request for amendment of a Human Ethics application** information sheet.

*Have you reviewed all current advertisements, plain language statements and consent forms to be used in the coming year?*

**2** Tick the checkbox to confirm the relevant documents are current or have been updated.

**Note:** if you do not tick this box, you will receive an error at the validation stage.

*Please confirm the relevant contact details for the HREC are included in documentation to be provided to participants.*

**3** Tick the checkbox to confirm the HREC contact details are included in participant documentation.

**Note:** if you do not tick this box, you will receive an error at the validation stage.

*Please confirm that all people or groups involved in recruitment have been instructed in the informed consent procedures approved by the approving HEAG/HESC?*

**4** Click on the appropriate radio button to indicate whether the involved people/groups have been instructed in informed consent procedures or that this is not applicable.

**Note:** if you do not select an option, you will receive an error at the validation stage.

**5** Click on the **Next** button.

The Other Comments screen will display.

## Enter any additional comments

The Other Comments screen enables you to include any additional comments related to your research.

Step 5 - Other Comments					
<input type="button" value="Cancel"/> <input type="button" value="Save"/> <input type="button" value="Back"/> <input type="button" value="Step 5 ▾"/> <input type="button" value="Next"/>					
<b>Other Comments</b> Please include any additional comments you may wish to make regarding this research. <div style="border: 1px solid #ccc; height: 60px; width: 100%;"></div>					

1 Enter any comments regarding your research project, if applicable.

2 Click on the **Next** button.

The Annual Report Review screen will display.

## Review the annual report

The Annual Report Review screen will identify any validation errors or omissions (e.g.: you have not entered dissemination details for your research findings) in relation to your annual report.

*If validation errors are identified*

Step 6 - Annual Report Review					
<input type="button" value="Cancel"/> <input type="button" value="Save"/> <input type="button" value="Back"/> <input type="button" value="Step 6 ▾"/> <input type="button" value="Next"/>					
<b>Annual Report Review</b> <div style="border: 1px solid #ccc; padding: 5px; background-color: #f0f8ff;">Data validation errors have been identified in this annual report. You cannot proceed to the submission page until the errors specified in the table below have been corrected.</div>					
<b>Data Validation Error</b> Details regarding how your research findings will be disseminated have not been entered					<b>Application Step</b> Step 3
<input style="border: 1px solid #ccc; padding: 2px 10px;" type="button" value="Go To Page"/>					

1 Click on the associated  icon in the Go To Page column.

This will link you directly to the appropriate page.

2 Update the information as required and click on the **Save** button to commit your changes.

3 Use the drop down list ( at the top or bottom of the screen to return to the review page.

4 Repeat the steps above for each of the validation errors.

5 Click on the **Next** button.

The Annual Report Submission screen will display.

## Submit the annual report

Once you have reviewed your annual report and corrected any validation errors, you may submit it.

1 Read the submission confirmation statement.

2 Tick the checkbox to the right of the statement.

**Note:** you will be unable to submit the report until you tick this box (i.e.: the **Submit Annual Report** button will not be active).

3 Click on the **Submit Annual Report** button.

A Confirmation of Submission screen will display.

Step 7 - Annual Report Confirmation																
<b>Ethics Application ID</b> 0600380.3		<b>Year</b> 2006	<b>Date of submission</b> 22-Feb-2007	<b>Application Type</b> Lodged												
<b>Title:</b> The best things about pizza <b>Researchers:</b> <table border="1" style="width: 100%;"> <thead> <tr> <th>Name</th> <th>Researcher Type</th> <th>Researcher Role</th> <th>Department/Organisation</th> </tr> </thead> <tbody> <tr> <td>Roni, Dr Pepe</td> <td>Staff</td> <td>Responsible Researcher</td> <td>018 - University Systems Project</td> </tr> <tr> <td>Aido, Professor Tom</td> <td>External</td> <td>Co researcher</td> <td>Pizza Hut Pty Ltd</td> </tr> </tbody> </table>					Name	Researcher Type	Researcher Role	Department/Organisation	Roni, Dr Pepe	Staff	Responsible Researcher	018 - University Systems Project	Aido, Professor Tom	External	Co researcher	Pizza Hut Pty Ltd
Name	Researcher Type	Researcher Role	Department/Organisation													
Roni, Dr Pepe	Staff	Responsible Researcher	018 - University Systems Project													
Aido, Professor Tom	External	Co researcher	Pizza Hut Pty Ltd													
<b>Annual Report Confirmation</b> Thank you for submitting the annual report for the above project. An email has been sent to all named researchers advising that the annual report has been submitted. Note that when the annual report has been approved an email will be forwarded to all researchers confirming that the project has either continuing approval or is no longer active.																

**Important:** once submitted, the Annual Report will no longer display in the Annual Reports Due table of your Workbench. If you wish to view the annual report, you may do so by searching for the appropriate Ethics Application (or accessing it via your Current Applications table) and navigating to the Annual Reports screen.

# Navigating the Annual Report Summary screen

The Annual Report Summary screen displays a summary of key information relating to the annual report record selected. In addition, it provides access to additional functions/screens for the selected application.

## To access the Annual Report Summary screen

- 1 Log on to Themis using the **UOM Research Self Service** responsibility.
- 2 Select the **Human Ethics Workbench** function listed under the Ethics section.  
The Human Ethics Home Page will display.
- 3 Locate the ethics application associated with the annual report you wish to access and click on the **View** icon.

You may access the appropriate ethics application via the Current Application section of your Workbench. Alternatively, if the application does not display in this section, you may perform a search to locate it.

The Ethics Record Overview screen will display. The Annual Reports table will display all reports that have been submitted for the selected ethics application.

Ethics Record Overview												
Ethics ID	Last Date Record Updated	Last Update By	Status	Status Reason	Status Date							
0600380	06-Nov-2006	Person, Mr Rious	Active	New	22-Sep-2006							
Application Type:	Minimal Risk		Approval Category:	HEAG								
Responsible HEAG:	Your HEAG		HESC:	Behavioural and Social Sciences								
Approval Date:	04-Oct-2006		Special Conditions of Approval:	<input type="checkbox"/>								
Annual Expiry Date:	31-Dec-2006		Maximum Expiry Date:	22-Sep-2011								
Administering Department	018 - University Systems Project		Administering Centre (if applicable)									
Related Documents												
Application Versions												
Version Name	System Status	Operational Status	Status Set By	Last Update	Last Updated By							
0600380.1	Contingent	Approved HEAG	Person, Mr Rious	26-SEP-2006	Person, Mr Rious							
Annual Reports												
Number	Year	System Status	Operational Status	Status Set By	Last Update							
1	2006	Submitted	Lodged	Person, Mr Rious	22-Feb-2007							

- 4 Locate the report you wish to access in the Annual Reports table and click on the **View** icon.

The Annual Report Summary screen will display. This screen provides a summary of the information entered during the annual report submission process.

Available Pages						Printable Page															
Project Details	0600380.3	HEAG	Minimal Risk	22-Sep-2011	1	2006															
Title: <b>The best things about pizza</b>																					
Associated Personnel																					
<table border="1"> <thead> <tr> <th>Details</th><th>Name</th><th>Role</th><th>Type</th><th>Department/Organisation</th></tr> </thead> <tbody> <tr> <td>► Show</td><td>Roni, Dr Pepe</td><td>Responsible Researcher</td><td>Staff</td><td>018 - University Systems Project</td></tr> <tr> <td>► Show</td><td>Aido, Professor Tom</td><td>Co researcher</td><td>External</td><td>Pizza Hut Pty Ltd</td></tr> </tbody> </table>							Details	Name	Role	Type	Department/Organisation	► Show	Roni, Dr Pepe	Responsible Researcher	Staff	018 - University Systems Project	► Show	Aido, Professor Tom	Co researcher	External	Pizza Hut Pty Ltd
Details	Name	Role	Type	Department/Organisation																	
► Show	Roni, Dr Pepe	Responsible Researcher	Staff	018 - University Systems Project																	
► Show	Aido, Professor Tom	Co researcher	External	Pizza Hut Pty Ltd																	
Status of Project: <b>Continuing - data collection not yet complete</b>																					
Estimated Completion Date: <b>28-FEB-2007</b>																					
Project Progress: <b>project continuing as expected</b>																					
Last Twelve Months Conditions met: <b>Yes</b> Changes to procedures: <b>No</b> Changes to consent procedures: <b>No</b> Project monitored: <b>Yes</b> Data stored securely: <b>Yes</b> Any incidents/unforeseen problems: <b>Yes - lost my computer, containing all the subject data</b> Any complaints: <b>No</b> Dissemination of results: <b>presenting at World Conference</b> <b>Continuing Projects</b> Amendments to project: <b>Not required</b> Relevant documentation updated: <b>Yes</b> HREC details provided in documentation: <b>Yes</b> Recruiters instructed in informed consent procedures: <b>Not Applicable</b> Other Comments:																					

- click on the **► Show** link to view additional details for the researchers associated with the project.
- click on the **Printable Page** button to access a printer friendly version of the Annual Report Summary screen.

## Available Pages

Use the **Available Pages** menu on the top left of the screen to navigate to additional functions.

The menu is divided into two sections:

- **Project Details** - enables you to view the overall project details for the selected annual report. You may view either a summary or full details of the report submitted
- **Application Management** - enables you to access information related to the review process for the selected annual report, including status history and correspondence generated by Themis

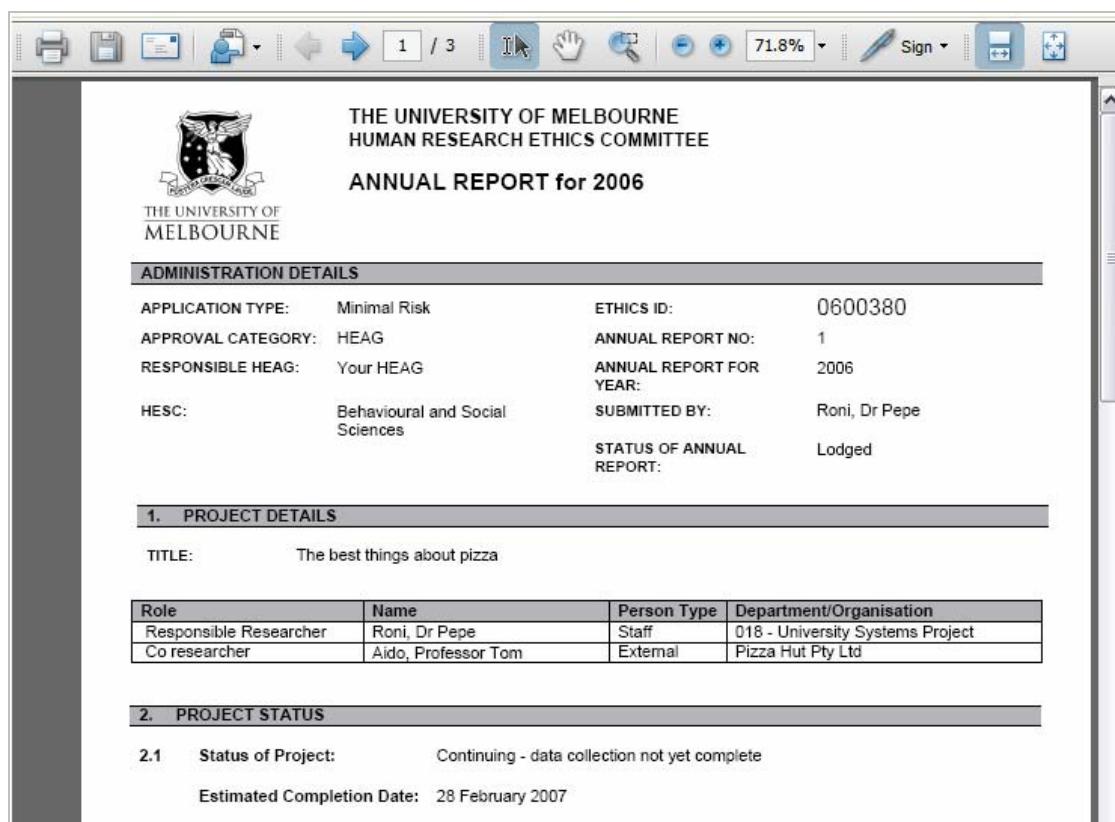
## Project Details

### *Annual Report Summary*

This is the default view and displays a summary of the information entered in the selected annual report.

### *Full Report*

This function enables you to access a PDF version of the full details of the annual report selected (i.e.: all report details and answers to questions). The PDF version of the annual report may then be printed and/or saved to your local computer.



The screenshot shows a software interface for viewing an annual report. At the top is a toolbar with various icons for file operations like print, save, and search, along with a zoom level of 71.8% and a sign-in button. Below the toolbar, the header reads "THE UNIVERSITY OF MELBOURNE HUMAN RESEARCH ETHICS COMMITTEE ANNUAL REPORT for 2006". To the left is the university crest and the text "THE UNIVERSITY OF MELBOURNE". The main content area is divided into sections:

- ADMINISTRATION DETAILS**: Shows application type (Minimal Risk), ethics ID (0600380), approval category (HEAG), responsible HEAG (Your HEAG), annual report number (1), HESC (Behavioural and Social Sciences), submitted by (Roni, Dr Pepe), and status of annual report (Lodged).
- 1. PROJECT DETAILS**: Title is "The best things about pizza". Below it is a table of roles and names:
 

Role	Name	Person Type	Department/Organisation
Responsible Researcher	Roni, Dr Pepe	Staff	018 - University Systems Project
Co researcher	Aido, Professor Tom	External	Pizza Hut Pty Ltd
- 2. PROJECT STATUS**: Status of Project is "Continuing - data collection not yet complete". Estimated Completion Date is "28 February 2007".

## Application Management

### *Status History*

This function enables you to access a history of the annual report status and identify any tracking steps that have been completed during the process.

Status history				
Details	System Status	Operational Status	Last Updated	Last Updated By
<a href="#">Show</a> Submitted	Lodged	22-Feb-2007 11:07:45		Person, Mr Rious
<a href="#">Show</a> Initiated	Draft	19-Feb-2007 09:51:22		

- click on the [Show](#) link to view the tracking steps associated with a particular status.

## Correspondence

This function enables you to access a history of the system generated correspondence associated with the selected application (e.g.: submission acknowledgement email).

Correspondence Summary								
				<input type="button" value="Return"/> <input type="button" value="Printable Page"/>				
<b>Ethics ID</b>		<b>Document</b>						
0600380		0600380.3						
<b>Summary</b>								
<b>Details</b>	<b>Date sent</b>	<b>From</b>	<b>Correspondence type</b>	<b>Document</b>	<b>System status</b>	<b>Status when sent</b>		<b>View Message</b>
 <a href="#">Hide</a>	22-FEB-2007		Email	0600380.3	Submitted	Op status	Tracking step	
<b>Correspondence Message</b>								
<b>To</b>				<b>Email</b>				
Aido, Professor Tom				tomaido@work				
Roni, Dr Pepe				peperoni@pizzahut				

- click on the **Return** button to return to the Annual Report Summary screen.
- click on the  [Show](#) link to view the parties to whom the correspondence was sent.
- click on the **View Message** icon to display the content of the correspondence sent.

Correspondence Sent Message																										
<input type="button" value="Printable Page"/> <input type="button" value="Return to Summary"/>																										
<b>Content</b>																										
<table border="1"> <thead> <tr> <th colspan="9"><b>Sent Message Text</b></th> </tr> </thead> <tbody> <tr> <td colspan="9">           Title: The best things about pizza            Researchers: Professor Tom Aido, Dr Pepe Roni            Ethics ID: 0600380            Application Type: Minimal Risk             The annual report for the above project for 2006 has been submitted for review. You are named on the relevant ethics application as a researcher associated with the project and, if you have access to Themis, will be able to view the annual report and track its status by logging on to your Themis account and searching for the relevant application.             You will be advised as soon as possible as to the status of continuing human research ethics clearance for the project.             If you have any queries regarding human research ethics clearance for this project, please contact the Administrator of the HEAG in the first instance.             Executive Officer,            Human Research Ethics            The University of Melbourne         </td> </tr> </tbody> </table>									<b>Sent Message Text</b>									Title: The best things about pizza Researchers: Professor Tom Aido, Dr Pepe Roni Ethics ID: 0600380 Application Type: Minimal Risk  The annual report for the above project for 2006 has been submitted for review. You are named on the relevant ethics application as a researcher associated with the project and, if you have access to Themis, will be able to view the annual report and track its status by logging on to your Themis account and searching for the relevant application.  You will be advised as soon as possible as to the status of continuing human research ethics clearance for the project.  If you have any queries regarding human research ethics clearance for this project, please contact the Administrator of the HEAG in the first instance.  Executive Officer, Human Research Ethics The University of Melbourne								
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- click on the **Return to Summary** button to return to the Correspondence Summary screen.

## Return to Ethics Record

This link returns you to the Human Research Ethics - Ethics Overview page for the selected ethics application.

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# **SECTION 3:**

# **Useful Information &**

# **External Resources**

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# **Human Research and Ethics**

Graduate School of Education  
University of Melbourne

## **Basic ethical principles**

- Research merit and integrity
- Justice
- Beneficence -- actions that promote the wellbeing of others
- Respect

## Which projects need approval?

- Current University and NHMRC policy states that **all** research projects involving human participants must be reviewed by institutional ethics committees.
- Some projects are exempt from ethical review
- See policy at  
<http://www.research.unimelb.edu.au/humanethics/policy/aboutus/>

## Projects which are exempt #1

- Use of data freely available in the public domain
- Research about a living individual using only public domain information
- Pure observation studies of public behaviour
- Pure observation studies in educational settings
- Quality assurance projects

## Projects which are exempt #2

- Testing within normal educational requirements, following normal practices
- Student education and training exercises (but no testing of each other allowed)
- Student coursework assignments and essays
- University student evaluations of teaching
- Taste and food quality evaluations

## Why do I need ethics approval?

- To protect the rights and welfare of human participants
- To ensure that any risk of discomfort or harm to participants is minimal, and justified by the potential benefits of the research
- To protect the University's reputation for research that it conducts and/or sponsors
- To minimise the potential for claims of negligence made against researchers and the University
- To meet the University's obligations under the NHMRC's *National Statement on Ethical Conduct in Human Research* (March 2007)

## What do ethics committees look out for?

- Is there a risk of physical, psychological, spiritual or emotional harm?
- Is there potential for infringement of privacy, confidentiality, or ownership?
- Does the person's involvement impose burdens that outweigh the benefit?

## Issues for Ethics Committees

- Aim of research
- Methodology:
  - Does what you say on the form match what you tell participants you are going to ask them to do? (in the Plain Language Statement)
  - Does what you are asking participants to do have the potential to yield the results you aim to find?
- Experience and training of researchers

## Issues for Ethics Committees

- Participants
  - who are they?
  - how vulnerable are they?
- Risks vs. Benefits
- Risk Management
  - immediate and later
  - unexpected outcomes

## Issues for Ethics Committees

- Recruitment: how? by whom?
- Dependent relationships: pupil/teacher; student/lecturer; family members; doctor/patient
- Cross cultural research: cultural sensitivities, translating, interpreting
- Confidentiality
  - legal limits
  - small sample size
  - data storage

## Issues for Ethics Committees

- Plain language statement and consent form
  - tailor to suit participants
- Informed consent:
  - clear full information
  - voluntary choice to participate
- Consent from whom:
  - parental consent for minors
  - legal guardians
  - community/organisations?

## Issues for Ethics Committees

- Publication of results of research
- Funding for research
- Conflict of interest?
- Payment to participants: compensation vs. inducement

## The University of Melbourne - Ethics Structure

- One central Human Research Ethics Committee (HREC) – decides policy
- Three Human Ethics Sub-Committees (HESC) – review projects
  - Health Sciences HESC
  - Behavioural & Social Sciences HESC
  - Humanities & Applied Sciences HESC
- Department HEAGs

## Ethics Approval Process - Low risk

- Start online via THEMIS to register and get the form
  - To get an account go to <http://accounts.unimelb.edu.au>
- Submit to Graduate School Human Ethics Advisory Group (HEAG) for review
- If doing research in schools, also need permission from relevant authority
- After review, the researchers complete the required revisions and return the application to HEAG
- Low/minimal risk projects are approved by HEAG

## **Process - Moderate or High Risk**

- As for low risk, then, in addition
- Moderate/High risk projects go on to the HESC for review at monthly meeting
- HESC then advises researchers re amendments or approval
- From initial submission to approval by the committee can take a couple of months
- Important to know when the ethics deadlines are
- Data collection overseas implies moderate risk at least

## **What is the supervisor's role?**

As a signatory of your application, the supervisor is responsible for:

- Briefing you about the ethics requirements when you are planning your project
- Guiding you in the completion of the application form
- Guiding you in the ethical conduct of your research
- Monitoring your project

## Ethics Approval Process

- No work to commence until written approval received
- All amendments require approval
- Any incidents or adverse effects are to be reported to the ethics committee
- Annual report to be submitted for yearly renewal of approval
- Approval renewed for up to 5 years

## External Documents

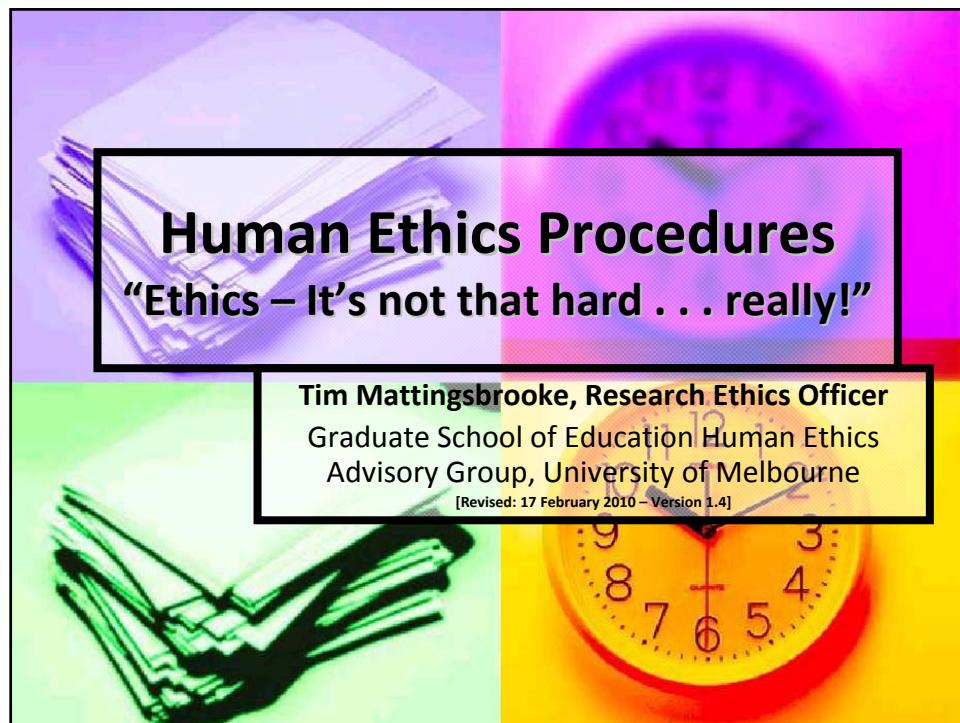
- American Psychological Association ethical principles of psychologists and code of conduct <http://www.apa.org/ethics/code.html>
- Children and Young Persons Act 1989 (in relation to Mandated Reporting Requirements) <http://www.dms.dpc.vic.gov.au/>
- Australian Association for Research in Education (AARE) Code of Ethics <http://www.swin.edu.au/aare/ethcfull.htm>
- NHMRC statement on Human research ethics  
<http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>
- Research in Government Schools  
<http://www.education.vic.edu.au/scln/research.htm>
- Research in Catholic Schools <http://www.ceo.melb.catholic.edu.au/>

## Internal sites and documents

- Graduate School of Education Human Ethics site
- [http://www.education.unimelb.edu.au/research/ethics/human\\_ethics.html](http://www.education.unimelb.edu.au/research/ethics/human_ethics.html)
- University of Melbourne Human Ethics site
- <http://www.research.unimelb.edu.au/humanethics/>
- University of Melbourne Human Ethics “hints” page
- <http://www.research.unimelb.edu.au/humanethics/external/hints/>

## Indigenous Research

- Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (NHMRC, June 1991) under review
- <http://www.nhmrc.gov.au/issues/asti.pdf>
- Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies, 2000)
- <http://www.aiatsis.gov.au/corp/docs/EthicsGuideA4.pdf>



# **Human Ethics Procedures**

**“Ethics – It’s not that hard . . . really!”**

**Tim Mattingsbrooke, Research Ethics Officer**  
Graduate School of Education Human Ethics  
Advisory Group, University of Melbourne  
[Revised: 17 February 2010 – Version 1.4]



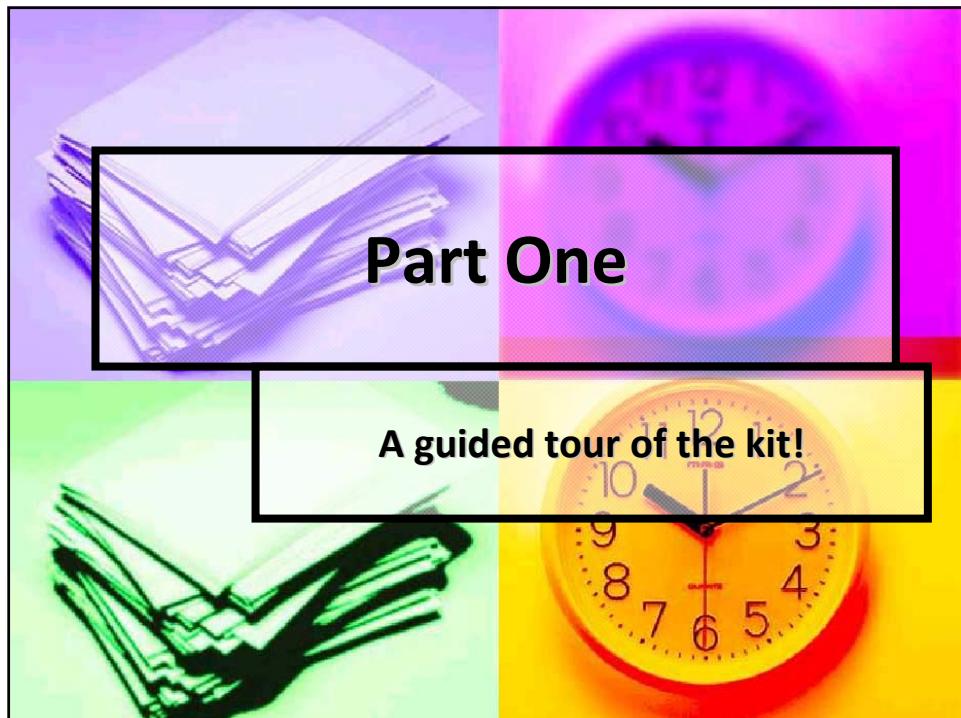
## **Welcome**

- Thank you for attending today's GOROD Workshop on **“Ethics – It’s not that hard . . . really!”**.
- Ensure you have obtained a copy of the **Melbourne Graduate School of Education: Human Research Ethics - Information Kit**.



## Today's Workshop

- Today's workshop is broken into two parts:
  - **Part One:** is a quick guided tour of the Information Kit concentrating mainly on **Section 2**, however will touch on Sections 1 & 3 to give you some context.
  - **Part Two:** is a quick run down on completing an ethics application online and the support available.



**Part One**

**A guided tour of the kit!**



## Information Kit

- The information kit covers roughly 90% of Human Ethic Research situations which arise.
- It is in NO way perfect . . . and it is constantly evolving.
- The kit is broken into three sections
  - Section 1: Background Information
  - Section 2: Themis On-line
  - Section 3: Useful Resources & External Sites
- Further copies of the information kit can be downloaded at:  
<http://www.edfac.unimelb.edu.au/research/ethics/Human%20Research%20Ethics%20-%202009%20Information%20Kit%20v1%202a.pdf>.



## Section 1 of the Information Kit

- **Section 1 of the Information Kit mainly consists of:**
  - Melbourne Graduate School of Education: Human Ethics Advisory Group [MGSE HEAG] – General Information ([revised on page 7](#))
  - Conducting research in Victorian Government & Victorian Catholic Schools
  - University Research or Related Work that does not require review by the Human Research Ethics Committee
  - Consent Form Guidelines
  - Plain Language Statement Guidelines
  - MGSE HEAG process for handling of Ethics applications using Themis Ethics Module ([revised on page 43](#))
  - Human Ethics Application Cycles and Deadlines for Submission of Human Ethics Applications ([new on page 46](#))
  - **NOTE: there is NO content on independent schools in the kit, as this varies from school to school.**



## Section 2 of the Information Kit

- **Section 2 of the Information Kit mainly consists of:**
  - University Systems Project: Student Access to Themis Research Module
  - Using the Human Ethics Workbench in Themis ([revised on page 51](#))
  - Searching for an Application in the Human Ethics Workbench ([revised on page 53](#))
  - Human Ethics 'Minimal Risk' Checklist ([new on page 59](#))
  - Creating a Human Ethics Application in Themis, in particular Minimal Risk, Standard Project, Program, Project Within a Program, Transfer, and Registration of External Ethics Clearance, all with a Sample Application Forms
  - Printing a Human Ethics application and related attachments ([revised on page 155](#))
  - Updating a Human Ethics Application via the Workbench
  - Request for Amendment of a Human Ethics application, with a Sample Application Form ([revised on page 161](#))
  - Completing a Human Ethics Annual Report



## Section 3 of the Information Kit

- **Section 3 of the Information Kit mainly consists of:**
  - Two PowerPoint Presentations
  - National Statement on Ethical Conduct in Human Research, including a summary of 'What's New'
  - University of Melbourne: Policy on the Management of Research Data and Records, with Sample MGSE Forms ([new on page 301](#))
  - Useful Websites ([revised on page 319](#))
  - Human Research Ethics Contacts and MGSE HEAG Committee ([revised on page 321](#))
  - Space for you to make your own notes on the back pages



## Human Ethics Applications

### ■ Who should complete an ethics application?

- In short, the easy answer is everyone who is doing research on **humans**!
- However, there is a list of ten exemption categories found on **page 29** of the information kit.
- For further information on 'who should complete an ethics application' see **pages 7-10** and on the MGSE HEAG website: [http://www.education.unimelb.edu.au/research/ethics/human\\_ethics.html](http://www.education.unimelb.edu.au/research/ethics/human_ethics.html).



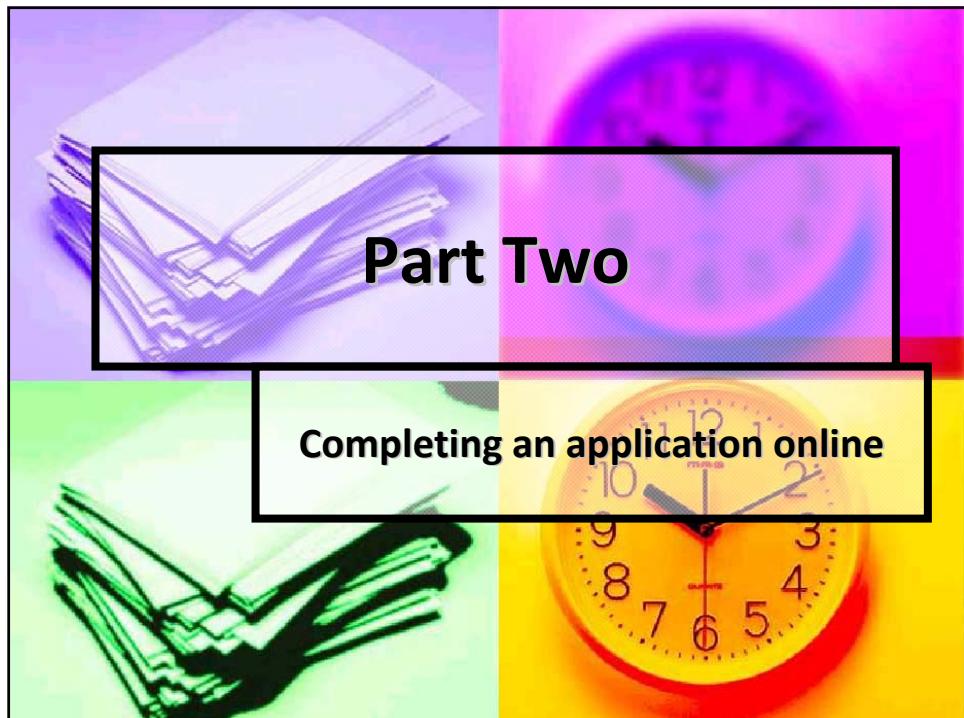
## High (Standard) Risk or Low (Minimal) Risk?

- What is 'high (standard) risk' and 'low (minimal) risk' research?
  - Generally speaking:
    - Projects involving children, persons undergoing medical treatment or otherwise likely to be seen as vulnerable will be **'high (standard) risk'**.
    - Projects involving consenting adults with non-controversial subject matter will be **'low (minimal) risk'**.
  - Good news is Themis has taken all the guess work out of determining high (standard) risk or low (minimal) risk, by distinguishing risk through multiple questions asked when you begin your application online. However, there are two exceptions:
    - First, if the application is funded external to the University; and
    - Second, if you are going overseas to collect data.
  - For further information on 'Standard and Minimal Risk', see **pages 7-10** and on the MGSE HEAG website: [http://www.education.unimelb.edu.au/research/ethics/human\\_ethics.html#WHR](http://www.education.unimelb.edu.au/research/ethics/human_ethics.html#WHR)



## Breakdown of Applications received by the MGSE HEAG

- The three most common applications received (85%) by the MGSE HEAG are:
  - Minimal Risk Human Ethics Applications (46%)
  - Standard Risk Human Ethics Applications (49%)
- All three application types are included in the kit with Sample Forms, and also gives you a rough idea what Themis may ask and what questions you need to answer on the paper copy.
- The remaining 5% of applications consists of Program Applications, Project within Program, Request for Amendment Applications and Transfer/Registration of External Projects, which are all included as well in the Information Kit, with samples.





## Student Access to Themis Research

- Student access to Themis Ethics is currently available to ALL postgraduate students.
- For information, on setting or resetting your Themis password to gain access, see **page 49** of the Information Kit.



## How can students or staff activate their Themis account?

- Students/Staff activate their Themis account via ARS (Account Registration System) and select the 'student' or 'staff' option. They will require the following information to activate their Themis account:
  - Full name
  - Student number or Staff number
  - Date of Birth (format is DD-MMM-YYYY)
  - Postcode of home residence
  - Library Barcode (for students) or Last four digits of bank account (for staff)
    - Press Log In
    - Select checkbox 'themisprod'
    - Press 'save' and you should receive a confirmation message on screen if you are successful.
- Using this information, the student logs in to the Accounts Registration System (ARS):  
<http://accounts.unimelb.edu.au/>



## Themis online

- All ethics applications are lodged through the Themis Ethics module, see **page 51** onwards in the Information Kit:

- Log in to <http://www.themis.unimelb.edu.au/> for the online application
- Click on UOM Research Service
- Click on Human Ethics Workbench



## Where can staff and students get help?

- Help documentation
  - Help documentation is available from the Themis website: [http://www.themis.unimelb.edu.au/support/help/ref\\_cards\\_research.html#humans](http://www.themis.unimelb.edu.au/support/help/ref_cards_research.html#humans)
- Themis Help Service Desk [also known as the Enterprise Applications (Themis) Service Desk]
  - **Online Incident Registration:** <http://servicedesk.unimelb.edu.au/itsc/themis/>
  - **Phone:** 8344 9500
  - **Fax:** 8344 2885
  - **Email:** [ea-help@unimelb.edu.au](mailto:ea-help@unimelb.edu.au)
  - **Operating Hours:** 9:00am to 5:00pm, Monday to Friday.
    - If the Enterprise Applications (Themis) Service Desk number is busy or you are calling outside our operating hours you are encouraged to log your issue, query or request using the Online Incident Registration, see above for website address.



## My contact details

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### HAPS HESC Secretary

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## Helpful Hints

- There are five things you can do to ensure a smoother passage of your ethics application:
  - Always submit a **signed, single sided** hardcopy and either clip or place in a plastics sleeve, do **not** staple.
  - Ensure **all** named in the ethics application have actually signed the ethics application.
  - Use the **MGSE letterhead** template provided on the MGSE HEAG website:  
<http://www.education.unimelb.edu.au/research/ethics/letterhead%20for%20ethics%20pls%20&%20consent%20forms.Doc> for **all** consent form/s and plain language statement/s.
  - **Populate the footer** at the bottom of the MGSE letterhead. Examples can be found on **pages 35 - 37 and page 41**.
  - Ensure **all revisions** are uploaded onto Themis electronically, and **must** match the hardcopy you submit or resubmit to me.



## The End . . .

- Any questions?

# National Statement on Ethical Conduct in Human Research

Developed jointly by  
National Health and Medical Research Council  
Australian Research Council  
Australian Vice-Chancellors' Committee



Australian Government

National Health and Medical Research Council  
Australian Research Council



Australian Vice-Chancellors' Committee  
*the council of Australia's university presidents*

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# THE NATIONAL STATEMENT: A USER GUIDE

This *National Statement on Ethical Conduct in Human Research* ('National Statement') is intended for use by:

- any researcher conducting research with human participants;
- any member of an ethical review body reviewing that research;
- those involved in research governance; and
- potential research participants.

This brief guide describes the structure of the document and suggests how each of these groups might use it. Note that 'review body' refers both to Human Research Ethics Committees (HRECs) and to non-HREC review bodies.

The *Preamble* sets out the historical context of the National Statement. This is followed by a brief explanation of its purpose, scope and limits. The document then has five sections, with multiple chapters in Sections 2 to 5.

- *Section 1: Values and principles of ethical conduct* sets out values and principles that apply to all human research. **It is essential that researchers and review bodies consider these values and principles and be satisfied that the research proposal addresses and reflects them.**
- *Section 2: Themes in research ethics: risk and benefit, consent* discusses the concept of risk in research and the role of participants' consent – themes in all human research – and is again **essential for all users.**

Chapter 2.1 will help **researchers** and **reviewers** to understand and describe the level of risk involved in the planned research, and how to minimise, justify

and manage that risk, and (with reference to Chapter 5.1) what level of ethical review is suitable.

Chapters 2.2 and 2.3 will help to identify the information that needs to be disclosed to participants. It will help **researchers** to draft information for participants and plan the consent process (or develop a proposal for waiver of consent). And it will help **reviewers** to assess the suitability of the proposed consent process.

All of Section 2 will help **participants** understand what information they are entitled to receive, and what their participation in research will characteristically involve.

- *Section 3: Ethical considerations specific to research methods or fields* will help **researchers** and **reviewers** to identify ethical matters specific to the research methods proposed.
- *Section 4: Ethical considerations specific to participants* will help **researchers** and **reviewers** to identify ethical matters relating to specific categories of research participants. **Participants** in these categories will also find this Section valuable.
- *Section 5: Processes of research governance and ethical review* will help **those involved in research governance** to understand their responsibilities for research ethics and ethical review and monitoring of human research, and provides criteria for their accountability. Chapter 5.2 will help **researchers** and **reviewers** to identify their responsibilities in relation to the ethical review of research.

This National Statement does not exhaust the ethical discussion of human research. Even a single research field covers a multitude of different situations about which the National Statement will not always offer specific guidance, or to which its application may be uncertain. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

# PREAMBLE

## ETHICAL BACKGROUND

All human interaction, including the interaction involved in human research, has ethical dimensions. However, ‘ethical conduct’ is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one’s fellow creatures. This National Statement on ‘ethical conduct in human research’ is therefore oriented to something more fundamental than ethical ‘do’s’ and ‘don’ts’ – namely, an ethos that should permeate the way those engaged in human research approach all that they do in their research.

Human research is research conducted with or about people, or their data or tissue. It has contributed enormously to human good. Much human research carries little risk and in Australia the vast majority of human research has been carried out in a safe and ethically responsible manner. But human research can involve significant risks and it is possible for things to go wrong. Sometimes risks are realised despite the best of intentions and care in planning and practice. Sometimes they are realised because of technical error or ethical insensitivity, neglect or disregard. On rare occasions the practice of research has even involved the deliberate and appalling violation of human beings – notoriously, the Second World War experiments in detention and concentration camps.

This range of possibilities can give rise to important and sometimes difficult ethical questions about research participation. Two considerations give further weight to those questions. First, research participants may enter into a relationship with researchers whom they may not know but need to trust. This trust adds to the ethical responsibility borne by those in whom it is placed. Secondly, many who contribute as participants in human research do so altruistically, for the common good, without

thought of recompense for their time and effort. This underscores the importance of protecting research participants.

Since earliest times, human societies have pondered the nature of ethics and its requirements and have sought illumination on ethical questions in the writings of philosophers, novelists, poets and sages, in the teaching of religions, and in everyday individual thinking. Reflection on the ethical dimensions of medical research, in particular, has a long history, reaching back to classical Greece and beyond. Practitioners of human research in many other fields have also long reflected upon the ethical questions raised by what they do. There has, however, been increased attention to ethical reflection about human research since the Second World War. The judgment of the Nuremberg military tribunal included ten principles about permissible medical experiments, since referred to as the Nuremberg Code. Discussion of these principles led the World Medical Assembly in 1964 to adopt what came to be known as the Helsinki Declaration, revised several times since then. The various international human rights instruments that have also emerged since the Second World War emphasise the importance of protecting human beings in many spheres of community life. During this period, written ethical guidelines have also been generated in many areas of research practice as an expression of professional responsibility.

But what is the justification for ethical research guidelines as extensive as this National Statement, and for its wide-reaching practical authority?

The National Statement has been extended to address many issues not discussed in the previous version, or discussed in less detail. This is in response to requests for clearer

guidance for those conducting research and those involved in its ethical review. At the same time, without compromising the protection of participants, the revised National Statement provides for greater flexibility in the practice of ethical review, depending on the type and area of research and the degree of risk involved.

Research often involves public interaction between people that serves a public good. There is, therefore, a public responsibility for seeing that these interactions are ethically acceptable to the Australian community. That responsibility is acknowledged and given effect in the wide-reaching authority of this National Statement, which sets out national standards for the ethical design, review and conduct of human research. Its content reflects the outcome of wide consultation with Australian communities who participate in, design, conduct, fund, manage and publish human research.

## Research governance

The National Statement should be seen in the broader context of overall governance of research. It not only provides guidelines for researchers, Human Research Ethics Committees (HRECs) and others conducting ethical review of research, but also emphasises institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices.

Responsibility for the ethical design, review and conduct of human research is in fact exercised at many levels, by: researchers (and where relevant their supervisors); HRECs and others conducting ethical review of research; institutions that set up the processes of ethical review, and whose employees, resources and facilities are involved in research; funding organizations; agencies that set standards; and governments. While the processes of ethical review are important in this field, individual researchers and the institutions within which they work hold primary responsibility for seeing that their research is ethically acceptable.

In addition to this National Statement, the *Australian code for the responsible conduct of research 2007*<sup>1</sup> (the 'Research Code') has an essential role in promoting good research governance. The Research Code sets down the broad principles of responsible and accountable research practice, and identifies the responsibilities of institutions and researchers in areas such as data and record management, publication of findings, authorship, conflict of interest, supervision of students and research trainees, and the handling of allegations of research misconduct.

## Authors of this National Statement

This National Statement has been jointly developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC). This joint undertaking reflects a widely shared conviction that there is a need for ethical guidelines that are genuinely applicable to all human research; and it gives expression to the shared responsibility for ethically good research described above.

The *National Health and Medical Research Council Act 1992* (NHMRC Act) establishes the NHMRC as a statutory body and sets out its functions, powers and obligations. Section 10(1) of the Act requires the Chief Executive Officer to issue human research guidelines precisely as developed by the Australian Health Ethics Committee (AHEC) and provided to the CEO by the Council. AHEC is established by the NHMRC Act as a Principal Committee of the NHMRC. All the guidelines in this National Statement that are applicable to the conduct of medical research involving humans are issued by the NHMRC in fulfilment of this statutory obligation.

---

<sup>1</sup> This is the proposed revision of the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997).

The *Australian Research Council Act 2001* (ARC Act) establishes the ARC to provide the responsible Minister with advice and recommendations about research, including which research programs should receive financial assistance. The functions of the ARC also include administering the regimes of financial assistance for research and providing for the funding of research programs.

The *Australian Vice-Chancellors' Committee* (AVCC) is the council of Australia's university vice-chancellors (or presidents). Its purpose is to advance higher education through voluntary, cooperative and coordinated action, and to serve the best interests of Australia's universities and, through them, the nation. The AVCC acts as a consultative and advisory body for all university affairs, making submissions to public inquiries of interest to the university sector, and preparing statements on major issues.

# PURPOSE, SCOPE AND LIMITS OF THIS DOCUMENT

## PURPOSE

The purpose of this National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

The National Statement is therefore designed to clarify the responsibilities of:

- institutions and researchers for the ethical design, conduct and dissemination of results of human research; and
- review bodies in the ethical review of research.

The National Statement will help them to meet their responsibilities: to identify issues of ethics that arise in the design, review and conduct of human research, to deliberate about those ethical issues, and to justify decisions about them.

## Use of this National Statement

This National Statement must be used to inform the design, ethical review and conduct of human research that is funded by, or takes place under the auspices of, any of the bodies that have developed this National Statement (NHMRC, ARC, AVCC).

In addition, the National Statement sets national standards for use by any individual, institution or organisation conducting human research. This includes human research undertaken by governments, industry, private individuals, organisations, or networks of organisations.

## What is research?

There is no generally agreed definition of research; however, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers. The British Research Assessment Exercise (RAE) definition of research is somewhat wider:

'Research'... includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.<sup>2</sup>

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<sup>2</sup> Higher Education Funding Council for England, Scottish Higher Education Funding Council, Higher Education Funding Council for Wales, & Department for Employment and Learning Northern Ireland (2005) *RAE 2008: Guidance to Panels*, p.28. At <http://www.rae.ac.uk/pubs/2005/01/rae0105.doc>, accessed 27th October 2006

To enable comparative assessment of academic activity, this definition sought to include the widest range of creative and experimental activities. Many items in the definition are uncontentious, but there may be disagreement about some – for example, ‘the invention and generation of new...images, performances, artefacts...where these lead to new or substantially improved insights’ – since this could count poetry, painting and performing arts as research.

For the purposes of this National Statement, two further questions are more important than any definition of research:

- What is *human* research?
- When and by what means does human research, or other activities such as quality assurance or improvement, or clinical audit, need ethical review? (See *When does quality assurance in health care require independent ethical review?* NHMRC 2003.)

## What is human research?

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

The term ‘participants’ is therefore used very broadly in this National Statement to include those who may not even know they are the subjects of research; for example, where the need for their consent for the use of their tissue or data has been waived by a Human Research Ethics Committee (HREC).

In addition, the conduct of human research often has an impact on the lives of others who are not participants. When this impact is reasonably foreseeable, it may raise ethical questions for researchers and for those ethically reviewing research.

## When is ethical review needed?

Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see *Section 2: Themes in research ethics: risk and benefit, consent, and Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers*). Research with more than a low level of risk (as defined in paragraph 2.1.6, page 18) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21 (page 79). Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23, page 79).

A judgement that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released.

## Ethics and law in human research

Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers and institutions. Australian common law obligations arise from the relationships between institutions, researchers and participants. Contractual arrangements may impose obligations on research funders and institutions.

This National Statement focuses on the ethical aspects of the design, review and conduct of human research. Research ethics is only part of an institution's responsibilities for research governance. Compliance with legal obligations (statutory or otherwise) forms another part, which is not within the scope of the National Statement.

Some human research is subject to specific statutory regulation, at Commonwealth and State and Territory levels. The National Statement identifies some specific Commonwealth legislation that refers to the National Statement. The National Statement does not identify State and Territory laws that may be relevant to human research, such as those relating to use of information held by state or territory authorities, use of human tissues, guardianship, and illegal and unprofessional conduct.

The responsibilities set out in this National Statement are intended to be consistent with the international human rights instruments that Australia has ratified.

It is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant.

# SECTION 1: VALUES AND PRINCIPLES OF ETHICAL CONDUCT

## INTRODUCTION

The relationship between researchers and research participants is the ground on which human research is conducted. The values set out in this section – respect for human beings, research merit and integrity, justice, and beneficence – help to shape that relationship as one of trust, mutual responsibility and ethical equality. For this reason, the National Statement speaks of research ‘participants’ rather than ‘subjects’.

While these values have a long history, they are not the only values that could inform a document of this kind. Others include altruism, contributing to societal or community goals, and respect for cultural diversity, along with the values that inform *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).

However, the values of respect, research merit and integrity, justice, and beneficence have become prominent in the ethics of human research in the past six decades, and they provide a substantial and flexible framework for principles to guide the design, review and conduct of such research. This National Statement is organised around these values, and the principles set out in paragraphs 1.1 to 1.13 give them practical expression.

Among these values, respect is central. It involves recognising that each human being has value in himself or herself, and that this value must inform all interaction between people. Such respect includes recognising the value of human autonomy – the capacity to determine one’s own life and make one’s own decisions. But respect goes further than this. It also involves providing for the protection of those with diminished or no autonomy, as

well as empowering them where possible and protecting and helping people wherever it would be wrong not to do so.

Reference to these values throughout the National Statement serves as a constant reminder that, at all stages, human research requires ethical reflection that is informed by them. The order in which they are considered reflects the order in which ethical considerations commonly arise in human research.

Research merit and integrity are discussed first. Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable.

At a profound level, justice involves a regard for the human sameness that each person shares with every other. Human beings have a deep need to be treated in accordance with such justice, which includes distributive justice and procedural justice. In the research context, distributive justice will be expressed in the fair distribution of the benefits and burdens of research, and procedural justice in ‘fair treatment’ in the recruitment of participants and the review of research. While benefit to humankind is an important result of research, it also matters that benefits of research are achieved through just means, are distributed fairly, and involve no unjust burdens.

Researchers exercise beneficence in several ways: in assessing and taking account of the risks of harm and the potential benefits of research to participants and to the wider community; in being sensitive to the welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of their work.

Respect for human beings is the common thread through all the discussions of ethical values. Turning to it as the final value is a reminder that it draws together all of the ethical deliberation that has preceded it.

The design, review and conduct of research must reflect each of these values.

## GUIDELINES

### Research merit and integrity

#### 1.1 Research that has merit is:

- (a) justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;
- (b) designed or developed using methods appropriate for achieving the aims of the proposal;
- (c) based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation;
- (d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;
- (e) conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research; and
- (f) conducted using facilities and resources appropriate for the research.

1.2 Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.

1.3 Research that is conducted with integrity is carried out by researchers with a commitment to:

- (a) searching for knowledge and understanding;
- (b) following recognised principles of research conduct;
- (c) conducting research honestly; and
- (d) disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

### Justice

#### 1.4 In research that is just:

- (a) taking into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair, and is accurately described in the results of the research;
- (b) the process of recruiting participants is fair;
- (c) there is no unfair burden of participation in research on particular groups;
- (d) there is fair distribution of the benefits of participation in research;
- (e) there is no exploitation of participants in the conduct of research; and
- (f) there is fair access to the benefits of research.

1.5 Research outcomes should be made accessible to research participants in a way that is timely and clear.

## Beneficence

- 1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.
- 1.7 Researchers are responsible for:
- (a) designing the research to minimise the risks of harm or discomfort to participants;
  - (b) clarifying for participants the potential benefits and risks of the research; and
  - (c) the welfare of the participants in the research context.
- 1.8 Where there are no likely benefits to participants, the risk to participants should be lower than would be ethically acceptable where there are such likely benefits.
- 1.9 Where the risks to participants are no longer justified by the potential benefits of the research, the research must be suspended to allow time to consider whether it should be discontinued or at least modified. This decision may require consultation between researchers, participants, the relevant ethical review body, and the institution. The review body must be notified promptly of such suspension, and of any decisions following it (see paragraphs 5.5.6 to 5.5.9, page 91–92).

## Respect

- 1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

- 1.11 Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be fulfilled.
- 1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.
- 1.13 Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

## Application of these values and principles

Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. In such circumstances, it is important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making. The National Statement is intended to contribute to the development of such awareness.

This National Statement does not exhaust the ethical discussion of human research. There are, for example, many other specialised ethical guidelines and codes of practice for specific areas of research. Where these are consistent with this National Statement, they should be used to supplement it when this is necessary for the ethical review of a research proposal.

These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.

# SECTION 2: THEMES IN RESEARCH ETHICS: RISK AND BENEFIT, CONSENT

Two themes must always be considered in human research: the risks and benefits of research, and participants' consent. For this reason, the two themes are brought together in

this section, before discussion in the following sections of ethical considerations specific to different research methods and categories of participants.

## CHAPTER 2.1: RISK AND BENEFIT

### INTRODUCTION

The conduct of research in Australia is characterised by high ethical and scientific standards, and the dangers to participants have been few. The continued promotion of ethically good human research – the purpose of this National Statement – will help to maintain these standards.

Application of the values in Section 1, in particular the value of beneficence, requires that risks of harm to research participants, and to others, be assessed. Research will be ethically acceptable only if its potential benefits justify those risks.

While this chapter provides guidance on the assessment of risk, such assessment inevitably involves the exercise of judgment.

#### What is risk?

A risk is a potential for harm, discomfort or inconvenience (discussed below). It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur; and
- the severity of the harm, including its consequences.

#### Assessment of risk

Assessment of risks involves:

- identifying any risks;
- gauging their probability and severity;
- assessing the extent to which they can be minimised;
- determining whether they are justified by the potential benefits of the research; and
- determining how they can be managed.

Assessment of risks engages:

- researchers, who need to identify, gauge, minimise and manage any risks involved in their project;
- institutions, in deciding the appropriate level of ethical review for research projects;
- Human Ethics Research Committees (HRECs) and other ethical review bodies (see paragraph 5.1.7, page 78), in reviewing research proposals and making judgements on whether risks are justified by potential benefits; and
- participants' perceptions of risks and benefits. These perceptions are a factor to be considered by review bodies in deciding whether the risks are justified by the benefits.

## Harm, discomfort and inconvenience

Research may lead to harms, discomforts and/or inconveniences for participants and/or others.

No list of harms can be exhaustive, but one helpful classification identifies the following kinds of potential harms in research<sup>3</sup>:

- physical harms: including injury, illness, pain;
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- economic harms: including the imposition of direct or indirect costs on participants;
- legal harms: including discovery and prosecution of criminal conduct.

Less serious than harm is discomfort, which can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.

Less serious again is inconvenience. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

Examples of risks to non-participants include the risk of distress for a participant's family member identified with a serious genetic disorder, the possible effects of a biography on family or friends, or infectious disease risks to the community. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.

Harms that may arise from research misconduct or fraud, and harms to members of research teams from other forms of misconduct (for example, harassment or bullying) are addressed primarily in the *Australian code for the responsible conduct of research*. These forms of misconduct may, of course, also lead to potential harms to participants.

## Low risk and negligible risk research

The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

Requirements for the ethical review of low risk research and negligible risk research are set out in paragraphs 5.1.18 to 5.1.23, page 79.

## Gauging risk

Gauging risk involves taking into account:

- the kinds of harm, discomfort or inconvenience that may occur;
- the likelihood of these occurring; and
- the severity of any harm that may occur.

These judgements should be based on the available evidence. The evidence may be quantitative or qualitative. In either case, the process needs to be transparent and defensible.

<sup>3</sup> Adapted from National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, Bethesda, 2001 pp.71-72

For those gauging the severity of the harm, the choices, experience, perceptions, values and vulnerabilities of different populations of participants will be relevant.

### Minimising risk

In designing a research project, researchers have an obligation to minimise the risks to participants. Minimising risk involves an assessment of the research aims, their importance, and the methods by which they can be achieved.

Where a researcher or review body judges that the level of risk in a research proposal is not justified by the benefits, either the research aims or the methods by which they are to be achieved, or both, will need to be reconsidered if the research is to proceed.

### Do the benefits justify the risks?

Research is ethically acceptable only when its potential benefits justify any risks involved in the research.

Benefits of research may include, for example, gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions.

Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to well people. Those ethically reviewing research should take such willingness into account in deciding whether the potential benefits of the research justify the risks involved.

For ethical review bodies, there can be a profound tension between the obligation on the one hand to give maximum scope to participants' freedom to accept risk, and on the other to see that research is conducted in a way that is beneficent and minimises harm.

### Managing risks

When risks have been identified, gauged and minimised, and the research has been approved, the risks must then be managed. This requires that:

- researchers include, in their research design, mechanisms to deal adequately with any harms that occur; and
- a monitoring process is in place and carried out (see *Chapter 5.5: Monitoring approved research*, page 91–92).

The greater the risk to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

### GUIDELINES

- 2.1.1 Institutions that choose to establish levels of ethical review other than by HREC for research that carries low or negligible risk (see paragraphs 5.1.18 to 5.1.23, page 79) should use this chapter (i.e. Chapter 2.1) to inform their identification of the level of risk.
- 2.1.2 Risks to research participants are ethically acceptable only if they are justified by the potential benefits of the research.
- 2.1.3 Steps to arriving at a judgement on the ethical acceptability of risks should include:
  - (a) identifying the risks, if any;
  - (b) assessing the likelihood and severity of the risks;
  - (c) identifying whom (participants and/or others) the risks may affect;
  - (d) establishing the means for minimising the risks;
  - (e) identifying the potential benefits; and
  - (f) identifying to whom benefits are likely to accrue.

- 2.1.4 In determining the existence, likelihood and severity of risks, researchers and those reviewing the research should base their assessments on the available evidence, whether qualitative or quantitative. They should consider whether to seek advice from others who have experience with the same methodology, population and research domain.
- 2.1.5 In considering whether the potential benefits of the research justify the risks involved, those reviewing research should take into account any willingness by participant populations to assume greater risks because of the potential benefits to them, their families, or groups to which they belong.
- 2.1.6 Research is ‘low risk’ where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
- 2.1.7 Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.
- 2.1.8 The greater the risks to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

# CHAPTER 2.2: GENERAL REQUIREMENTS FOR CONSENT

## INTRODUCTION

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

What is needed to satisfy these conditions depends on the nature of the project, and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted.

Variations of these conditions may be ethically justified for some research. Respect for human beings must, however, always be shown in any alternative arrangements for deciding whether potential participants are to enter the research.

It should be noted that a person's consent to participate in research may not be sufficient to justify his or her participation.

This chapter provides guidelines on the requirement for consent. *Chapter 2.3: Qualifying or waiving conditions for consent* then discusses and provides guidelines on conditions under which the requirement may be qualified or waived.

## GUIDELINES

2.2.1 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate

understanding of both the proposed research and the implications of participation in it. For qualifications of this principle, see *Chapter 2.3: Qualifying or waiving conditions for consent*, page 23.

- 2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.
- 2.2.3 This information must be presented in ways suitable to each participant (see paragraph 5.2.16, page 84).
- 2.2.4 The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.
- 2.2.5 Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:
  - (a) the nature, complexity and level of risk of the research; and
  - (b) the participant's personal and cultural circumstances.
- 2.2.6 Information on the following matters should also be communicated to participants. Except where the information in specific sub-paragraphs below is also deemed necessary for a person's voluntary decision to participate,

it should be kept distinct from the information described in paragraphs 2.2.1 and 2.2.2:

- (a) any alternatives to participation;
  - (b) how the research will be monitored;
  - (c) provision of services to participants adversely affected by the research;
  - (d) contact details of a person to receive complaints;
  - (e) contact details of the researchers;
  - (f) how privacy and confidentiality will be protected;
  - (g) the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;
  - (h) the amounts and sources of funding for the research;
  - (i) financial or other relevant declarations of interests of researchers, sponsors or institutions;
  - (j) any payments to participants;
  - (k) the likelihood and form of dissemination of the research results, including publication;
  - (l) any expected benefits to the wider community;
  - (m) any other relevant information, including research-specific information required under other chapters of this National Statement.
- 2.2.7 Whether or not participants will be identified, research should be designed so that each participant's voluntary decision to participate will be clearly established.

### Renegotiating consent

- 2.2.8 In some research, consent may need to be renegotiated or confirmed from time to time, especially where projects are complex or long-running, or participants are vulnerable. Research participants

should be told if there are changes to the terms to which they originally agreed, and given the opportunity to continue their participation or withdraw (see paragraphs 5.2.16 and 5.2.17, page 84).

### Coercion and pressure

- 2.2.9 No person should be subject to coercion or pressure in deciding whether to participate. Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes. Here as always, a person should be included as a participant only if his or her consent is voluntary.

### Reimbursing participants

- 2.2.10 It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.

- 2.2.11 Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted.

### Where others need to be involved in participation decisions

- 2.2.12 Where a potential participant lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the person's best interests. Researchers should bear

in mind that the capacity to consent may fluctuate, and even without that capacity people may have some understanding of the research and the benefits and burdens of their participation. For implications of these factors, see *Chapter 4.2: Children and young people*, *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*, and *Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness*.

2.2.13 Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research.

### Consent to future use of data and tissue in research

2.2.14 Consent may be:

- (a) ‘specific’: limited to the specific project under consideration;
- (b) ‘extended’: given for the use of data or tissue in future research projects that are:
  - (i) an extension of, or closely related to, the original project; or
  - (ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);
- (c) ‘unspecified’: given for the use of data or tissue in any future research.

The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent (see paragraph 2.2.2).

- 2.2.15 Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank (see paragraph 3.2.9, page 31).
- 2.2.16 When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.
- 2.2.17 Subsequent reliance, in a research proposal, on existing unspecified consent should describe the terms of that unspecified consent.
- 2.2.18 Data or tissue additional to those covered by the original extended or unspecified consent will sometimes be needed for research. Consent for access to such additional data or tissue must be sought from potential participants unless the need for this consent is waived by an ethical review body.

### Declining to consent and withdrawing consent

- 2.2.19 People who elect not to participate in a research project need not give any reason for their decision. Researchers should do what they can to see that people who decline to participate will suffer no disadvantage as a result of their decision.
- 2.2.20 Participants are entitled to withdraw from the research at any stage. Before consenting to involvement in the research, participants should be informed about any consequences of such withdrawal.

# CHAPTER 2.3: QUALIFYING OR WAIVING CONDITIONS FOR CONSENT

## INTRODUCTION

Consent to participate in research must be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

The requirement for consent may sometimes be justifiably waived. In this case research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

'Limited disclosure' to participants of the aims and/or methods of research may also sometimes be justifiable. This is because in some human research (for example, in the study of behaviour), the aims of the research cannot be achieved if those aims and/or the research method are fully disclosed to participants.

Research involving limited disclosure covers a spectrum, from simply not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants. Examples along the spectrum include: observation in public spaces of everyday behaviour; covert observation, for example of the hand-washing behaviour of hospital employees; undisclosed role-playing by a researcher to investigate participants' responses; telling participants the aim of the research is one thing when it is in fact quite different. At the beginning of that spectrum (for instance, observation in public spaces), limited disclosure research shades into research for which waiver of consent might be sought.

## GUIDELINES

### Limited disclosure

2.3.1 Where limited disclosure does not involve active concealment or planned deception, ethical review bodies may approve research provided researchers can demonstrate that:

- (a) there are no suitable alternatives involving fuller disclosure by which the aims of the research can be achieved;
- (b) the potential benefits of the research are sufficient to justify both the limited disclosure to participants and any risk to the community's trust in research and researchers;
- (c) the research involves no more than low risk to participants (see paragraph 2.1.6, page 18), and the limited disclosure is unlikely to affect participants adversely;
- (d) the precise extent of the limited disclosure is defined;
- (e) whenever possible and appropriate, after their participation has ended, participants will be:
  - (i) provided with information about the aims of the research and an explanation of why the omission or alteration was necessary; and
  - (ii) offered the opportunity to withdraw any data or tissue provided by them.

2.3.2 Where limited disclosure involves active concealment or explicit deception, and the research does not aim to expose illegal activity, researchers should in addition demonstrate that:

- (a) participants will not be exposed to an increased risk of harm as a result of the concealment or deception;
- (b) a full explanation, both of the real aims and/or methods of the research, and also of why the concealment or deception was necessary, will subsequently be made available to participants; and

- (c) there is no known or likely reason for thinking that participants would not have consented if they had been fully aware of what the research involved.
- 2.3.3 Where research involving limited disclosure aims to expose illegal activity (see paragraph 4.6.1, page 67), the adverse effects on those whose illegal activity is exposed must be justified by the value of the exposure.
- 2.3.4 Only a Human Ethics Research Committee (HREC) can review and approve research that:
  - (a) involves active concealment or planned deception; or
  - (b) aims to expose illegal activity.

## Waiver

- 2.3.5 Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.
- 2.3.6 Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:
  - (a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants;
  - (b) the benefits from the research justify any risks of harm associated with not seeking consent;
  - (c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
  - (d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;
  - (e) there is sufficient protection of their privacy;
  - (f) there is an adequate plan to protect the confidentiality of data;
  - (g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, *via* a disease-specific website or regional news media);
  - (h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;
  - (i) the waiver is not prohibited by State, federal, or international law.
- 2.3.7 Before deciding to waive the requirement for consent in the case of research aiming to expose illegal activity, an HREC must be satisfied that:
  - (a) the value of exposing the illegal activity justifies the adverse effects on the people exposed (see paragraph 4.6.1, page 67);
  - (b) there is sufficient protection of their privacy;
  - (c) there is sufficient protection of the confidentiality of data; and
  - (d) the waiver is not otherwise prohibited by State, federal, or international law.
- 2.3.8 Given the importance of maintaining public confidence in the research process, it is the responsibility of each institution to make publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived under paragraphs 2.3.6 and 2.3.7. Waiver decisions under paragraph 2.3.7 should not be made publicly accessible until the research has been completed.

# SECTION 3: ETHICAL CONSIDERATIONS SPECIFIC TO RESEARCH METHODS OR FIELDS

This section discusses various research methods and fields. Some chapters are a result of the further expansion of this revised National Statement beyond health and medical research. The focus is on general principles – the section is not intended to be exhaustive. It reflects the interdisciplinary nature of many types of research and the use, in some research projects, of a number of different research methods.

Human research may be conducted only with ethical approval. Section 5 describes the processes that institutions may use to provide that approval. Those processes include ethical review by Human Research Ethics Committees (HRECs) or other ethical review bodies, according to the risks of the research (see paragraphs 5.1.6 to 5.1.8, page 78).

Ethical review by an HREC is required for any research that involves more than low risk (paragraph 5.1.6, page 78). It is also required for

research discussed in *Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations*, *Chapter 3.5: Human genetics*, and *Chapter 3.6: Human stem cells*, as well as for research discussed in several chapters of Section 4.

As stated at the end of Section 1, this National Statement does not exhaust the ethical discussion of human research. Even a single research field covers a multitude of different situations about which the National Statement will not always offer specific guidance, or to which its application may be uncertain. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

## CHAPTER 3.1: QUALITATIVE METHODS

### INTRODUCTION

Qualitative research involves disciplined inquiry that examines people's lives, experiences and behaviours, and the stories and meanings individuals ascribe to them.<sup>4</sup> It can also investigate organisational functioning, relationships between individuals and groups, and social environments.

This approach to research can involve the studied use and collection of a variety of empirical materials such as case studies, personal experience, life stories, interviews, observations, and cultural texts. It may bring new insights into the experiences of individuals,

groups or communities, or into issues such as environmental change, public policies and planning. Qualitative research may also have quantitative elements or aspects.

Qualitative research contributes to the development of new knowledge by:

- enabling researchers to gain a better understanding of complex concepts or social processes;
- investigating how communities and individuals interpret and make sense of their experiences;

4. Denzin NK & Lincoln YS (eds) 2000 Handbook of Qualitative Research, Sage: California

- eliciting contextual data in order to improve the validity of quantitative tools such as surveys.

### Commonly used approaches to data collection in qualitative research

Data in qualitative research can be collected using a range of approaches. The following are some common examples.

- Interviews** involve researchers talking to one or more participants, where the categories of response are focused but not necessarily pre-determined. Interviews are usually recorded by audio- or video-tape, or notes. These records are research data in themselves, but also may be transcribed. Interviews are usually conducted in locations mutually acceptable to participants and interviewers.

Interviews can take many forms, including:

- > *structured interviews*, which follow a set list of questions;
- > *semi-structured interviews*, which use an interview guide listing a set of issues to be explored;
- > *unstructured interviews*, which involve spontaneous generation of questions in the natural flow of interaction, and where the interview is driven by the interviewee rather than the interviewer.

The reason for choosing an ‘informant’ for interview may vary. For example:

- > *Key informant interviews* are conducted with individuals or groups with specific knowledge or expertise about the issue being investigated; for example, interviews with political leaders about historical events in which they played important roles.
- > *Sample informant interviews* are conducted with people whose experience or expertise is taken

as representative of a broader group; for example, interviews with ordinary people about their experiences during a time of social turmoil or difficulty, or interviews with employees of a particular firm.

- **Life story or oral history** can involve structured, semi-structured or unstructured interviews. This is a form of research commonly undertaken in the humanities.
- **Focus groups** of participants discuss a set of research questions or topics. This may entail the researcher acting as a moderator for the discussion.
- **Observation** involves the researcher observing participant/s in their own environment, or in the environment being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment.
- **Archival research** refers to materials that are usually but not necessarily deposited in official or private libraries or archives.
- **On-line research** includes conducting on-line real-time group discussions using web-based chat-room technology (also known as E-groups) through the use of electronic bulletin boards and moderated email groups. On-line recruitment of participants provides the opportunity for extensive global participation in research. Data collection and dissemination can also be utilised on-line.
- **Action research** is often community- or organisation-based and is carried out in the field. This approach involves testing ideas in practice as a means of improving social, economic or environmental conditions and increasing knowledge. Action research proceeds in a spiral of steps consisting of planning, action, and evaluation. It provides a basis for further planning of critically informed action.

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 3.1.1 A range of relationships between participants and researchers may develop as a result of the duration and nature of the interaction. Where such relationships threaten to compromise the research role, researchers must consider whether to modify those relationships, or to modify or even discontinue the research.
- 3.1.2 Where a researcher has professional skills (for example, counselling) that become relevant to the relationship with a participant, the researcher needs to decide, when continuing the research, whether:
- it is ethically acceptable to exercise those skills; or
  - to refer that participant to another professional.
- 3.1.3 Researchers have a duty to inform participants whenever they are acting in a non-research professional role.
- 3.1.4 Qualitative research emphasises the significance of particular contexts and settings. It is not necessary to be able to generalise the results of qualitative research. Even so, qualitative research should aim to provide a sufficiently detailed account and/or analysis to enable others to determine whether there are other circumstances to which the findings may be applicable.
- 3.1.5 If a sampling strategy is used, the most common type is purposive sampling, which aims at the selection of information-rich cases relevant to the research question. While random and representative sampling are not precluded in qualitative studies, many sampling frames are grounded in the specific aims of the research question.
- 3.1.6 The rigour of a qualitative study should not be judged on sample size. When sampling is appropriate, the objectives and theoretical basis of the research should determine the size of the sample and the sampling strategy. For example, some qualitative methods use a principle of 'saturation', where sampling occurs until no new information is being obtained. This is only one of several criteria for assessing sample size.
- 3.1.7 Research proposals that include sampling should clearly describe the recruitment strategy and criteria for selecting participants.
- 3.1.8 The rigour of qualitative research should be assessed primarily by criteria of quality and credibility of data collection and analysis, and not by matters of validity and reliability as defined in research designs that employ quantitative methods.

### Justice

- 3.1.9 The criteria for inclusion and exclusion of participants in qualitative research are often complex. For this reason, researchers should state these criteria clearly and be able to justify them (*see also* paragraphs 3.1.14 to 3.1.16).

### Beneficence

- 3.1.10 Participants are often easily identifiable (for example, as members of small communities or groups, or as key informants), and the information they provide may be sensitive. For these reasons, care should be taken that participants are not identifiable by the information they provide, unless they have agreed to be identified. Special care

- should be taken to protect the identity of participants when disseminating information and storing material.
- 3.1.11 Where possible, participants should be informed about any potential to be identified in the results of research even if identifiers, such as name and address, are removed.
- 3.1.12 Qualitative research that explores sensitive topics in depth may involve emotional and other risks to both participant and researcher. There should be clear protocols for dealing with distress that might be experienced by participants.
- 3.1.13 Predicting what topics are likely to lead to distress will not always be easy. Researchers should have sufficient training to help them in making such predictions.
- 3.1.14 Qualitative research may involve methods of data collection that require the development of personal relationships with participants. Researchers should reflect on the impact that they may have on the participants and vice versa, and as far as possible should describe in the research proposal any anticipated impact of this nature.
- 3.1.17 In some circumstances, consent may be implied by participation, for example the return of a survey, or the answering of a verbal question (*see also* paragraph 2.2.5, page 19).

## Respect

- 3.1.15 Researchers should consider whether respect for the participants requires that the accuracy or completeness of each interview transcript should be verified by the relevant participant before analysis is complete.
- 3.1.16 The method of providing consent in qualitative research depends on various factors, including the type of research, its level of sensitivity, its cultural context, and the potential vulnerability of the participants. In some contexts, the protection of vulnerable participants may favour a formal, written process of consent; in other contexts, an oral process.

# CHAPTER 3.2: DATABANKS

## INTRODUCTION

This chapter covers a wide range of data types and methodologies. Given that the nature of data, data collection, research methodologies and data usage may change over time, the chapter presents principles rather than prescriptions.

Types of research that commonly make use of databanks include epidemiology, pathology, genetics and social sciences.

The term ‘databanks’, as used in this National Statement, includes databases.

### What are data?

Data are pieces of information, for example:

- what people say in interviews, focus groups, questionnaires, personal histories and biographies;
- analysis of existing information (clinical, social, observational or other);
- information derived from human tissue such as blood, bone, muscle and urine.

### Data identifiability

Data may be collected, stored or disclosed in three mutually exclusive forms:

- **individually identifiable data**, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual’s name, image, date of birth or address;
- **re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets;
- **non-identifiable data**, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-

identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person’s identity remains unknown.

This National Statement avoids the term ‘de-identified data’, as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual (‘non-identifiable’), it is also used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. When the term ‘de-identified data’ is used, researchers and those reviewing research need to establish precisely which of these possible meanings is intended.

### Tissue and data

With advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples should always be regarded as, in principle, re-identifiable.

The increased ability to link data has greatly enhanced the contribution that collections of data can make to research, as it enables researchers to match individuals in different data sets without being able to identify the person. For example, in epidemiological research (concerned with the study of populations), information about individuals and groups may be collected so that features of groups of people can be investigated. These data may or may not have originally been obtained for research purposes.

### Banking

While most data are collected, aggregated and stored for a single purpose or activity. Permission may sometimes be sought from participants to ‘bank’ their data for possible use in future research projects.

'Banked' data may be deposited in a warehouse, similar to an archive or library, and aggregated over time. The Australian Social Science Data Archive, for example, collects computer-readable data on social, political and economic affairs and makes them available for further analysis. Archived data can usually be made available for secondary analysis, unless access is constrained by restrictions imposed by the depositor/s.

## Use of the National Statement's values and principles

The values and principles of this National Statement apply to data collection by researchers, and by others whom they authorise to collect data or to whom they outsource the collection.

These ethical principles for the use of databanks should be applied in the guidelines and procedures established by institutions for the setting up of data collections.

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 3.2.1 When planning a databank, researchers should clearly describe how their research data will be collected, stored, used and disclosed, and outline how that process conforms to this National Statement, particularly the requirements for consent set out in paragraphs 2.2.14 to 2.2.18, page 21.
- 3.2.2 To promote access to the benefits of research, such data should be collected, stored and accessible in such a way that they can be used in future research projects.

### Data usage

- 3.2.3 Researchers' use of data from databanks must comply with conditions specified by the providers of the data; in particular, any conditions on the identifiability of the data (see paragraphs 2.2.14 to 2.2.18, page 21).
- 3.2.4 Where research involves linkage of data sets, approval may be given to the use of identifiable data to ensure that the linkage is accurate, even if consent has not been given for the use of identifiable data in research. Once linkage has been completed, identifiers should be removed from the data to be used in the research unless consent has been given for its identifiable use.
- 3.2.5 It is the duty of the custodian to ensure that the data are used responsibly and respectfully, and that the privacy of participants is safeguarded.
- 3.2.6 Whenever research using re-identifiable data reveals information that bears on the wellbeing of participants, researchers have an obligation to consider how to make that information available to the participants. Where individual notification is warranted, the custodian of the data will need to take all reasonable steps to re-identify those data.
- 3.2.7 In most situations, the custodian of data will be the individual researcher or agency who collected the information, or an intermediary such as a data warehouse that manages data coming from a number of sources. In some cases, an independent custodian may be necessary. For example, when coded data are stored in a databank, a custodian independent of both the data collectors and the researchers may be appointed, to maintain the data in coded form while enabling individual participants to access their own identified results or data.

3.2.8 Some uses of data in a databank may be detrimental to people to whom the data relate. Researchers and/or custodians should consider denying or restricting access to some or all of the data for those uses.

## Consent

3.2.9 When collecting data for deposit in a databank, researchers should provide clear and comprehensive information about:

- (a) the form in which the data will be stored (identifiable, re-identifiable, non-identifiable);
- (b) the purposes for which the data will be used and/or disclosed; and
- (c) whether they will seek:
  - (i) specific, extended or unspecified consent for future research (see paragraphs 2.2.14 to 2.2.16, page 21); or
  - (ii) permission from a review body to waive the need for consent (see paragraphs 2.3.5 and 2.3.6, page 24).

3.2.10 Researchers should recognise that data stored in an identifiable form cannot be used in research that is exempt from ethical review.

3.2.11 Any restrictions on the use of participants' data should be recorded and the record kept with the collected data so that it is always accessible to researchers who want to access those data for research.

3.2.12 Researchers and custodians of the databank should observe any confidentiality agreement about stored data with the participant, and custodians should take every precaution to prevent the data becoming available for uses to which participants did not consent.

# CHAPTER 3.3: INTERVENTIONS AND THERAPIES, INCLUDING CLINICAL AND NON-CLINICAL TRIALS, AND INNOVATIONS

## INTRODUCTION

### Clinical research

Clinical research increasingly involves a range of different health professionals studying a wide range of matters, including disease prevention and causation, diagnostic methods, treatments, and effects of and response to illness. Such research can occur in a number of settings, including public and private hospitals and clinics, other institutions or organisations, community settings, and general or specialist medical practices.

This chapter focuses especially on randomised clinical trials, even though clinical trials are not always randomised. Further, as noted below, randomisation may be used in other areas of human research (eg education research) and therefore some of the ethical issues outlined will be relevant to such research.

At times it may be difficult to distinguish clinical and related research from quality improvement and clinical audit. In such situations, guidance is available from the NHMRC publication *When does quality assurance need review by a Human Research Ethics Committee?* (NHMRC 2003).

### Innovations in clinical practice

Innovations in clinical practice and complementary medicine include new diagnostic or therapeutic methods that aims to improve health outcomes but have not yet been fully assessed for safety and/or efficacy. The spectrum of innovations may range widely from minor variations or extensions of existing methods, to new indications, through to completely novel technologies. Where a proposed intervention is innovative and/or experimental, this should always be made clear to those who might be subject to it.

Whether a change in an individual's investigation or treatment is simply an innovation or actually constitutes clinical research is generally a matter for the responsible clinician's judgement, guided by institutional policies. Systematic evaluation of an innovation is research and requires ethical review.

### Clinical and other trials

A clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.

Clinical trials of new therapeutic substances are typically categorised into Phase I, II , III or IV trials. The following definitions, adapted from the Therapeutic Goods Administration (TGA), describe these phases in trials of medications:

- Phase I studies involve the first administration of the medicine to humans. Medicines are usually given to small numbers of healthy volunteers, but sometimes to people affected by the disease the medicine is intended to treat. The purpose may be to determine the medicine's safety, pharmacokinetics, pharmacological activity, side effects, preferred routes of administration, or appropriate doses (for later studies). The studies are usually undertaken in centres equipped for specialised monitoring and a high degree of surveillance.

- Phase II studies are typically the first trials of the medicine in people with the health condition for which the medicine is intended. The principal aim is to determine efficacy and safety and establish an appropriate dosing regimen. These studies are undertaken in a small number of closely supervised patients and conducted by researchers regarded as specialists in the health condition and its treatment.
- Phase III studies are undertaken if the Phase II studies indicate the medicine has potential benefits that outweigh any hazards. The studies involve greater numbers of patients with the health condition under study, and aim to determine whether the medicine confers clinical benefit in that health condition and whether the incidence and nature of adverse effects are acceptable.
- Phase IV studies are those undertaken after the medicine has been approved for marketing for the treatment of a particular disease or for a particular indication. They may include studies to compare the medicine with a wider range of therapies, and may also further investigate the use of the medicine in the normal clinical setting of the disease (which may differ markedly from the conditions under which pre-marketing trials were conducted). Such studies also gather more comprehensive safety data, adding to the information known from the pre-marketing studies.

In pharmaceutical and medical device trials there are established codes of good clinical research practice that define clearly what is meant by a clinical trial for those purposes (see the *Australian code for the responsible conduct of research*). This chapter's main application is to biomedical clinical trials, but it also applies to any other interventions claiming therapeutic benefit. Trials involving experimentation with therapeutic goods, whether drugs or devices, that are not yet registered, listed or entered on the Australian Register of Therapeutic Goods (ARTG) are subject to regulation by the TGA.

## Application of randomised trial methods to other areas of human research

Research methods intended to avoid or reduce bias include randomisation and 'blinding' participants and researchers to the identity of agents being compared. These research methods were first applied to the study of new therapies, and are now used in various other fields including, for example, psychology and education. Researchers who propose to use such methods should be aware of the ethical issues that may arise in the design and conduct of such research. In particular, paragraphs 3.3.3 and 3.3.6 will apply in all situations, while other paragraphs may be relevant depending on the nature of the research and the relationship between the researcher and potential participants.

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78).**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 3.3.1 Health care and medical institutions should establish standards to determine when an innovative intervention requires systematic investigation to determine its safety and efficacy.
- 3.3.2 When such systematic investigation is required, it should be treated as clinical research needing formal consideration by an HREC.

3.3.3 Researchers should show that:

- (a) the research is directed to answering a specific question or questions;
- (b) there is a scientifically valid hypothesis being tested that offers a realistic possibility that the interventions being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burdens, costs and risks;
- (c) the size and profile of the sample to be recruited is adequate to answer the research question; and
- (d) the research meets the relevant requirements of the *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95), *ISO 14155 Clinical Investigation of Medical Devices*, and the TGA.

3.3.4 Researchers must inform the HREC of:

- (a) any business, financial or other similar association between a researcher and the supplier of a drug or surgical or other device to be used in the trial;
- (b) any other possible conflicts of interest; and
- (c) any restrictions on publication.

3.3.5 In any clinical research, especially clinical trials, an HREC should be satisfied that:

- (a) funding is sufficient to conduct and complete the trial as designed;
- (b) any payment in money or kind, whether to institutions, researchers or participants, will not adversely influence the design, conduct, findings or publication of the research; and
- (c) the facilities, expertise and experience available are sufficient for the trial to be conducted safely.

## Justice

3.3.6 The research methodology should provide a rationale for the selection of participants and a fair method of recruitment (see paragraph 1.4, page 12).

## Risks

3.3.7 In research without likely benefit to participants, any known risk to participants should be lower than would be ethically acceptable where there are such likely benefits. In 'first-time-in-humans' research projects, risks are uncertain, and recruitment into the study should therefore be gradual and monitored with special care.

3.3.8 In clinical research, where patient care is combined with intent to contribute to knowledge, any risks of participation should be justified by potential benefits to which the participants attach significance.

3.3.9 The prospect of benefit from research participation should not be exaggerated, either to justify to an HREC a higher risk than that involved in the participant's current treatment or to persuade a participant to accept that higher risk.

3.3.10 The use of a placebo alone or the incorporation of a non-treatment control group:

- (a) is ethically unacceptable in a controlled clinical trial where:
  - (i) other available treatment has already been clearly shown to be effective; and
  - (ii) there is known risk of significant harm in the absence of treatment;
- (b) may be considered if there is genuine uncertainty as to whether currently available treatments have a net clinical benefit.

## Records

- 3.3.11 Data should be accurately recorded in a durable and appropriately referenced form that complies with established legislation, policies and guidelines. Where a trial is using materials of biological origin, or other materials where there is limited experience of their long-term use, records should be preserved for long enough to enable participants to be traced in case evidence emerges of late or long-term effects (see *Australian code for the responsible conduct of research*, paragraph 3.1.1).
- 3.3.12 Before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible register.

## Respect

- 3.3.13 Due to the potential complexity of information to be provided to participants, the requirements of paragraphs 2.2.2 to 2.2.6 (page 19) should be carefully considered and followed. Written information should not be unduly long or complex. Adequate time should be allowed for prospective participants to read and take in what is proposed, and they should be encouraged to ask questions.
- 3.3.14 Particular care should be taken in clinical trials to make it clear to participants whether there is intended to be any therapeutic benefit to them from the trial.

- 3.3.15 It should always be made clear to those who might be subject to a proposed intervention whether it is innovative and/or experimental.

- 3.3.16 In clinical research, where patient care is combined with an intent to contribute to knowledge, the following matters should be carefully weighed:

- (a) the seriousness of the condition being treated;
- (b) the risks involved in the proposed research; and

- (c) the possible effects of an unequal or dependent relationship between the treating health professional or researcher and the potential participant (see *Chapter 4.3: People in dependent or unequal relationships*).

- 3.3.17 Where the researcher is also the treating health professional, it should be considered whether an independent person should seek the consent of potential participants.

- 3.3.18 An HREC should be satisfied that:

- (a) payment in money or incentives of any kind, whether to researchers or participants, does not result in pressure on individuals to consent to participate (see paragraphs 2.2.10, and 2.2.11, page 20);
- (b) research participants are adequately informed of the funding arrangements of the research and given the option of knowing the details of any capitation payments to researchers or clinicians; and
- (c) it has been made clear to participants whether they will have continued access after the trial to treatments they have received during the trial, and on what terms.

## Monitoring of approved clinical research

- 3.3.19 The ultimate responsibilities of institutions for monitoring the conduct of approved research are described in *Chapter 5.5: Monitoring approved research* (page 91–92). In clinical research, and especially clinical trials, research sponsors also have such responsibilities.

- 3.3.20 Institutions responsible for the conduct of clinical research should require that:

- (a) monitoring arrangements are commensurate with the risk, size and complexity of the trial;

- (b) for each project, there are mechanisms for reporting and reviewing:
    - (i) serious adverse events at any site for which the institution is responsible;
    - (ii) serious adverse drug reactions (ADRs), serious unexpected suspected adverse reactions (SUSARs), and serious adverse device events from any site for which the institution is responsible;
  - (c) for a large multi-centre trial, a Data and Safety Monitoring Board (DSMB) is used and there is a mechanism for informing the HREC of any relevant emerging data from the DSMB;
  - (d) for a local trial, there is an identified person/s or committee with suitable expertise to assist and advise the HREC about reports of serious adverse events.
- 3.3.21 HRECs should review approved projects in light of information provided to them under paragraph 3.3.20.
- 3.3.22 In addition to the requirements outlined in *Chapter 5.5: Monitoring approved research* (page 91–92), the granting and continuation of ethical approval of clinical research must be on the condition that, for any trial site under the HREC's responsibility, the researcher:
- (a) conducts the trial in compliance with the approved protocol;
  - (b) provides reports of the progress of the trial to the HREC, at a frequency directed by the HREC (but at least annually), and related to the degree of risk to participants;
  - (c) informs the HREC, and seeks its approval, of amendments to the protocol including amendments that:
    - (i) are proposed or undertaken in order to eliminate immediate risks to participants;
    - (ii) may increase the risks to participants; or
    - (iii) significantly affect the conduct of the trial;
  - (d) notifies, in the manner and form specified by the HREC, any serious adverse events at any of those trial sites;
  - (e) informs the HREC as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the trial or may indicate the need for amendments to the trial protocol;
  - (f) informs the HREC, giving reasons, if the trial is discontinued before the expected date of completion; and
  - (g) for trials with implantable medical devices, confirms the existence of, or establishes, a system for
    - (i) tracking the participant, with consent, for the lifetime of the device; and
    - (ii) reporting any device incidents to the TGA.

## Discontinuance of trials

3.3.23 It may be unethical for a researcher to continue a trial if:

- (a) there are or have been substantial deviations from the trial protocol;
- (b) side-effects of unexpected type, severity, or frequency are encountered; or
- (c) as the trial progresses, one of several treatments or procedures being compared appears to be so much better or worse than the other/s that the continuation of the trial would disadvantage some of the participants.

The clearer it becomes that one treatment is substantially better or worse than the others, the stronger the need to consider discontinuing the trial.

## Insurance

- 3.3.24 Institutions must be satisfied that sponsors of trials have made the indemnity or insurance and compensation arrangements required by *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95), *ISO 14155 Clinical Investigation of Medical Devices* and the TGA.
- 3.3.25 In addition to the requirements in paragraph 3.3.24, institutions must also have arrangements to compensate participants for harm resulting from negligence in research to which this chapter applies.

# CHAPTER 3.4: HUMAN TISSUE SAMPLES

## INTRODUCTION

Samples of tissue, including blood and other body fluids, are collected from people in hospitals and other health care institutions, and in field research. Samples collected for diagnostic purposes in the course of treatment have also traditionally been used for teaching or quality assurance activities and for research. Directors of Pathology have traditionally exercised discretion in the use of clinical samples in testing and developing laboratory procedures, and should continue to do so.

Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. This means that most hospitals have collections of stored samples whose use in research may lead to important advances in the understanding and treatment of disease.

State and Territory laws also regulate collection and some uses of human tissue.

This chapter provides ethical guidance for any research involving human tissue samples. *Chapter 3.5: Human genetics*, *Chapter 3.6: Human stem cells*, and *Chapter 4.1: Women who are pregnant and the human foetus* offer additional guidance on specific aspects of such research.

**Research involving the use of gametes or embryos is governed by *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004).**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Institutional policy

- 3.4.1 Institutions should develop a policy for the collection, storage, use and disposal of human tissue in research. This policy should cover:
  - (a) what information needs to be recorded about the source, nature and reason for collection of the tissue;
  - (b) requirements about participant consent (see *Chapter 2.2: General requirements for consent*), including circumstances where waiver of consent may be justified (see paragraphs 2.3.5 and 2.3.6, page 24);
  - (c) confidentiality;
  - (d) privacy of samples and information;
  - (e) access to samples and information;
  - (f) disposal of samples;
  - (g) socio-cultural considerations bearing on these issues.

- 3.4.2 This policy should conform to relevant legislation and be consistent with this National Statement.

- 3.4.3 Researchers should demonstrate that tissues will be collected, stored, used and disposed of in accordance with this policy.

### Imported tissue

- 3.4.4 Where tissue is imported from another country for use in Australia, researchers should try to establish whether there are ethical and professional policies in that country, or the relevant institution,

governing the collection of tissue for use in research.

- (a) Where such a policy exists, and reasonable enquiry reveals no reason to believe the collection of the tissue contravened it, a Human Ethics Research Committee (HREC) may consider waiving consent for the use of this tissue, in accordance with paragraph 2.3.6 (page 24).
- (b) Where it cannot be established that a policy exists, or where it exists but enquiry reveals reason to believe the tissue was not collected in accordance with it, the tissue should not be used in research in Australia (*see also Chapter 4.8: People in other countries*).
- (c) For research with tissues that were in collections either imported or existing overseas before the release of this National Statement, an HREC may consider waiving consent without reference to (a) and (b) (see paragraph 2.3.6, page 24).

## Information and consent

- 3.4.5 Participants should receive clear information about whether their tissue samples will be identified, and if so, how.
- 3.4.6 If the research is likely to produce information relevant to the health and wellbeing of the person from whom the tissue was derived, procedures to allow participants to be identified for appropriate follow-up should, wherever possible, be included in the research proposal.
- 3.4.7 Consent for the use of tissue may be specific, extended or unspecified (see paragraph 2.2.14, page 21). When consent is given for the use of human tissue in specific research only, that tissue should not be used for any other purpose without the consent of the tissue donor unless an HREC or other review body has

waived the requirement to seek further consent, in accordance with paragraph 2.3.6 (page 24).

## Cadaveric tissue

- 3.4.8 Any wish expressed by a person about the use of his or her post-mortem tissue for research should be respected. If no such wish is discovered, consent for the use of the tissue should be sought from the senior available next of kin.
- 3.4.9 At the time of seeking this consent it should be agreed with the next of kin how the tissue is to be disposed of when the research has been completed. Researchers should try to accommodate any reasonable wishes of the next of kin about this.

## Commercialisation

- 3.4.10 There should be no trade in human tissue for research purposes.

# CHAPTER 3.5: HUMAN GENETICS

## INTRODUCTION

The genome is an individual's biological inheritance. An individual's biological characteristics are determined by the interaction of his or her genome with the environment. An individual's genome contains all of his or her genes.

Genetics is the study of the structure, location, function, expression, interaction, abnormalities and effects of the genes or genetic material and their products, including but not limited to studies of the structure of the nucleic acids and other molecules that make up the genetic material.

Genes and genetic information are being studied increasingly in clinical, epidemiological and social research, as well as in basic research.

Genetic research may involve study of:

- single or multiple genes, gene-to-gene interaction or gene-environment interaction;
- acquired somatic variation;
- inherited gene sequences, and their variants or their products;
- gene expression, including the influence on those genes of environmental factors, pharmaceuticals and other therapeutic products;
- the genes of individuals, families or populations;
- epigenetics;
- use of informatics and genetic information; and
- clinical phenotypes.

Some research that falls within this broad description of genetic research does not involve information that is relevant to the future health of the individual participant and does not generate sensitivities for the individual, or his or her family or community. The guidelines in

this chapter differentiate between research that necessitates special precautions in that respect, and research that is unlikely to be of concern to individual participants, their families or their communities.

For genetic research using stored data, *see also Chapter 3.2: Databanks*; and for genetic research using human tissue samples, *see Chapter 3.4: Human tissue samples*.

There are ethical issues specific to genetic research because:

- many of an individual's genes are shared with close genetic relatives (commonly called 'blood relatives') and with unrelated people in the population; and
- genetic research can reveal information about predispositions to disease. Although people with such a predisposition may not develop the disease, the information may have implications for their access to employment and education and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have similar implications for blood relatives.

Research results and genetic material and information collected for genetic research may be significant for blood relatives of research participants. These family members may have an interest in their relatives' genetic material, or in information the research generates, because testing that material or acquiring that information may create new options for life decisions, including those with potential to improve health. However, some family members may prefer not to be given such information, or even not to know of its existence. In addition, other family members who are not blood relatives, such as partners and spouses, may have an interest because of concerns about the health of offspring. Genetic research can also

reveal information about previously unknown paternity or maternity. Genetic research also has uses outside health, such as for tracing migration patterns and in studies of cultural relatedness.

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

3.5.1 Where research may discover or generate information of potential importance to the future health of participants, or their blood relatives, researchers must prepare and follow an ethically defensible plan to disclose or withhold that information.

3.5.2 This plan must take into account the clinical relevance of the research information, the types of genetic test used in the research, and the results of those tests. In addition:

- (a) The plan should:
  - (i) enable participants to decide whether they wish to receive the information and who else may be given the information;
  - (ii) set out a process for finding out whether those other people want to receive information;

(iii) include procedures to inform participants that the information would remain potentially identifiable;

(iv) include measures to protect the degree of confidentiality that participants wish to maintain.

(b) When participants or their relatives are to be given or notified of genetic information that may be important for their health, the plan should either provide access to genetic and clinical advice and counselling, or clearly recommend to participants that they seek these services. Such advice and counselling should be provided by professionals with appropriate training, qualifications and experience.

(c) Where participants or relatives prefer not to receive genetic information that is important for their health, they should be advised that they will be approached to confirm this decision when the results of the research are available.

(d) Where the potential relevance of genetic information to participants' health is not clear until after interim analysis of the research information, participants should again be given:

- (i) the option of being notified of the existence of that information;
- (ii) the option of receiving the information; and/or
- (iii) access to, or a recommendation to seek, advice or counselling about the implications of these decisions.

3.5.3 Advice about the results of genetic research needs to include a clear explanation of the difference between research and clinical testing, and to clarify any need for clinical testing of research results.

## Justice in the use and disclosure of genetic information

3.5.4 Researchers should consider the potential psychological, social and cultural significance of their research. Where complex socially significant characteristics or the genetic characteristics of communities are being investigated, there is a risk that the research may be misrepresented or misused in ways that lead to prejudice, disrespect or other harm to participants or communities. In designing, conducting and reporting research of this nature, researchers should consider how to counter the possibility of such harm.

## Beneficence

3.5.5 Identifiers of genetic material or related information:

- (a) should not be removed without the consent of participants, if removal would make it difficult to communicate personal results;
- (b) should be removed if participants request it, provided they have been informed that the material or information would remain potentially identifiable.

3.5.6 Genetic information can sometimes be misused to stigmatise people or to discriminate against them unfairly. Researchers should therefore take special care to protect the privacy and confidentiality of this information. Statutory or contractual duties may require participants to disclose the results of genetic tests or analysis to third parties (for example, insurance companies, employers, financial and educational institutions), particularly where results provide information about health prospects. Genetic research should be designed to minimise any resultant risk that participants will be deprived of benefits available to others in the community. Potential research participants should be advised of any such risks.

3.5.7 Researchers should not transfer genetic material or related information to any researcher not engaged in the research project unless:

- (a) either
  - (i) participants have been informed about and have specifically consented to that transfer and, where the material or information is identified, there is a defensible plan as specified in paragraphs 3.5.1 and 3.5.2 for withholding or disclosing it; or
  - (ii) the provisions for extended or unspecified consent set out in paragraph 2.2.14 (page 21) have been met; or
  - (iii) an HREC has judged that the conditions for waiver of consent have been met (see paragraph 2.3.6, page 24), and has approved the transfer;
- (b) the transferring and receiving researchers are conducting research that has been ethically approved in Australia or through an equally stringent process in another country; and
- (c) the receiving researcher/s undertake/s not to permit attempts to re-identify the material or information or otherwise reduce the protection of the privacy of the participants or of the confidentiality of the information.

## Family involvement

3.5.8 Where people are asked to consent to the collection of their genetic material or information for research, they should be given information required by paragraph 2.2.2 (page 19) and, in addition, be advised:

- (a) that genetic material is in principle re-identifiable, even if identifiers are removed;

- (b) that they are free to decline without giving reasons;
- (c) about arrangements to ensure the privacy and confidentiality of their genetic information with regard to both family members and others, in accordance with the defensible plan for disclosing and withholding information (see paragraph 3.5.2);
- (d) whether information from or about family members, in addition to that provided by participants, is required for the research;
- (e) whether the research may reveal information of potential importance to their future health, or the future health of their blood relatives;
- (f) that, if it is proposed to approach blood relatives, consent to do so will first be sought from the participant;
- (g) that, if the research discloses that a family member may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the approval of an HREC, be offered by a clinician to the family member, even if the research participant does not consent to this; and
- (h) whether the research has the potential to detect previously unknown paternity or maternity, or non blood-relationship to siblings, and whether, how and to whom this information will be disclosed, according to the approved plan.
- 3.5.9 In deciding if relatives should be approached, researchers should consider:
- (a) the privacy and any known sensitivities of the relatives;
- (b) accepted habits of communication within the family; and
- (c) whether the harms that might result from the relatives' participation in the research are justified by the potential benefits of their participation.
- 3.5.10 Where a participant has given consent to approach relatives, the opportunity to make initial contact should be given to the participant or someone else he or she chooses.
- ## Community involvement
- 3.5.11 Consent should be sought from appropriate community representatives as well as from the individuals concerned (see paragraph 2.2.13, page 21), where:
- (a) researchers propose to collect genetic material and information from individuals who are chosen because of their membership of a particular community;
- (b) the research involves sensitivities for that community; and
- (c) there is known to be a culturally relevant community structure involved in such matters.
- ## Other information to be given
- 3.5.12 Those whose consent is being sought for collection of identified or potentially identifiable genetic material or related information should also be informed:
- (a) if the research has potential to generate information that a participant may be legally required to disclose to a third party, for instance, for the purposes of insurance, employment, finance or education;
- (b) that genetic material and data may have uses unrelated to research. Participants should be advised that their material and data will not be released for such uses without their consent, unless required by law;

- (c) about any proposal, subject to participants' consent, to store their genetic material and data because it might be useful for as yet unspecified future research;
- (d) that, if such consent is not given, the genetic material and data will be disposed of at the end of the research, once the sample storage and record-keeping requirements of good research practice have been met;
- (e) that any wishes about the method of disposal will be recorded at the start of the research and taken into account at the time of disposal;
- (f) that they are free to withdraw from the research at any time. Participants should be informed of any consequences of such withdrawal, including that they may request their genetic material and data to be disposed of, if the samples can be identified. They should also be clearly informed of any practical limitations on the granting of this request; and
- (g) that, in research studying large numbers of genes simultaneously, participants will not be given the names of all the individual genes to be studied.

## Confidentiality

3.5.13 Researchers must ensure the confidentiality and privacy of stored genetic information or research results relating to identified or re-identifiable participants. Such information or research results should be disclosed to treating clinicians only in accordance with the consent given for the research.

3.5.14 The rarity of some genetic disorders might allow certain families or individuals to be identified by other researchers, and in some cases by members of the community, even if information is given to others in non-identifiable form. For this

reason, where genetic data are stored, confidentiality might sometimes require restrictions on the release of data for research use (see paragraph 3.2.8, page 31).

# CHAPTER 3.6: HUMAN STEM CELLS

## INTRODUCTION

Stem cells are relatively ‘unspecialised’ cells that have the unique potential to develop into ‘specialised’ cell types in the body (for example, blood cells, muscle cells or nerve cells). They occur at all stages of human development, from embryo to adult, and in many (possibly most) tissues of the body.

As well as being central to normal human growth and development, stem cells are a potential source of new cells for the regeneration of diseased or damaged tissue.

Stem cells have considerable capacity to be of clinical benefit, but they may also carry significant risks in clinical use, especially if their growth and differentiation is unable to be controlled.

Stem cells and their sources can be described as follows:

- *embryonic stem cells*, which have been derived from human embryos in the first 3–5 days of development, usually after a blastocyst has formed;
- *somatic stem cells* (also known as non-embryonic stem cells or adult stem cells), which are derived from the human body after the embryonic stage. They include foetal and umbilical cord stem cells, as well as cells such as mesenchymal and haematopoietic stem cells that have been used in clinical practice for a number of years; and
- *stem cells derived from primordial germ cells*.

Most parts of the human body contain somatic stem cells that lie dormant in most circumstances. A new area of research involves attempts to stimulate the activity of these stem cells for therapeutic purposes. This activity carries possibilities for benefit and harm similar to those of transplanted stem cells and must meet similar ethical requirements for intervention and safety.

## Legislation

The *Research Involving Human Embryos Act 2002* (the RIHE Act) and corresponding State and Territory legislation establishes a regulatory framework for the use of excess assisted reproductive technology (ART) embryos. This legislation and the licensing authority established by it does not regulate the use in research of stem cells or stem cell lines after they have been derived from an excess ART embryo.

The RIHE Act refers to *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004), known as the ‘ART guidelines’. At paragraphs 17.10 – 17.18, these guidelines provide guidance for the design, ethical review and conduct of research involving excess ART embryos, but they do not regulate the use of stem cells obtained from human embryos.

## Stem cell research

Research into stem cells is in two major classes:

- research into new and developing therapies. Some of these are based on long-standing cellular therapies, the ethics of which have their origin in well established ethical practice in transplant and blood transfusion. Such research also includes clinical trials and innovative therapy involving stem cells or their products;
- research on the cells themselves, leading to knowledge about cellular disease processes. This research includes studies on the pluripotentiality or multipotentiality of stem cells, studies related to drug metabolism and therapeutics, and attempts to improve understanding of specific diseases.

## Scope of this chapter

The guidelines in this chapter relate to research using derived human stem cells or stem cell lines, whether embryonic, somatic or derived from primordial germ cells.

## Applicability of other chapters and documents

For the purpose of these guidelines, human stem cells are regarded as human tissue, so that *Chapter 3.4: Human tissue samples* also applies to research involving their use.

Since these cells carry the human genome and may either carry the genome of a born individual or be genetically related to born individuals, *Chapter 3.5: Human genetics* also applies.

Research to derive and study stem cells from the human umbilical cord, placental tissue, human foetal tissue or amniotic fluid is also subject to the guidelines set out in *Chapter 4.1: Women who are pregnant and the human foetus*.

The guidelines in this chapter deal only with the use of stem cells, not the ethical issues pertaining to the method by which they were derived and collected. They also deal only with the use of stem cells of entirely human origin, not those of transspecies origin.

Where clinical research is proposed using stem cells, reference may be needed to the requirements of the Therapeutic Goods Administration (TGA), the *Australian Code of Good Manufacturing Practice for Medicinal Products*, and the *Australian Code of Good Manufacturing Practice for Human Blood and Tissues*.

Cells, however derived, with the capacity of gametes, are subject to the NHMRC *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research* (2004).

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research**

**uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 3.6.1 Researchers and HRECs should seek advice from the NHMRC on clinical research that proposes novel uses of stem cells.
- 3.6.2 Clinical trials involving the grafting, transplant or activation of human stem cells in humans should be conducted only where there is substantial evidence, from pre-clinical models, of safety and efficacy.

### Justice

- 3.6.3 Identifiers should not be removed from stem cells without the consent of the donor if the removal would make it difficult to communicate information that could benefit the donor or his or her blood relatives.
- 3.6.4 Potential donors of material from which stem cells are derived should be informed that the individual donor may remain identifiable even if his or her genome is only partly represented in those stem cells. This is particularly so if analysis of the stem cells is combined with other sources of information such as genealogical, phenotypic (including medical record) or genetic data.

## Beneficence

3.6.5 Those conducting research involving stem cells derived from a human embryo or foetus should have no involvement in the clinical care of the woman from whom an ovum, embryo or foetus was obtained. Such research should be conducted in a location that maintains a separation of the woman's clinical care from research (see paragraph 4.1.11, page 53, and the ART guidelines, clause 15.5).

## Respect

3.6.6 In addition to the information described in paragraph 2.2.2 (page 19), those who are considering donating embryos or tissue for the derivation of stem cells for research should also be given:

- (a) an explanation of the research for which the stem cells are to be used and, where extended or unspecified consent is sought, sufficient information to meet the requirements of paragraphs 2.2.1 (page 19) and 2.2.16 (page 21);
- (b) an explanation of the implication of removing identifiers (see paragraphs 3.6.3 and 3.6.4) from stem cells, including loss of a say in the use of the stem cells and, potentially, loss of their use for treatment for the participant or his or her blood relatives;
- (c) an assurance that they are free to decline to participate in research and entitled to withdraw from research at any time before identifiers are removed and a cell line is created;
- (d) an explanation that the research could result in the production of a stem cell line that could be maintained for many years, distributed to other parts of the world, and used for various research purposes; and

- (e) an explanation that the research participants will not benefit financially from any future commercialisation of cell lines, and that the donor will not have any authority over any cell lines created once their identifiers have been removed.

## Conscientious objection

3.6.7 Those who conscientiously object to being involved in conducting research with embryos, foetuses or embryonic or foetal tissue should not be obliged to participate, nor should they be put at a disadvantage because of their objection.

## Imported stem cell lines

3.6.8 Where stem cell lines have been created in another country, their use in research in Australia is also subject to paragraph 3.4.4 (page 39).

# SECTION 4: ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS

In addition to the ethical considerations pertaining to all research participants, specific issues arise in the design, conduct and ethical review of research involving the categories of participants identified in this section.

The Introduction to this National Statement contains a definition of participants and notes that the impact of research on wider populations is an important ethical consideration in the design, review and conduct of human research.

Human research may be conducted only with ethical approval. Section 5 describes the processes that institutions may use to provide that approval. Those processes include ethical review by Human Ethics Research Committees (HRECs) or other ethical review bodies, according to the risks of the research (see paragraphs 5.1.6 to 5.1.8, page 78).

Ethical review by an HREC is required for any research that involves more than low risk (see paragraph 5.1.6, page 78). It is also required for research discussed in several chapters of

Section 3, as well as for research discussed in the following chapters of this section: *Chapter 4.1: Women who are pregnant and the human foetus, Chapter 4.4: People highly dependent on medical care who may be unable to give consent, Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness, Chapter 4.6: People who may be involved in illegal activities, Chapter 4.7: Aboriginal and Torres Strait Islander Peoples and Chapter 4.8: People in other countries.*

As stated at the end of Section 1, this National Statement does not exhaust the ethical discussion of human research. Even a single research field covers a multitude of different situations about which the National Statement will not always offer specific guidance, or to which its application may be uncertain. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

## CHAPTER 4.1: WOMEN WHO ARE PREGNANT AND THE HUMAN FOETUS

### INTRODUCTION

This chapter provides guidelines for the ethical conduct of research involving women who are pregnant, the human foetus *ex utero*, and human foetal tissue after the separation of the foetus from the woman. The chapter is arranged to reflect the following established categories of such research:

- research on the woman who is pregnant and the foetus *in utero*; and
- research on the separated human foetus or on foetal tissue.

This chapter does not apply to research involving:

- gametes, embryos and/or participants in assisted reproductive treatments – this research is covered by the

*Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004);

- embryos excess to the needs of those for whom they were created using assisted reproductive technology – this research is covered by Australian legislation.

For the purpose of this chapter, the term *foetus* applies to the developing human being from fertilisation to delivery, and whether alive or dead at delivery.

*Foetal tissue* includes membranes, placenta, umbilical cord, amniotic fluid, and other tissue that contains the genome of a foetus. Foetal tissue is regarded as part of the foetus prior to separation of the foetus from the woman.

After separation, the following chapters of this National Statement may also be relevant to the design and conduct of research involving foetal tissue: *Chapter 3.4: Human tissue samples* and *Chapter 3.6: Human stem cells*.

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### The woman who is pregnant and the foetus *in utero*

- 4.1.1 The wellbeing and care of the woman who is pregnant and of her foetus always takes precedence over research considerations.
- 4.1.2 The research participation of a young person who is pregnant should be guided by the requirements of *Chapter 4.2: Children and young people*.
- 4.1.3 Research involving the woman may affect the foetus, and research involving the foetus will affect the woman. The risks and benefits to each should be carefully considered in every case, and should be discussed with the woman. This must include the effect of the research on the foetus *in utero* (including consideration of foetal stress) and on the child who may subsequently be born.
- 4.1.4 The possibility of providing access to counselling for the woman about these issues should be part of this discussion.
- 4.1.5 Researchers should ask the woman whether, in her decisions about the research, she wishes to involve others for whom the research may have implications.
- 4.1.6 Except in the case of therapeutic innovative therapy, the process of providing information and obtaining consent for involvement in research should be separate from clinical care. Information about research projects should also be separate from information about routine clinical care.
- 4.1.7 If it is consistent with promoting the life and health of the foetus, research on the foetus *in utero* may be ethically acceptable. Such research may, for example, provide information about the health of the foetus.

- 4.1.8 Research should be designed so as to minimise pain or distress for the foetus, and should include steps for monitoring for signs of foetal pain or distress, and steps for suspending or ceasing the research if necessary.
- 4.1.9 ‘Innovations in clinical practice’ (page 39), in *Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations*, should be considered for any innovative therapy involving the foetus. *See also* paragraph 3.3.15 (page 36).
- 4.1.10 It is ethically unacceptable to conduct non-therapeutic research that involves administering drugs or carrying out a procedure on the woman or her foetus, where the research carries risk for the foetus.

### The human foetus, or foetal tissue, after separation

- 4.1.11 Those conducting research involving the human foetus *ex utero* or foetal tissue, after termination of pregnancy, should have no involvement in the clinical care of the woman from whom the foetus or foetal tissue was derived, and no financial or legal relationships with those who are so involved. Such research should be conducted in a location that maintains a separation of the woman’s clinical care from research.
- 4.1.12 Researchers should demonstrate that there are no suitable alternatives by which the aims of research using the separated human foetus or foetal tissue can be achieved.
- 4.1.13 There should be no trade in human foetal tissue.
- 4.1.14 Those who conscientiously object to being involved in conducting research with separated foetuses or foetal tissue should not be compelled to participate, nor should they be put at a disadvantage because of their objection.
- 4.1.15 Where research involves a separated foetus, researchers should ask the woman whether, in her decisions about the research, she wishes to involve others for whom the research may have implications.
- 4.1.16 A foetus or foetal tissue may become available for research as the result of termination. The process through which the woman is approached, informed about, and her consent sought for research on that foetus should be separate from the process under which she decides whether to terminate her pregnancy, and should not begin until a decision to terminate has been made. Consenting to the research must not compromise the woman’s freedom to change that decision.
- 4.1.17 Where research involves her separated foetus or its foetal tissue, arrangements should be made for the woman to have access to counselling and support.
- 4.1.18 Research on a terminated foetus or its tissues, including the timing and content of the process of seeking the woman’s consent for the research, should be designed so as not to compromise the woman’s decisions about the timing and method of termination.
- 4.1.19 Consideration of a woman’s wishes and her physical, psychological and emotional welfare should inform:
- (a) a decision whether to approach her about proposed research involving her, her separated foetus or its tissue; and
  - (b) if she is approached, the way information is provided about the research and her consent for it sought.
- 4.1.20 In addition to information required to be disclosed under paragraphs 2.2.2 and 2.2.6 (page 19) of this National Statement, the woman should also be informed:

- (a) that she should consider whether to seek consent to the proposed research from any other person (see paragraphs 4.1.5 and 4.1.15);
- (b) whether it is possible to store the foetus or foetal tissues for later use in research;
- (c) that she is free to withdraw her consent to the research at any time, whether before or after a termination or other loss of a foetus;
- (d) whether there is potential for commercial application of outcomes of the research, including the development of cell lines;
- (e) that she will not be entitled to a share in the profits of any commercial applications; and
- (f) whether foetal organs or stem cell lines developed from them will be exported to another country.

4.1.21 A foetus delivered alive is a child, and should be treated as a child and receive the care that is due to a child.

4.1.22 Organs and tissues may be removed from a foetus delivered dead and used for research only if the conditions of paragraphs 4.1.11 and 4.1.12 are met, and:

- (a) the woman and any others she wishes to involve (see paragraph 4.1.15) have given consent to the removal and the research;
- (b) the foetus is available for research only as a result of separation by natural processes or by lawful means; and
- (c) death of the foetus has been determined by a registered medical practitioner who has no part (or financial interest) in the research.

4.1.23 If, for research purposes, foetal cells are to be derived from the foetal tissue and stored or propagated in tissue culture, or tissues or cells are to be used in human transplantation, the woman's consent is required. Others whom the woman identifies (*see also* paragraph 4.1.15) may also need to be involved in decisions about these matters.

# CHAPTER 4.2: CHILDREN AND YOUNG PEOPLE

## INTRODUCTION

Research involving children and young people raises particular ethical concerns about:

- their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation;
- their possible coercion by parents, peers, researchers or others to participate in research; and
- conflicting values and interests of parents and children.

These considerations apply to all research involving children and young people. However, they assume special prominence in educational and health research, where there are particular tensions between not placing children at risk in studies of new interventions and the need for knowledge about how such interventions are best used for children.

Researchers must respect the developing capacity of children and young people to be involved in decisions about participation in research. The child or young person's particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation. Different levels of maturity and of the corresponding capacity to be involved in the decision include:

- (a) infants, who are unable to take part in discussion about the research and its effects;
- (b) young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required;
- (c) young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of

these young people is required, but is not sufficient to authorise research; and

- (d) young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian.

It is not possible to attach fixed ages to each level – they vary from child to child. Moreover, a child or young person may at the one time be at different levels for different research projects, depending on the kind and complexity of the research. Being responsive to developmental levels is important not only for judging when children or young people are able to give their consent for research: even young children with very limited cognitive capacity should be engaged at their level in discussion about the research and its likely outcomes.

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.2.1 The research and its methods should be appropriate for the children or young people participating in the research.
- 4.2.2 In the research design researchers should:
  - (a) specify how they will judge the child's vulnerability and capacity to consent to participation in research;

- (b) describe the form of proposed discussions with children about the research and its effects, at their level of comprehension; and
  - (c) demonstrate that the requirements of this chapter will be satisfied.
- 4.2.3 In educational research, discussion with the school community should be built into the research design.
- ### Justice
- 4.2.4 When children and young people are not of sufficient maturity to consent to participation in research, it is justifiable to involve them only when:
- (a) it is likely to advance knowledge about the health or welfare of, or other matters relevant to, children and young people; or
  - (b) children's or young people's participation is indispensable to the conduct of the research.
- ### Beneficence
- 4.2.5 The circumstances in which the research is conducted should provide for the child or young person's safety, emotional and psychological security, and wellbeing.
- ### Respect
- 4.2.6 Researchers should be attentive to the developmental level of children and young people when engaging them in understanding the nature and likely outcomes of research, and when judging their capacity to consent to the research.
- 4.2.7 Except in the circumstances described in paragraphs 4.2.10 and 4.2.11, specific consent to a child's or young person's participation in each research project should be obtained from:
- (a) the child or young person whenever he or she has the capacity to make this decision; and
  - (b) either
    - (i) one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents; or where applicable
    - (ii) the guardian or other primary care giver, or any organisation or person required by law.
- 4.2.8 An ethical review body may approve research to which only the young person consents if it is satisfied that he or she is mature enough to understand and consent, and not vulnerable through immaturity in ways that would warrant additional consent from a parent or guardian.
- 4.2.9 A review body may also approve research to which only the young person consents if it is satisfied that:
- (a) he or she is mature enough to understand the relevant information and to give consent, although vulnerable because of relative immaturity in other respects;
  - (b) the research involves no more than low risk (see paragraph 2.1.6, page 18);
  - (c) the research aims to benefit the category of children or young people to which this participant belongs; and
  - (d) either
    - (i) the young person is estranged or separated from parents or guardian, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5). (In this case, although the child's circumstances may mean he or she is at some risk, for example because of being homeless, the research itself must still be low risk); or

- (ii) it would be contrary to the best interests of the young person to seek consent from the parents, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5).

### Standing parental consent

4.2.10 'Standing parental consent' enables parents to give standing consent (for example at the beginning of each school year) to their child's involvement in certain types of research in the school setting during that year. Under standing consent, parents are notified of each project, but are not required to give further consent for each project. They should be reminded with each notification that they may withdraw their consent for that project, and also may withdraw their standing consent at any time.

4.2.11 Schools may arrange for standing parental consent to be given for a child's participation in research that:

- (a) is for the benefit of children; and
- (b) comprises no more than overt observation in school classrooms or anonymous or coded (potentially identifiable) questionnaires or surveys on subject matters not involving sensitive personal information or personal or family relationships.

4.2.12 For any other research, except under the conditions described in paragraphs 4.2.8 and 4.2.9, specific parental consent is needed for each project.

### Best interests of the child

4.2.13 Before including a child or young person in research, researchers must establish that there is no reason to believe that such participation is contrary to that child's or young person's best interest.

4.2.14 A child or young person's refusal to participate in research should be respected wherever he or she has the capacity to give consent to that same research (see levels of maturity (c) and (d) in the Introduction to this chapter). Where a child or young person lacks this capacity, his or her refusal may be overridden by the parents' judgement as to what is in the child's best interest.

# CHAPTER 4.3: PEOPLE IN DEPENDENT OR UNEQUAL RELATIONSHIPS

## INTRODUCTION

This chapter is about pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. Examples may include relationships between:

- carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients, or people in residential care or supported accommodation;
- health care professionals and their patients or clients;
- teachers and their students;
- prison authorities and prisoners;
- governmental authorities and refugees;
- employers or supervisors and their employees (including members of the Police and Defence Forces);
- service-providers (government or private) and especially vulnerable communities to whom the service is provided.

Those mentioned first in each of these examples will sometimes be involved as researchers, as well as being involved in facilitating or implementing the research.

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.3.1 Being in a dependent or unequal relationship may influence a person's decision to participate in research. While this influence does not necessarily invalidate the decision, it always constitutes a reason to pay particular attention to the process through which consent is negotiated.
- 4.3.2 In the consent process, researchers should wherever possible invite potential participants to discuss their participation with someone who is able to support them in making their decision. Where potential participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate.
- 4.3.3 In the research design, researchers should identify and take steps to minimise potentially detrimental effects of:
- (a) an unequal or dependent relationship on the conduct of the research; and
  - (b) the research on participants involved in the relationship.

### Justice

- 4.3.4 People in the categories of relationship described in the Introduction to this chapter are vulnerable to being over-researched because of the relative ease of access to them as research populations. Researchers should take account of this vulnerability in deciding whether to seek out members of these populations as research participants.

- 4.3.5 Where participants are in a relationship of dependency with researchers, researchers must take particular care throughout the research to minimise the impact of that dependency.

## Beneficence

- 4.3.6 Researchers need to be mindful that in some relationships of dependency, participants may have an unrealistic expectation of the benefits of research.
- 4.3.7 A person declining to participate in, or deciding to withdraw from, research should not suffer any negative consequences, such as unfair discrimination, reduction in the level of care, dismissal from employment, or any other disadvantage (see paragraphs 2.2.19 and 2.2.20, page 21).

## Respect

- 4.3.8 The design of research involving those in dependent relationships should not compromise respect for them.
- 4.3.9 Where the researcher has a pre-existing relationship with potential participants, it may be appropriate for their consent to be sought by an independent person.
- 4.3.10 Researchers should take special care to safeguard confidentiality of all information they receive, particularly in settings such as shared workplaces, hospital rooms or rooms in residential care.

# CHAPTER 4.4: PEOPLE HIGHLY DEPENDENT ON MEDICAL CARE WHO MAY BE UNABLE TO GIVE CONSENT

## INTRODUCTION

Medical care increasingly offers interventions or treatment for people at times of serious risk to their life or wellbeing. These risks may be temporary or permanent. People can become highly dependent on those interventions and treatments and may be incapable of comprehending their situation or of communicating about it. At the same time, research on those interventions and treatments is necessary to assess and improve their efficacy.

This chapter describes conditions under which research involving people highly dependent on medical care might proceed although their capacity to give consent is limited or non-existent.

In every instance, relevant jurisdictional laws will need to be taken into account.

Significant ethical issues are raised by research conducted in the following settings:

- neonatal intensive care;
- terminal care;
- emergency care;
- intensive care; and
- the care of unconscious people.

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in**

**Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.4.1 Research involving people who are highly dependent on medical care may be approved where:
- (a) it is likely that the research will lead to increased understanding about, or improvements in, the care of this population;
  - (b) the requirements of relevant jurisdictional laws are taken into account; and
  - (c) either
    - (i) any risk or burden of the proposed research to this particular participant is justified by the potential benefits to him or her; or
    - (ii) where participants have capacity to consent, any risk or burden is acceptable to them and justified by the potential benefits of the research.

### Justice

- 4.4.2 People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into

research might seem unfair. However, those people are entitled to participate in research and, when the conditions of paragraph 4.4.1 are met, their involvement is not unfair.

## Beneficence

- 4.4.3 The distinguishing features of *neonatal intensive care research* are the small size and unique developmental vulnerability of the participants and the potential for very long-range impact on their growth, development and health. In this research, risks and potential benefits should be assessed with particular care by individuals or groups with relevant expertise.
- 4.4.4 The distinguishing features of *terminal care research* are the short remaining life expectancy of participants and their vulnerability to unrealistic expectations of benefits. Terminal care research should be designed so that:
- (a) the benefits of research to individual participants or groups of participants, or to others in the same circumstances, justify any burden, discomfort or inconvenience to the participants;
  - (b) the prospect of benefit from research participation is not exaggerated;
  - (c) the needs and wishes of participants to spend time as they choose, particularly with family members, are respected; and
  - (d) the entitlement of those receiving palliative care to participate is recognised.

## Respect

- 4.4.5 People involved in research to which this chapter applies may have impaired capacity for verbal or written communication. Provision should be made for them to receive information, and to express their wishes, in other ways.

4.4.6 In *emergency care research*, recruitment into a research project often has to be achieved rapidly. Where the research involves emergency treatment and meets the requirements of 4.4.1, consent for the research may be waived provided the conditions of paragraph 2.3.6 (page 24) are satisfied.

- 4.4.7 In *intensive care research*, heavy sedation may impair participants' cognition, and communication is difficult with people receiving ventilatory assistance. Whenever possible, consent to intensive care research, based on adequate information, should be sought from or on behalf of potential participants before admission to that level of treatment. When prior consent to research is not possible, the process described in paragraphs 4.4.9 to 4.4.14 should be followed.
- 4.4.8 In *research with unconscious people*, the participants cannot be informed about the research and their wishes cannot be determined. Those who are unconscious should be included only in minimally invasive research, or in research designed both to be therapeutic for them and to improve treatment for the condition from which they suffer.

## Process to be followed

- 4.4.9 Consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them.
- 4.4.10 Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should be sought from the participant's guardian, or person or organisation authorised by law, except under the circumstances described in paragraph 4.4.13.

- 4.4.11 When consent is to be sought, either from the potential participant or another on his or her behalf, steps should be taken to minimise the risk that:

- (a) stress or emotional factors may impair the person's understanding of the research or the decision to participate; and
- (b) the dependency of potential participants and their relatives on the medical personnel providing treatment may compromise the freedom of a decision to participate.

4.4.12 Where the researcher is also the treating health professional, it should be considered whether an independent person should make the initial approach and/or seek consent from potential participants or from others on their behalf.

4.4.13 When neither the potential participant nor another on his or her behalf can consider the proposal and give consent, an HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent if:

- (a) there is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent;
- (b) the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised;
- (c) the project is not controversial and does not involve significant moral or cultural sensitivities in the community;

and, where the research is interventional, only if in addition:

- (d) the research supports a reasonable possibility of benefit over standard care;
- (e) any risk or burden of the intervention to the participant is justified by its potential benefits to him or her; and

- (f) inclusion in the research project is not contrary to the interests of the participant.

4.4.14 As soon as reasonably possible, the participant and/or the participant's relatives and authorised representative should be informed of the participant's inclusion in the research and of the option to withdraw from it without any reduction in quality of care.

# CHAPTER 4.5: PEOPLE WITH A COGNITIVE IMPAIRMENT, AN INTELLECTUAL DISABILITY, OR A MENTAL ILLNESS

## INTRODUCTION

The three kinds of condition discussed in this chapter are different. They are discussed in the one chapter, however, because many of the ethical issues they raise about research participation are very similar.

People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research. While research involving these people need not be limited to their particular impairment, disability or illness, their distinctive vulnerabilities as research participants should be taken into account.

The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons, including:

- the nature of the condition;
- the person's medication or treatment;
- the person's discomfort or distress;
- the complexity of the research project;
- fluctuations in the condition. For example, while intellectual disability is usually permanent, cognitive impairment and mental illness are often temporary or episodic.

Even when capable of giving consent and participating, people with these conditions may be more-than-usually vulnerable to various forms of discomfort and stress.

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research**

**uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.5.1 The research design should take into account factors that may affect the capacity to receive information, to consent to the research, or to participate in it. These factors may be permanent or may vary over time.
- 4.5.2 Care should be taken to determine whether participants' cognitive impairment, intellectual disability or mental illness increases their susceptibility to some forms of discomfort or distress. Ways of minimising effects of this susceptibility should be described in the research proposal.

### Justice

- 4.5.3 People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research, and to do so for altruistic reasons.

## Beneficence

4.5.4 Because of the participants' distinctive vulnerability, care should be taken to ensure that the risks and any burden involved in the proposed research are justified by the potential benefits of the research.

## Respect

4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law. Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.

4.5.6 The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests.

4.5.7 Consent under paragraph 4.5.5 should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

4.5.8 Where consent has been given by a person authorised by law, the researcher should nevertheless explain to the participant, as far as possible, what the research is about and what participation involves. Should the participant at any time recover the capacity to consent, the researcher should offer him or her the

opportunity to continue participation (under the terms of paragraph 4.5.6) or to withdraw.

4.5.9 Researchers should inform HRECs how they propose to determine the capacity of a person with a cognitive impairment, an intellectual disability, or a mental illness to consent to the research. This information should include:

- (a) how the decision about the person's capacity will be made;
- (b) who will make that decision;
- (c) the criteria that will be used in making the decision; and
- (d) the process for reviewing, during the research, the participant's capacity to consent and to participate in the research.

4.5.10 Refusal or reluctance to participate in a research project by a person with a cognitive impairment, an intellectual disability, or a mental illness should be respected.

# CHAPTER 4.6: PEOPLE WHO MAY BE INVOLVED IN ILLEGAL ACTIVITIES

## INTRODUCTION

Research may in some instances discover illegal activity (including notifiable activity) by participants or others, or may discover information indicating future illegal activity. Such research may:

- be intended to study, and perhaps to expose, illegal activity;
- be not specifically intended to discover illegal activity, but likely to do so;
- discover illegal activity inadvertently and unexpectedly.

In the first category there may be particular ethical questions about participants' consent (see *Chapter 2.2: General requirements for consent*). In all three categories both ethical and legal questions for researchers and institutions might arise from:

- what researchers might be obliged to disclose;
- the vulnerability of participants and researchers because of discovery of participants' illegal activity (see paragraph 5.1.2(b)(ii), page 77).

Legal implications may include:

- a statutory obligation for a researcher to disclose information revealed or discovered;
- legal orders that compel disclosure of information obtained by a researcher.

This chapter is not concerned with investigation conducted as part of law enforcement. Nor does it contain information or guidance about legal obligations of researchers arising from their conduct of any research that discovers illegal activity. Further, it is not the role of a Human Ethics Research Committee (HREC) or other ethical review body to provide legal advice on the existence or performance of any of those obligations.

**Research that is intended to study or expose illegal activity or that is likely to discover it must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.6.1 Research designed to expose illegal activity should be approved only where the illegal activity bears on the discharge of a public responsibility or the fitness to hold public office. Variation of consent requirements for such research must comply with either paragraph 2.3.3 (page 24) or paragraph 2.3.7 (page 24).
- 4.6.2 Participants may be subject to risks because of their involvement in research that discovers illegal activity. It should be clearly established that these risks are justified by the benefits of the research. Where the research is designed to expose illegal activity under paragraph 4.6.1, that exposure may sometimes be benefit enough.

## Justice

4.6.3 Where research discovers information about illegal activity by participants or others, researchers and institutions may become subject to orders to disclose that information to government agencies or courts. Decisions by researchers and institutions about how to respond to those orders should have regard to values and principles set out in this National Statement and to scholarly values of academic freedom and inquiry.

response the researcher will make to any legal obligation or order to disclose such information.

- 4.6.7 Researchers should be satisfied that participants who are subject to criminal justice processes:
- (a) are aware that the research may discover illegal activity; and
  - (b) do not have unrealistic expectations of benefit from their participation.

## Beneficence

4.6.4 Consideration should be given to the use of pseudonyms, or to the removal of links between names and data, for participants whose illegal activity may be revealed or discovered in research.

## Respect

4.6.5 Researchers may have contact with those participants in other professional roles. Where this is the case, researchers should make every effort to ensure both that the research is not compromised by contact in those other roles, and that other obligations to participants are not compromised by the research activity. In research that is likely, but not designed, to discover illegal activity, researchers should also make clear to participants when a contact or intervention is part of research and when it is not.

4.6.6 In research that may foreseeably discover illegal activity but is not designed to expose it, researchers should explain to participants as clearly as possible:

- (a) the likelihood of such discovery and of any resulting legal obligation of disclosure the researcher may incur; and
- (b) the extent to which the researcher will keep confidential any information about illegal activity by participants or others, and the

# CHAPTER 4.7: ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES

## INTRODUCTION

Research with Aboriginal and Torres Strait Islander Peoples spans many methodologies and disciplines. There are wide variations in the ways in which Aboriginal and Torres Strait Islander individuals, communities or groups are involved in or affected by research to which this chapter applies. The variations depend on the scope of the project, the demographics of participants, the illnesses or social phenomena under study, and their historical, social and cultural context and connections.

Researchers should address relevant issues of research design, ethics, culture and language. Depending on the field of study and complexity of the proposed research, these issues might be addressed in numerous ways. A cornerstone of an ethical research relationship with Aboriginal and Torres Strait Islander Peoples is respect for and valuing of cultural and language diversity.

For health research fitting the above description, researchers must consult *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003) ('Values and Ethics').

Other documents that might provide useful guidance for researchers are *Keeping research on track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (NHMRC 2005) and the *Guidelines for Ethical Research in Indigenous Studies* (Australian Institute of Aboriginal and Torres Strait Islander Studies 2002).

Human Research Ethics Committees (HRECs) are also required to apply the Values and Ethics guidelines as the basis for assessing proposals for health research with Aboriginal and Torres Strait Islander participation.

In applying Sections 1 and 2 of this National Statement, researchers from other disciplines, HRECs and other ethical review bodies may also find the Values and Ethics guidelines informative.

The Values and Ethics guidelines are based on six core values identified as being important to Aboriginal and Torres Strait Islander Peoples. The message for researchers is that there is great diversity across the many Aboriginal and Torres Strait Islander cultures and societies. Application of these core values, and of additional cultural and local-language protocols, should be determined by the Aboriginal and Torres Strait Islander communities or groups involved in the research. The six core values are:

- Reciprocity
- Respect
- Equality
- Responsibility
- Survival and protection
- Spirit and integrity.

**Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78). The HREC process must have included assessment by or advice from:**

- **people who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples; and**

- **people familiar with the culture and practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.**

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.7.1 The researcher should ensure that research methods are respectful and acknowledge the cultural distinctiveness of discrete Aboriginal and Torres Strait Islander communities or groups participating in the research – including national or multi-centre research.
- 4.7.2 There should be evidence of support for the research project from relevant Aboriginal and Torres Strait Islander communities or groups and the research methodology should engage with their social and cultural practices.
- 4.7.3 The researcher should ensure that research methods provide for mutually agreed mechanisms for such matters as:
- (a) appropriate recruitment techniques;
  - (b) suitable information about the research;
  - (c) notification of participants' consent and of research progress; and
  - (d) final reporting.
- 4.7.4 The researcher should seek to identify any potential negative consequences of the proposed research, to design processes to monitor them, and to advise steps for minimising them.

### Justice

- 4.7.5 The research methods and processes should provide opportunities to develop trust and a sense of equal research partnerships.
- 4.7.6 Where:
- (a) the geographic location of the research is such that a significant number of the population are likely to be Aboriginal and Torres Strait Islander, and/or
  - (b) the research is focused on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander Peoples and the population base has a significant proportion of Aboriginal and Torres Strait Islander people,

the research should provide fair opportunity for involvement of Aboriginal and Torres Strait Islander Peoples, and the guidelines in this chapter apply to those participants.

### Beneficence

- 4.7.7 The benefits from research should include the enhancement or establishment of capabilities, opportunities or research outcomes that advance the interests of Aboriginal and Torres Strait Islander Peoples.
- 4.7.8 The described benefits from research should have been discussed with and agreed to by the Aboriginal or Torres Strait Islander research stakeholders.
- 4.7.9 The realisable benefits for Aboriginal and Torres Strait Islander participants from the research processes, outcomes and outputs should be distributed in a way that is agreed to and considered fair by these participants.

### Respect

- 4.7.10 The research proposal should demonstrate evidence of respectful engagement with Aboriginal and Torres

Strait Islander Peoples. Depending on the circumstances, this might require letters of support from Aboriginal and/or Torres Strait Islander community Councils or other organisations accepted by the participating communities (see *Chapter 2.1: Risk and benefit* and *Chapter 2.2: General requirements for consent*, especially paragraph 2.2.13, page 21). The research processes should foster respectful, ethical research relationships that affirm the right of people to have different values, norms and aspirations.

- 4.7.11 The research approach should value and create opportunities to draw on the knowledge and wisdom of Aboriginal and Torres Strait Islander Peoples by their active engagement in the research processes, including the interpretation of the research data.
- 4.7.12 National or multi-centre researchers should take care to gain local level support for research methods that risk not respecting cultural and language protocols.

# CHAPTER 4.8: PEOPLE IN OTHER COUNTRIES

## INTRODUCTION

When a researcher from an Australian institution proposes to conduct research in another country, additional ethical considerations may arise. In some situations, regard for the beliefs, customs and cultural heritage of participants will require recognition of values other than those of this National Statement. Sometimes these values will be in tension with one or more of the ethical values of this National Statement. Sometimes the legal, regulatory or ethical review processes of another country may also demand conduct that is in tension with the ethical values of this National Statement. The guidelines in this chapter must inform any resolution of these tensions.

**Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.**

## GUIDELINES

### Research merit and integrity

- 4.8.1 Research conducted overseas by researchers from Australian institutions must comply with this National Statement.
- 4.8.2 Local cultural values should be acknowledged in the design and conduct of the research. It should be clearly established that such acknowledgement will result in participants being accorded no less respect and protection than this National Statement requires.
- 4.8.3 As far as is necessary to satisfy the requirements of paragraphs 1.10 to 1.13 (page 13), the design and conduct of the research should reflect continuing consultation with the local participant population and the communities to which they belong ( paragraph 4.8.19).
- 4.8.4 Researchers should inform ethical review bodies in Australia:
  - (a) whether, in the country in which they intend to do research, there are ethics approval processes that are relevant to that research, and whether any such processes are mandatory or voluntary in relation to the proposed research; and
  - (b) how such processes function, the values and principles on which they rely, and whether they require reporting of the Australian review body's approval.
- 4.8.5 Where there are no ethics approval processes in an overseas country, this National Statement may provide the only applicable process for ethical approval. In this case, the Australian ethical review body should take account of the available resources and means to conduct the research and avoid imposing unrealistic requirements, providing always that research participants are accorded no less respect and protection than this National Statement requires.
- 4.8.6 Some funding or national requirements will direct researchers and review bodies to conform to the ethics guidelines of local institutions or to recognised international guidelines or instruments. Research conducted under those guidelines or instruments should be approved only if participants will be accorded no less respect and protection than this National Statement requires.

- 4.8.7 Researchers should have enough experience or access to expertise to enable them to engage with participants in ways that accord them due respect and protection.
- 4.8.8 When research is to be conducted overseas by a researcher who is subject to academic supervision, researchers should inform the Australian ethical review body of how that supervision is to be effected so that due respect and protection will be accorded to participants.
- 4.8.9 When co-researchers are to be recruited in an overseas country, researchers should inform a review body of how the capacity and expertise to conduct that part of the research assigned to the co-researchers will be established.
- 4.8.10 It is the responsibility of researchers to satisfy themselves that those co-researchers will carry out the research in a way that accords participants no less respect and protection than this National Statement requires.

## Justice

- 4.8.11 The distribution of the burdens and benefits of research in overseas countries, for the participants and in some instances the broader community, should be fair and the research should not be exploitative.
- 4.8.12 The conduct of the research in other countries should take into account the opinions and expectations of participants and their communities about the effect of any limits of resources on:
  - (a) the way the research will be conducted;
  - (b) participants' post-research welfare; and
  - (c) application of the results of the research.

- 4.8.13 Institutions and researchers should find out whether research they are planning to do in another country is lawful in that country.

## Beneficence

- 4.8.14 Researchers need to inform review bodies when participants will be in dependent relationships with researchers, whether through previous or proposed arrangements (see *Chapter 4.3: People in dependent or unequal relationships*).
- 4.8.15 Researchers need to know enough about the communities, and how to engage with them, to be able to assess the burdens and benefits of their research to the communities. Political and social factors that may jeopardise the safety of participants need to be taken into account. Researchers should inform review bodies about these likely burdens and benefits.
- 4.8.16 A local, readily accessible contact should be available to participants to receive responses, questions and complaints about the research. Responses and questions should be handled by the researcher. Researchers should ensure that there is a process independent of the researcher for dealing with complaints (see *Chapter 5.6: Handling complaints*).
- 4.8.17 In proposing mechanisms for monitoring research, researchers should take account of local circumstances.
- 4.8.18 Conducting research in other countries can expose researchers to risks of harm. Institutions and researchers should try to identify and evaluate any such risks, and make provision for dealing with them, for instance by establishing local academic or institutional affiliations.

## Respect

- 4.8.19 Respect for participants in other countries requires having due regard for their beliefs, customs and cultural heritage, and for local laws.
- 4.8.20 Local beliefs and practices regarding recruitment, consent, and remuneration to participants or contributions to communities for participating in research should be taken into account in the design and the conduct of the research, and in the ethical review process.
- 4.8.21 It should be clearly established that the processes to be followed in recruiting participants and through which they choose whether to be involved are respectful of their cultural context.

# SECTION 5: PROCESSES OF RESEARCH GOVERNANCE AND ETHICAL REVIEW

Human research encompasses a wide range of activities with an equally wide range of risks and potential benefits. The National Statement allows for different levels of ethical review of research, reflecting the difference in degree of risk involved (see *Chapter 2.1: Risk and benefit*, page 15).

This Section sets out the processes by which institutions establish, conduct and oversee those

different levels of ethical review, and includes the operations of Human Research Ethics Committees (HRECs). The section also describes other processes of research governance that must be in place if the ethical review of research is to be undertaken well. These are considered only briefly, as they are more fully set out in the *Australian code for the responsible conduct of research*.

## CHAPTER 5.1: INSTITUTIONAL RESPONSIBILITIES

### GUIDELINES

#### Research governance

- 5.1.1 Institutions must see that any human research they conduct or for which they are responsible is:
- (a) designed and conducted in accordance with the *Australian code for the responsible conduct of research*; and
  - (b) ethically reviewed and monitored in accordance with this National Statement.
- 5.1.2 Each institution needs to be satisfied that:
- (a) its human research meets relevant scholarly or scientific standards;
  - (b) those conducting its human research:
    - (i) are either adequately experienced and qualified, or supervised;
    - (ii) understand the need to assess risks to their own safety and that of participants; and
- (iii) are free to withdraw from research on conscientious grounds.
- 5.1.3 Institutions may establish their own processes for ethical review of research, or use those of another institution.
- 5.1.4 Whichever option under 5.1.3 is adopted, institutions need to be satisfied that processes are in place for:
- (a) managing conflicts of interest (Chapter 5.4);
  - (b) monitoring research (Chapter 5.5);
  - (c) handling complaints (Chapter 5.6); and
  - (d) ensuring accountability (Chapter 5.7).
- 5.1.5 Institutions should use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.

## Processes for ethical review

- 5.1.6 The following types of research require review by a Human Research Ethics Committee (HREC):
- (a) all research that involves more than low risk;
  - (b) research falling under the following chapters (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review – see paragraphs 5.1.22 and 5.1.23):  
*Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations*  
*Chapter 3.5: Human genetics,*  
*Chapter 3.6: Human stem cells,*  
*Chapter 4.1: Women who are pregnant and the human foetus,*  
*Chapter 4.4: People highly dependent on medical care who may be unable to give consent,*  
*Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness,*  
*Chapter 4.7: Aboriginal and Torres Strait Islander Peoples,*  
and some categories of research falling under *Chapter 4.6: People who may be involved in illegal activities* (see first bolded paragraph on page 67 for details).

5.1.7 For research that carries only low risk (see paragraph 2.1.6, page 18) and does not fall under any of the chapters listed in paragraph 5.1.6, institutions may choose to establish other levels of ethical review. These levels are described in paragraphs 5.1.18 to 5.1.21.

5.1.8 Research that carries only negligible risk (see paragraph 2.1.7, page 18) and meets the requirements of paragraphs 5.1.22 and 5.1.23 may be exempted from ethical review.

## Legal protection for those involved in ethical review of research

- 5.1.9 Institutions should provide an assurance of legal protection to all those involved in ethical review of research, for liabilities that may arise in the course of *bona fide* conduct of their duties in this capacity.

## Oversight and review of ethical review procedures

- 5.1.10 Institutions that set up levels of ethical review other than HREC, as described in paragraphs 5.1.18 to 5.1.23, must establish criteria for allocating research to these different levels of review (including exemption from review), taking into account *Chapter 2.1: Risk and benefit*. These criteria must be readily accessible to all those involved in the conduct and review of research.
- 5.1.11 The ethical values and principles in this National Statement should be the basis on which institutions establish different levels of ethical review, allocate different kinds of research to them, and review those allocations.
- 5.1.12 Institutions must monitor any processes of ethical review of low risk research to ensure those processes continue to provide sufficient protection for participants.
- 5.1.13 Institutions should regularly assess all their ethical review processes, including the criteria for allocating research to different levels of review, to ensure that those processes continue to enable the institution to meet its responsibilities under this National Statement.
- 5.1.14 Where possible this assessment should be informed by the documented experience of research participants and/or by involving participants or the wider community in the assessment.

5.1.15 Institutions should also remain alert to emerging ethical issues in any area of human research that may warrant changing the level of ethical review required.

5.1.16 To enable assessment of their ethical review processes, institutions should prepare and make readily accessible regular reports on all of those processes.

5.1.17 Institutions should have in place an auditing process to confirm that:

- (a) research in their institution is being reviewed at the levels of review their criteria require;
- (b) research is being exempted from review only in accordance with the criteria set out in paragraphs 5.1.22 and 5.1.23.

### **Research involving no more than low risk**

5.1.18 Institutions that establish any non-HREC levels of ethical review for low risk research must have the resources and capacity to carry out such review competently and professionally.

5.1.19 Where institutions establish such non-HREC levels of ethical review for low risk research, that review must:

- (a) be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;
- (b) be informed by *Section 1: Values and Principles of Ethical Conduct*, *Section 3: Ethical Considerations Specific to Research Methods or Fields* and *Section 4: Ethical Considerations Specific to Participants*;
- (c) take account of researchers' judgements as to whether their research is suitable for review by a non-HREC process;
- (d) have due regard to relevant privacy regulation.

5.1.20 The levels of ethical review referred to in paragraph 5.1.18 may include, but need not be limited to:

- (a) review or assessment at departmental level by the head of department;
- (b) review or assessment by a departmental committee of peers (with or without external or independent members);
- (c) delegated review with reporting to an HREC; or
- (d) review by a subcommittee of an HREC.

5.1.21 Those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk.

### **Research that can be exempted from review**

5.1.22 Institutions may choose to exempt from ethical review research that:

- (a) is negligible risk research (as defined in paragraph 2.1.7, page 18); and
- (b) involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

5.1.23 Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.

### **HRECs: research involving more than low risk**

5.1.24 Each institution that conducts human research involving more than low risk must ensure that this research is reviewed and approved by an HREC that is constituted and functioning in accordance with this National Statement, whether or not that HREC is established by the institution.

5.1.25 Institutions<sup>5</sup> that establish HRECs are responsible for ensuring that those HRECs are established and continue to operate in accordance with this National Statement.

### Establishment of HRECs

5.1.26 Institutions that individually or jointly establish HRECs should adequately resource and maintain them. Resourcing should be sufficient to enable HRECs:

- (a) to satisfy the requirements for sound ethical review (see paragraph 5.1.37);
- (b) to communicate well with researchers (see paragraphs 5.2.13 to 5.2.15, page 84);
- (c) not to charge fees where doing so would discourage research the institution has an obligation to support.

5.1.27 When establishing an HREC, an institution should set out and publicise its terms of reference, including:

- (a) the scope of its responsibilities for ethical review;
- (b) its relationship to other processes of research review;
- (c) its relationship to non-affiliated researchers;
- (d) its institutional accountability;
- (e) its mechanisms of reporting;
- (f) categories of minimum membership; and
- (g) remuneration, if any, for members.

5.1.28 Where an institution has established an HREC, the institution is responsible for ensuring that:

- (a) members have relevant experience and/or expertise;

- (b) members undertake:
  - (i) appropriate induction, which could include mentoring by a current HREC member, and
  - (ii) continuing education;
- (c) review of research proposals is thorough;
- (d) review processes and procedures are expeditious;
- (e) decisions are transparent, consistent, and promptly communicated;
- (f) actual and potential conflicts of interest that may affect research and its review are identified and managed (see *Chapter 5.4: Conflicts of interest*, page 89–90);
- (g) membership of the HREC is made public in annual reports or by other routine processes, and is available to researchers submitting research proposals to that HREC;
- (h) good communication between the institution/s, the HREC and researchers is promoted;
- (i) the workload of the HREC does not compromise the quality and timeliness of ethical review; and
- (j) any institution using the HREC can be assured the HREC is operating in accordance with this National Statement.

### Composition of HRECs

5.1.29 The minimum membership of an HREC is eight. As far as possible:

- (a) there should be equal numbers of men and women; and
- (b) at least one third of the members should be from outside the institution for which the HREC is reviewing research.

<sup>5</sup> Where the context is the establishment and maintenance of an HREC, ‘institutions’ also includes any body or agency that establishes an HREC but does not conduct human research.

5.1.30 This minimum membership is:

- (a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
- (b) at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- (c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- (d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- (e) at least one lawyer, where possible one who is not engaged to advise the institution; and
- (f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

5.1.31 No member may be appointed in more than one of the categories listed in paragraph 5.1.30, but institutions are encouraged to establish a pool of inducted members in each category. These members may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review.

5.1.32 Wherever possible one or more of the members listed in 5.1.30 should be experienced in reflecting on and analysing ethical decision-making.

5.1.33 The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.

### Appointment of HREC members

- 5.1.34 Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.
- 5.1.35 Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion.
- 5.1.36 Members should be provided with a formal notice of appointment.

### HREC procedures

- 5.1.37 An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review, including procedures for:
  - (a) frequency of meetings;
  - (b) attendance at meetings;
  - (c) conduct and structure of meetings and deliberations;
  - (d) preparation of agendas and minutes;
  - (e) timely distribution of papers before meetings;
  - (f) presentation of applications for ethical review;
  - (g) timely consideration and review of applications;
  - (h) managing conflicts of interest (see paragraphs 5.4.1 to 5.4.6, page 89–90);

- (i) communicating with researchers, including face to face, by telephone and in writing (including email) (see paragraphs 5.2.13 to 5.2.15, page 84);
- (j) reporting on its activities to the institution;
- (k) methods of decision making;
- (l) prompt notification of decisions;
- (m) record keeping (see paragraphs 5.2.23 to 5.2.27, page 85);
- (n) monitoring of approved research (see paragraphs 5.5.1 to 5.5.5, page 91);
- (o) reporting and handling of adverse events;
- (p) receiving and handling of complaints (see paragraphs 5.6.1 to 5.6.7, page 93);
- (q) advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.9, page 92);
- (r) attendance, as observers, of people other than members or researchers (see paragraph 5.2.18, page 84) at meetings;
- (s) fees, if any, to be charged; and
- (t) appropriate confidentiality of the content of applications and the deliberations of review bodies.

# CHAPTER 5.2: RESPONSIBILITIES OF HRECS, OTHER ETHICAL REVIEW BODIES, AND RESEARCHERS

## GUIDELINES

### Review body procedures

5.2.1 Institutions that set up non-HREC levels of ethical review should ensure that they have good working procedures for those levels. These should include the procedures from paragraph 5.1.37 (page 81) and paragraphs 5.2.24 to 5.2.27 that are necessary for sound review at each of those levels.

### Review body member responsibilities

5.2.2 Each member of an ethical review body is responsible for deciding whether, in his or her judgement, a proposal submitted to the review body meets the requirements of this National Statement and is ethically acceptable.

5.2.3 To fulfil that responsibility, each member of a review body should:

- (a) become familiar with this National Statement, and consult other guidelines relevant to the review of specific research proposals;
- (b) prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences; and
- (c) attend continuing education or training programs in research ethics at least every three years.

5.2.4 Members of a review body should disclose to it any actual or potential conflict of interest, including any financial or other interest or affiliation, that bears on any research coming before the review body (see paragraph 5.4.5, page 89).

### Researcher responsibilities

5.2.5 In each research proposal, the researcher/s should demonstrate that the research has merit and reflects the ethical values of justice, beneficence and respect for humans (see paragraph 1.1, page 12).

5.2.6 Research proposals should be clear and comprehensive, and written in lay language.

5.2.7 A researcher should disclose to the review body the amount and sources or potential sources of funding for the research.

5.2.8 A researcher developing or designing a research proposal involving two or more institutions should inform them all at an early stage in this process.

5.2.9 A researcher should keep an auditable record of any research he or she is undertaking that is exempted from ethical review in accordance with paragraphs 5.1.22 and 5.1.23 (page 79).

5.2.10 A researcher should disclose to the review body any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on the research (see *Chapter 5.4: Conflicts of interest*, page 89–90).

5.2.11 When reporting the research, a researcher should again disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on the research.

5.2.12 For researcher responsibilities in relation to monitoring, see *Chapter 5.5: Monitoring approved research*, page 91–92.

## Good communication between review bodies and researchers

- 5.2.13 Good ethical review requires open communication between review bodies and researchers, and a shared commitment to the review process. The process should not be adversarial. Institutions should encourage this shared commitment by promoting:
- (a) awareness of this National Statement among researchers; and
  - (b) ready accessibility of review bodies and their staff to researchers.

5.2.14 Misunderstandings can often arise when only written communication is used. From the outset review bodies should encourage informal communication with researchers, and should consider face-to-face meetings to resolve issues about research proposals that have not been resolved by written or telephone communication.

5.2.15 Open communication of these kinds has implications for the resourcing of review bodies (see paragraphs 5.1.18, page 79, and 5.1.26, page 80).

## Participants' interests

5.2.16 Information about research should be presented to participants in ways that help them to make good choices about their participation, and support them in that participation. These ways must take into account:

- (a) whether the information is best communicated through speech, writing, some other way, or a combination of these;
- (b) the need for accurate and reliable translation (written and/or oral) into a participant's first language or dialect;
- (c) culture and its effects on how language (English or other) is understood;
- (d) educational background and level;

- (e) age;
- (f) visual, hearing or communication impairment.

5.2.17 A review body should consider consulting a participant advocate to help it assess whether a proposal under consideration adequately provides for participants' decision making and understanding.

## Researchers or experts at review body meetings

5.2.18 A review body (HREC or other) may invite researcher/s, and researchers may request, to be present for discussion of their proposed research.

5.2.19 A review body may seek advice from experts to help in considering a research proposal (eg, as in paragraph 5.1.33, page 81). Such experts should be bound by the same confidentiality requirements as the review body members. Any conflicts of interest they may have should be disclosed and managed (see paragraphs 5.4.1 to 5.4.6, page 89–90).

5.2.20 Communication between a research sponsor and a review body should be avoided where it may, or may be perceived to, influence the ethical review and approval of the project.

## Making and communicating decisions

5.2.21 A review body may approve, request amendment of, or reject a research proposal on ethical grounds.

5.2.22 The review body must clearly communicate its decision to the researcher/s:

- (a) Where a proposal is approved, communication must be in writing (which may include email) and should include an explicit statement that the proposal meets the requirements of this National Statement.

- (b) Where amendments are requested, communication may be written or, where appropriate, informal (see paragraph 5.2.14). Reasons should be given for the requested amendments.
  - (c) Where a proposal is rejected, communication of the rejection must be in writing (which may include email) and should include reasons linked to this National Statement.
  - (m) relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.
- 5.2.25 In addition, a review body should retain on file a copy of each research proposal and application for ethical approval, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved.
- 5.2.26 A review body should record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to this National Statement.

## Documents and records

5.2.23 All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the review body.

5.2.24 A review body should maintain a record of all research proposals received and reviewed, including at least the:

- (a) name/s of the institution/s to which the research approval is provided;
- (b) project identification number/s;
- (c) name/s of principal researcher/s;
- (d) title of the project;
- (e) correspondence between the review body and the researcher about the review;
- (f) acceptance or rejection of any changes to the proposal;
- (g) proposed date of completion of the proposal;
- (h) formal advice of final ethical approval or non-approval, with date;
- (i) terms and conditions, if any, of approval of any proposal;
- (j) duration of the approval;
- (k) name of any other review body whose opinion was considered;
- (l) mechanisms to be used to monitor the conduct of the research; and

5.2.27 Where more than one review body has reviewed a research proposal, each such review body should record, as far as possible (see paragraph 5.3.3, page 87):

- (a) details of other review body/ies involved;
- (b) the decision/s of each other review body; and
- (c) details of any amendments required by each other review body.

## HREC meetings

5.2.28 As far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend (see paragraphs 5.1.29 to 5.1.32, page 80–81). Meeting papers should be provided enough in advance to enable members to be fully informed.

5.2.29 Decisions by an HREC about whether a research proposal meets the requirements of this National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership (see paragraph 5.1.30, page 81). This exchange should, ideally, take place at a meeting with all those members present.

- 5.2.30 Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.
- 5.2.31 An HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.

# CHAPTER 5.3: MINIMISING DUPLICATION OF ETHICAL REVIEW

## INTRODUCTION

Research projects that may generate duplication of ethical review in Australia include:

- a research project conducted at more than one institution, either by the same or different researchers;
- a research project conducted jointly by researchers affiliated with different institutions;
- a research project conducted at one institution by a researcher affiliated with another institution, for example, a university-based researcher conducting research at a hospital;
- a research project approved at one institution and transferred to another, for example, when a researcher changes institutions; and
- any other research for which more than one institution has responsibility for ethical review and approval.

## GUIDELINES

- 5.3.1 Wherever more than one institution has a responsibility to ensure that a human research project is subject to ethical review (see paragraph 5.1.1, page 77), each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review.
- 5.3.2 Different institutions that regularly have review responsibilities for the same research (for example, universities and related teaching hospitals) should agree on a single review body to review the research.

- 5.3.3 Where an institution decides to rely on ethical review by a body it has not established, it should undertake:
- (a) to identify any local circumstances relevant to the ethical review of its research, disclose these circumstances to the review body/ies, and provide for their management;
  - (b) to exchange relevant information and advice with the review body/ies;
  - (c) not to duplicate an existing, duly authorised scientific/technological/methodological assessment of the research;
  - (d) to establish the roles, if any, the institution and the review body/ies may have in monitoring the research;
  - (e) to inform participants if the research is discontinued; and
  - (f) to adopt any other administrative procedures that will avoid unnecessary duplication of ethical review.

- 5.3.4 Where paragraphs 5.3.1 to 5.3.3 apply, researchers should inform the ethical review body that reviews and approves the research:
- (a) of all other sites at which the research will be conducted, and of the name and location of any other body that will conduct an ethical review of the research; and
  - (b) of any previous decisions made about the research by other review bodies (in Australia or elsewhere).

# CHAPTER 5.4: CONFLICTS OF INTEREST

## INTRODUCTION

A conflict of interest in the context of research exists where:

- a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or
- an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.

A conflict of interest may compromise the research process itself and/or the institutional processes governing research, and may lead researchers or institutions to base decisions about the research on factors outside the research requirements.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about an individual's integrity or an institution's management practices.

## GUIDELINES

- 5.4.1 Institutions should establish transparent processes to identify and manage actual and potential conflicts of interest involving:
- (a) the institution itself;
  - (b) researchers; or
  - (c) ethical review bodies, their members or advisors.

- 5.4.2 An institution with a conflict of interest bearing on research should inform relevant ethical review bodies about the conflict.

5.4.3 Ethical review bodies should see that measures are adopted to manage conflicts of interest involving researchers (see paragraph 5.2.10, page 83). These measures may include requiring that:

- (a) the information be disclosed to research participants;
- (b) a person other than the researcher make the initial approach to participants;
- (c) the information be disclosed in any report of the research;
- (d) the research be conducted by another researcher; or
- (e) the research not be conducted.

5.4.4 Where an ethical review body becomes aware that there may be a conflict of interest involving the institution, the review body should notify the institution.

5.4.5 An ethical review body should require its members, and also any experts whose advice it seeks, to disclose any actual or potential conflict of interest in research to be reviewed, including any:

- (a) personal involvement or participation in the research;
- (b) financial or other interest or affiliation; or
- (c) involvement in competing research.

The review body should adopt measures to manage such conflicts. In the case of members these measures may include exclusion from a meeting, or from some or all of the body's deliberations, or in the case of expert advisors, requesting only written advice from them.

- 5.4.6 Sometimes a researcher who discloses the fact that he or she has a conflict of interest may have an ethically acceptable reason for not disclosing what the conflict is, for example, that this might breach another person's privacy. The researcher may then remain involved in the research only if the review body is satisfied that the conflict can be managed without its nature being disclosed.

# CHAPTER 5.5: MONITORING APPROVED RESEARCH

## INTRODUCTION

Monitoring of research here refers to the process of verifying that the conduct of research conforms to the approved proposal. Responsibility for ensuring that research is reliably monitored lies with the institution under which the research is conducted.

Mechanisms for monitoring can include:

- (a) reports from researchers;
- (b) reports from independent agencies (such as a data and safety monitoring board);
- (c) review of adverse event reports;
- (d) random inspections of research sites, data, or consent documentation; and
- (e) interviews with research participants or other forms of feedback from them.

## GUIDELINES

### Monitoring approved research

- 5.5.1 Each institution has ultimate responsibility for ensuring, *via* its research governance arrangements, that all its approved research is monitored.
- 5.5.2 The frequency and type of monitoring should reflect the degree of risk to research participants.
- 5.5.3 Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies, and take prompt steps to deal with any unexpected risks.

For monitoring of approved clinical research, see paragraphs 3.3.19 to 3.3.22 (pages 36–37).

- 5.5.4 Researchers are responsible for notifying the review body that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.
- 5.5.5 At regular periods – reflecting the degree of risk, and at least annually and at the completion of the project – researchers should provide reports to the relevant review body/ies and institution/s, including information on:
  - (a) progress to date, or outcome in the case of completed research;
  - (b) maintenance and security of records;
  - (c) compliance with the approved proposal; and
  - (d) compliance with any conditions of approval.

### Suspension or cessation of research

- 5.5.6 Researchers should inform the relevant institution/s, the review body/ies that approved the research and, wherever possible, the research participants, if the research project is to be discontinued before the expected date of completion, and why. For research at more than one site, or research where there has been multiple ethical review, it must be clearly established, before the research begins, how this information will be communicated.

- 5.5.7 Where a review body finds reason to believe that continuance of a research project will compromise participants' welfare, it should immediately seek to establish whether ethical approval for the project should be withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.
- 5.5.8 Where ethical approval for a research project is withdrawn:
- (a) the researcher, the institution/s and, where possible, the participants should be informed of the withdrawal;
  - (b) the institution must see that the researcher promptly suspends the research and makes arrangements to meet the needs of participants; and
  - (c) the research may not be resumed unless either
    - (i) the researcher subsequently establishes that continuance will not compromise participants' welfare; or
    - (ii) the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved.
- 5.5.9 If an institution or review body considers that urgent suspension of research is necessary before the process described in paragraphs 5.5.7 and 5.5.8 is undertaken, the instruction to stop should come *via* the management of the institution.
- 5.5.10 In the light of reports received under paragraph 5.5.3 and paragraph 5.5.5, review bodies may require researchers to amend research procedures to protect participants. If such amendments cannot achieve that end, a review body may rely on the provisions of paragraphs 5.5.6 to 5.5.9.

# CHAPTER 5.6: HANDLING COMPLAINTS

## INTRODUCTION

Institutions may receive complaints about researchers or the conduct of research, or about the conduct of a Human Research Ethics Committee (HREC) or other ethical review body. Complaints may be made by participants, researchers, staff of institutions, or others. All complaints should be handled promptly and sensitively.

The *Australian code for the responsible conduct of research* describes ‘research misconduct’ and specifies institutional processes for dealing with it. Where complaints about researchers or research raise the possibility of misconduct fitting this description, they should be dealt with under those processes. Where complaints about researchers are serious and fall outside that description of research misconduct, they should be handled under institutional processes for dealing with other forms of misconduct, for example harassment or bullying.

There can be justifiable differences of opinion as to whether a research proposal meets the requirements of this National Statement. For this reason, while this chapter provides for complaints about the process of review, it does not provide for appeals by researchers against a final decision to reject a proposal.

## GUIDELINES

- 5.6.1 To handle complaints about researchers or the conduct of research, institutions should:
- identify a person, accessible to participants, to receive these complaints; and
  - establish procedures for receiving, handling and seeking to resolve such complaints.

- 5.6.2 Where such complaints raise the possibility of ‘research misconduct’ as described in the *Australian code for the responsible conduct of research*, they should be handled in accordance with the ‘research misconduct’ processes specified in that document.
- 5.6.3 Where complaints about researchers allege serious misconduct that falls outside the range of ‘research misconduct’ as described in the *Australian code for the responsible conduct of research*, they should be dealt with under institutional processes for dealing with other forms of misconduct, for example harassment or bullying.
- 5.6.4 Institutions should also establish procedures for receiving, handling and seeking to resolve complaints about the conduct of review bodies in reviewing research proposals.
- 5.6.5 Where these complaints cannot be readily resolved by communication between the complainant and the review body that is the subject of the complaint, complainants should have access to a person external to that review body to handle the complaint.
- 5.6.6 Institutions should identify a person or agency external to the institution to whom a person can take a complaint that has not been resolved by the processes referred to in paragraphs 5.6.1 to 5.6.5.
- 5.6.7 Institutions should publicise their complaints-handling procedures.

# CHAPTER 5.7: ACCOUNTABILITY

## INTRODUCTION

Responsibility for the ethical design, review and conduct of human research is exercised at different levels, from the detail of research conduct to the more general oversight of review and funding. Accordingly, responsibility is exercised at the different levels by:

- researchers (and where relevant their supervisors);
- Human Research Ethics Committees (HRECs) and other ethical review bodies;
- institutions whose employees, resources or facilities are involved;
- funding organisations;
- agencies that set standards; and
- governments.

The line of accountability for these responsibilities runs:

- from researchers to review bodies and institutions;
- from review bodies and institutions to funders and other agencies;
- from agencies to government; and
- from government to the Australian public.

Typically, this accountability involves reporting from one level to the next.

## GUIDELINES

5.7.1 Researchers have responsibilities for the ethical design and conduct of research. The measures of accountability by which researchers demonstrate, to institutions and to review bodies, fulfilment of those responsibilities appear in *Chapter 5.1: Institutional responsibilities, Chapter 5.2: Responsibilities of HRECs, other ethical review bodies and researchers*,

and paragraph 3.3.22, page 37, on the monitoring of approved clinical research. Researchers also have responsibilities under the *Australian code for the responsible conduct of research*.

5.7.2 Review bodies have responsibilities for the ethical review of research. The measures of accountability by which review bodies demonstrate to institutions their fulfilment of those responsibilities appear in *Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers*.

5.7.3 Institutions have responsibilities:

- (a) to ensure that ethical review of research occurs. These responsibilities are set out in *Chapter 5.1: Institutional responsibilities*; and
- (b) for the conduct of research. These responsibilities are set out in the *Australian code for the responsible conduct of research*. They include ensuring that research is both sound and lawful, and is conducted or supervised by educated and experienced researchers.

5.7.4 In addition to providing information annually, institutions shall, on reasonable request, provide other information about their ethical review processes to the NHMRC.

5.7.5 Institutions that are in receipt of NHMRC research funding, or intend to remain eligible for it, must be registered with the NHMRC. Registration will include information about any HREC/s or other review bodies which the institution has decided to use or has established.

- 5.7.6 The deed of agreement attached to any NHMRC funding requires that institutions attest annually to the NHMRC in writing that their research governance and ethical oversight processes remain compliant with this National Statement and the *Australian code for the responsible conduct of research.*

# APPENDIX: PROCESS REPORT

## BACKGROUND

The *National Statement on Ethical Conduct in Research Involving Humans* ('the National Statement') 1999 has been revised in line with the National Health and Medical Research Council (NHMRC) policy that all its guidelines be reviewed at least every five years. In September 2003 the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC, established a working committee to review the National Statement. The revision was undertaken jointly by the NHMRC, the Australian Research Council (ARC), and the Australian Vice Chancellors' Committee (AVCC), and the Working Committee consisted of the following members from AHEC, the ARC and the AVCC:

### Working Committee

Dr Christopher Cordner (Chair)	Member of AHEC 2003 - 2006 triennium
Dr Kerry Breen	Chair of AHEC 2003 - 2006 triennium
Mr Christopher Coyne	Member of AHEC 2003 - 2006 triennium, Member of AHEC 2006 - 2009 triennium
Professor Joy Damousi	AVCC Nominee
Associate Professor Terry Dunbar	Member of AHEC 2003 - 2006 triennium, Member of AHEC 2006 - 2009 triennium
Professor Graeme Hugo	ARC Nominee
Reverend Professor John Morgan	Member of AHEC 2003 - 2006 triennium
Professor Elim Papadakis	ARC Nominee
Associate Professor Wendy Rogers	Member of AHEC 2003 - 2006 triennium
Professor Doreen Rosenthal AO	Member of AHEC 2003 - 2006 triennium
Mr Noel Spurr OAM	Member of AHEC 2003 - 2006 triennium
Professor Jane Stein-Parbury	AVCC Nominee.
Ms Fiona Stoker	Member of AHEC 2003 - 2006 triennium
Professor Colin Thomson	NHMRC consultant 2003 - 2006 triennium, Chair AHEC 2006 - 2009 triennium.
Dr Nicholas Tonti-Filippini	Member of AHEC 2003 - 2006 triennium, Member of AHEC 2006 - 2009 triennium
Reverend Bill Uren	Member of AHEC 2003 - 2006 triennium

### Secretariat

Ms Nerida Lawrentin	September 2003 - June 2005
Ms Nicola Cooper	June 2005 - December 2006
Mr Matthew Sammels	May 2006 - March 2007

### Consultant

Dr Angela Kirsner	Technical Writer
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## Process

Following the development of a first draft, and in accordance with section 13 of the *National Health and Medical Research Council Act 1992*, Australian Health Ethics Committee (AHEC) undertook public consultation from January to March 2005. This consultation resulted in 178 submissions. A second draft was then prepared taking into account the submissions received. A further consultation was undertaken from January to March 2006, which resulted in 184 submissions. These submissions informed the final draft. Details of the submissions that were not confidential were placed on the website during the revision process at:

**<http://www.nhmrc.gov.au/ethics/human/ahec/consultation/submissions/statement.htm>**

**<http://www.nhmrc.gov.au/ethics/human/ahec/consultation/submissions/statementsec.htm>**

Experts were consulted throughout the redrafting process on a number of issues. A workshop was also held with several institutions that are known to have developed models for devolving review of low risk research, to determine the methods of streamlining ethical review of research.

After completion of the final draft and agreement by the AHEC from the 2006 – 2009 triennium, both the Australian Research Council and the Australian Vice Chancellors' Committee were invited to approve the final draft. This agreed version was then presented to the Council of the NHMRC at its 164<sup>th</sup> Session in March 2007 for consideration.

At that Session the Council agreed to advise the CEO that the final draft should be issued.

# GLOSSARY

## **accountability**

The measures by which researchers, review bodies and institutions can demonstrate that their responsibilities have been, or are being, fulfilled. Typical accountability measures involve reporting from one level of the hierarchy to a higher (or more general) level.

## **adverse device event**

A clinical sign, symptom or condition that is causally related to the device implantation procedure, the presence of the device, or the performance of the device system.

## **adverse drug reaction**

Any noxious and unintended response to an unapproved medicinal product, related to any dose. The phrase “response to an unapproved medicinal product” means that a causal relationship between the product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. (‘Unapproved medicinal product’ here includes approved products used at levels or in ways that are unapproved).

or

A noxious and unintended response to a drug that occurs at doses of marketed medical products normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

## **adverse event (device)**

Any undesirable clinical occurrence in a subject, whether it is considered to be device-related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

## **beneficence**

Doing good to others: here also includes ‘non-maleficence’, avoiding doing harm.

## **benefit**

That which positively affects the interests or welfare of an individual or group.

## **blood relatives**

Close genetic relatives.

## **capitation payments**

Per capita payments to researchers, usually from sponsors of clinical trials, for recruiting participants for research.

## **child**

Subject to law in the relevant jurisdiction, a minor who lacks the maturity to make a decision whether or not to participate in research.

*See also*  
young person

## **clinical trial**

A form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure.

## **confidentiality**

The obligation of people not to use private information – whether private because of its content or the context of its communication - for any purpose other than that for which it was given to them.

## **conflict of interest**

In the research context: where a person’s individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or where an institution’s interests or responsibilities have the potential to influence the carrying out of its research obligations.

## **consent**

A person’s or group’s agreement, based on adequate knowledge and understanding of relevant material, to participate in research.

## **data**

Pieces of information.

**databank**

A systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable.

**deception**

Where relevant material is withheld from research participants, and/or they are intentionally misled about procedures and/or purposes of research.

**discomfort**

A negative accompaniment or effect of research, less serious than harm.

**ethical / unethical**

Right or morally acceptable / wrong or morally unacceptable.

**ethical review**

Review of research by an HREC or other body.

**ethical review body**

Body set up to carry out ethical review of human research.

**ethics**

The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

**genetic material**

Any source of DNA or RNA that can be tested to obtain genetic information. It includes cells (whether isolated or as part of tissues) and extracted DNA and RNA.

**harm**

That which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.

**HREC**

Human Research Ethics Committee.

**human tissue**

The substance, structure, and texture of human organs or body parts when separated from human beings; includes blood, blood components and waste products.

**identifier**

Details attached to data, such as name and/or contact information, that identify an individual. (It may remain possible to identify an individual even after all identifiers have been removed, if a code number has been assigned and there is access to the code, or if the data or tissue can be cross-linked to other data or tissue banks).

**inconvenience**

A minor negative accompaniment or effect of research, less serious than discomfort.

**individually identifiable data**

Data from which the identity of a specific individual can reasonably be ascertained.

**integrity**

Honesty and probity as qualities of character and behaviour.

**justice**

Regard for the human sameness shared by all human beings, expressed in a concern for fairness or equity. Includes three aspects of justice: procedural justice, involving fair methods of making decisions and settling disputes; distributive justice, involving fair distribution of the benefits and burdens of society; and corrective justice, involving correcting wrongs and harms through compensation or retribution.

**limited disclosure**

Not disclosing to research participants all of the aims and/or methods of the research.

**low risk (research)**

Research in which the only foreseeable risk is one of discomfort.

**monitoring (of research)**

The process of verifying that the conduct of research conforms to the approved proposal.

**negligible risk**

Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

**non-identifiable data**

Data that have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known they are about the same data subject, although the person's identity remains unknown,

**non-therapeutic (intervention)**

An intervention not directed towards the benefit of the individual but rather towards improving scientific knowledge or technical application, or the benefit of others.

**participant (in research)**

Anyone who is the subject of research in any of the ways set out on page 8.

**personal information**

Information by which individuals can be identified.

**placebo (in research)**

A substance not containing an active agent under study, administered to some participants to compare the effects of the active agent administered to other participants.

**privacy**

A domain within which individuals and groups are entitled to be free from the scrutiny of others.

**protocol**

A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

**qualitative research**

Research involving the studied use of empirical materials such as case studies, personal experience, life stories, interviews, observations, and cultural texts.

**re-identifiable data**

Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.

**research**

Includes at least investigation undertaken to gain knowledge and understanding or to train researchers.

**research misconduct**

Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. Also includes failure to follow research proposals approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, other animals or the environment. Also includes the wilful concealment or facilitation of research misconduct by others

**respect for human beings**

Recognition that each human being has value in himself or herself.

**risk**

The function of the magnitude of a harm and the probability that it will occur.

**serious adverse event**

Any untoward medical occurrence that:

- results in death;
- is life-threatening (NOTE: The term "life-threatening" refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe);
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;

- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

**serious unexpected suspected adverse reaction**

A serious adverse event (see definition above) for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

**sponsor**

An individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of research.

**therapeutic (intervention)**

Intervention directed towards the wellbeing of the individual concerned.

**unexpected adverse drug reaction**

An adverse reaction, the nature or severity of which is not consistent with the applicable scientific information (e.g. Investigator's Brochure for an unapproved investigational product or Product Information (PI) document or similar for an approved, marketed product).

**voluntary participation**

Participation that is free of coercion and pressure.

**young person**

In the context of this National Statement, a minor who (subject to the law in the relevant jurisdiction) may have the maturity to make a decision whether or not to participate in research.

*See also*  
child

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**The University of Melbourne**

## **Policy on the Management of Research Data and Records**

Approved by: Academic Board, 24 February 2005  
Enquiries: Manager, Records Services Department, tel: 8344 6996  
Web: [www.unimelb.edu.au/records/research.html](http://www.unimelb.edu.au/records/research.html)

**The University of Melbourne**  
**Policy on the Management of Research Data and Records**

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# **Policy on the Management of Research Data and Records<sup>1</sup>**

## **1. Purpose of the Policy**

The retention of complete, accurate and retrievable results is integral to the research process. Good research practice entails the retention of research data and records for periods of at least five years after the publication of results (or longer depending on regulatory or sponsor requirements and archival/historical value). This allows for the discussion of data and research methods with colleagues and for verification of the research such as might be required to refute allegations of falsification of data.

The purpose of this Policy is to assist departments and individual researchers to fulfill their responsibilities with respect to the storage and retention of data and records associated with, and arising from, their research activities.

## **2. Key Principles**

The [University's Code of Conduct for Research](#) specifies that:

- research methods and results should be open to scrutiny and debate;
- data must be retained intact for a period of at least five years from the date of any publication which is based upon it;
- research units and departments must establish formally documented procedures for retention of data; and
- research workers must comply with these retention procedures.

Researchers should ensure that:

- Research data and records are accurate, complete, authentic and reliable. Research data and records should correctly reflect what was communicated, decided or done. Research data should be recorded in a form that is adequate for verification of research results.
- Research data and records include sufficient detail to establish their authenticity and confirm the validity of the conclusions and to enable responses to questions that may result from unintentional error or misinterpretation. Statistical formulas, equipment calibration, experiment set up, equipment operation logs, concentration of solutions, codebooks, computer data input files used to generate data may be crucial elements in establishing authenticity and validity.

The requirements described in this Policy are also informed by the [Joint NHMRC / AV-CC Statement and Guidelines on Research Practice](#) which specifies:

- Data (including electronic data) must be recorded in a durable and appropriately referenced form. Data management should comply with relevant privacy protocols, such as the Australian Standard on personal privacy protection.
- The department or research unit must establish procedures for the retention of data and for the keeping of records of data held.
- Data must be held for sufficient time to allow reference. For data that is published this may be for as long as interest and discussion persists following publication. It is recommended that the minimum period for retention is at least 5 years from the date of publication but for specific types of research, such as clinical research, longer retention periods apply
- Wherever possible, original data must be retained in the department or research unit in which they were generated. Individual researchers should be able to hold copies of the data for their own use. Retention solely

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<sup>1</sup> This Policy was approved by Academic Board on 24 February 2005. It replaces the *Guidelines for the Management of Research Data and Records* (Oct 1997).

by the individual researcher provides little protection to the researcher or the institution in the event of an allegation of falsification of data.

- Data related to publications must be available for discussion with other researchers. Where confidentiality provisions apply (for example, where the researchers or institution have given undertakings to third parties, such as the participants in the research), it is desirable for data to be kept in a way that reference to them by third parties can occur without breaching such confidentiality.
- Confidentiality agreements to protect intellectual property rights may be agreed between the institution, the researcher and a sponsor of the research. Where such agreements limit free publication and discussion, limitations and restrictions must be explicitly agreed.
- It is the obligation of the researcher to enquire whether confidentiality agreements apply and of the Head of the Department or research unit to inform researchers of their obligations with respect to these provisions.
- All confidentiality agreements should be made known at an early stage to the head of the research institution, or nominated representative.
- The procedures formulated by institutions must include guidelines on the establishment and ownership of and access to data bases containing confidential information, and any limits on this.
- When the data are obtained from limited access data-bases, or via a contractual arrangement, written indication of the location of the original data, or key information regarding the data-base from which it was collected, must be retained by the researcher or research unit.
- Researchers must be responsible for ensuring appropriate security for any confidential material, including that held in computing systems. Where computing systems are accessible through networks, particular attention to security of confidential data is required. Security and confidentiality must be assured in a way that copes with multiple researchers and the departure of individual researchers.

### **3. Definitions**

For the purposes of this document the following definitions are used:

- **Confidential Research Data and Records**

Confidential research data and records are those which, in research involving humans, link the research participant with the research study.

It includes identifying information such as names and addresses, signed consent forms, master lists of names or matching codes for a current study or similar listings which may be held for a period of time for a follow up study; data which is sensitive (for example identified highly personal data, data which may be incriminating either to the provider of the data or to a third party, personal data which although not identified by name is in such a form (such as a case study or life history that it may be able to identify the subject; data which even if not sensitive may identify people (for example photographs, videotape, audiotape).

- **Electronic Data and Records**

Data and records created and maintained by means of electronic equipment and which may also be communicated through electronic means.

- **Research**

The careful study and investigation of new information concerning a particular subject.

- **Research Data**

Data are facts, observations or experiences on which an argument, theory or test is based. Data may be numerical, descriptive or visual. Data may be raw or analysed, experimental or observational. Data includes: laboratory notebooks; field notebooks; primary research data (including research data in hardcopy or in computer readable form); questionnaires; audiotapes; videotapes; models; photographs; films; test responses. Research collections may include slides; artefacts; specimens; samples.

- **Research Records**

Records are documents containing data or information of any kind and in any form (including both paper-based and electronic format) created or received by an organisation or person for use in the course of their work and subsequently kept by that organisation or individual as evidence of that work, or because of the informational value of the data that such documents contain. Records associated with the research process include correspondence (including electronic mail as well as paper-based correspondence); project files; grant applications; ethics applications; technical reports; research reports; master lists; signed consent forms; and information sheets for research participants.

- **Researchers**

A researcher is any staff member who in the course of their employment conducts research.

- **Student Researchers**

A student researcher is any honours or postgraduate student undertaking a research thesis.

## 4. Responsibilities

### 4.1 Researchers

Researchers are responsible for:

- Conducting research in accordance with the provisions of the Code of Conduct for Research and other relevant University and departmental policy and procedures;
- Developing appropriate procedures for the collection, storage, use and retention of the research data and records associated with their research program, including confidential research data and records;
- Establishing and documenting clear procedures for the collection, ownership and storage of research data and records when involved in a joint research project, collaborative research or research undertaken in accordance with a contractual agreement. (When a research project is undertaken under a contractual agreement the Principal Investigator has overall responsibility for the management of data and records. In the case of multi-institutional projects the institution of the Principal Investigator is ultimately responsible.);
- Ensuring that the integrity and security of their data and records is maintained, and that this material is stored in an identifiable and retrievable way;
- Reporting any breach of confidentiality to the Head of Department;
- Negotiating with their Head of Department for the relocation of data and records within the University; and
- Making recommendations to the Head of Department for destruction of research data and records in accordance with all of the relevant requirements and legislation.

### 4.2 Heads of Department

Heads of Departments are responsible for:

- Authorising the procedures adopted by researchers and student researchers (following consultation with their supervisor) for the storage of their research data and records;
- Authorising the destruction of research data and records on the recommendation of the researcher;
- Authorising the destruction of student researchers' data and records;
- Negotiating with researchers for the relocation of research data and records within the University;
- Ensuring that staff conducting human research, and students under their supervision, are aware of all of their responsibilities such as the confidentiality of research data and records collected in the course of their research;
- Ensuring that staff are aware of the need to report any breach of confidentiality to the Head of Department;

- Ensuring that staff conducting human research are aware of their responsibilities to ensure that their practices, and those of students under their supervision, conform to University and departmental policy and procedures;
- Establishing and implementing departmental procedures for the storage and retention of research data and records;
- Ensuring that University and departmental policy and procedures are disseminated to researchers;
- Providing storage space for research data and records that meets security and confidentiality requirements, particularly in the case of human research data and records;
- Assigning the responsibility for the management of central or shared storage area(s) within the department to a staff member;
- Ensuring the provision of expert advice on the storage and retention of electronic data including advice on technological obsolescence and migration requirements; ensuring systems reliability and continuing operation; and facilitating access to electronic data of continuing value over time.

### **4.3 Student Researchers and their Supervisors**

- Student researchers are jointly responsible with their supervisor, for the collection, storage, security and use of research data and records including confidential research data and records, in accordance with University and departmental policy and procedures.
- During the research process, student researchers must establish collection and storage procedures for their research data and records that are acceptable to their supervisor. In certain circumstances research data and records may need to be deposited with the supervisor at specific stages of the research process rather than waiting until the completion of the research project and the thesis submission.
- Student researchers undertaking research involving human participants must negotiate appropriate arrangements for the security of the research data and records with their supervisor. These arrangements should be outlined in their application for ethics clearance.
- In certain circumstances, related for example to confidentiality of data, it may be agreed that the student will store and retain the research data and records outside of the department. In such situations the specified arrangements must be satisfactory to the supervisor and Head of Department, and the department must keep a record of this arrangement in the department register of stored research data and records.
- When submitting a thesis for examination the student researcher should be required to make a declaration that they have complied with the Code of Conduct for Research and that research data and records collected, used and maintained in the conduct of their research will be retained for five years from the point of thesis submission unless publication, or public release of the work of research subsequently occurs, in which case the research data and records will then be retained for five years after publication, or public release, of the work of research. These declarations are included on the form "*Submission of a PhD Thesis: statement by candidate, supervisor and chairperson of examiners*" that must be submitted to the School of Graduate Studies when a PhD thesis is submitted for examination. Such declarations should also be incorporated into Faculty forms for the submission of Masters by Research theses.
- At the point of thesis submission, student researchers must arrange with their supervisor for the storage of their research data and records in the department. This is because the University may need to respond to allegations of falsification of data. It is also required in all cases where the University has filed a patent application to protect commercially exploitable research outcomes. Except where restrictions apply (eg. confidentiality or contract agreements) student researchers may keep a copy of their research data and records for their own use.

### **5. Period of Retention of Data and Records**

- Research data and records should be maintained for as long as they are of continuing value to the researcher and as long as specified by patent law, legislative and other regulatory requirements..
- The minimum retention period for research data and records is five (5) years from the date of any publication or public release of the work of the research.
- Clinical trials require that records and data be retained for a minimum of fifteen (15) years from the date of termination of the study and preferably for the lifetime of the product.

- The Australian Psychological Society advises members that files/records of adult clients should be maintained for a minimum period of seven (7) years from the last date upon which the client received services. In the case of children the records should be kept for a minimum period of seven (7) years after the child reaches the age of 18.
- Time intervals for the retention of data are generally based on those established by external organisations, such as the NHMRC, and may be amended from time to time.
- Funding bodies may have specific requirements for the retention of research data and records.
- Where there are known disciplinary practices or codes establishing norms for retention of research data and records these should be adopted.
- In many instances, departments and researchers will resolve to retain research data and records for a longer period than the minimum requirement.

## **6. Storage of Data and Records**

- Research data and records should be able to be quickly and easily identified and retrieved when required. (Even if access is limited to one person for confidentiality reasons it must be possible to demonstrate that they can be retrieved.)
- Wherever possible research data and records should be stored in the department or the laboratory in which they were generated.
- Research data and records may be retained securely within the department in the researcher's own office, or transferred to a central or shared storage area within the department.
- Responsibility for the management of a central or shared storage area(s) within the department should be formally assigned to a staff member. A departmental register (paper or electronic) should be maintained specifying the location of research data and records including paper, electronic data, and audio-visual data. The departmental register should include a description of the research data and records, the name(s) of the researchers, and the location of the data. Research data and records should be correspondingly boxed and labeled with the researcher's name, project title, date of publication (or date of transfer to the central storage area) and number of boxes eg. Box 1 of 10. When research data and records are relocated or destroyed this action must be recorded in the departmental register. Records must be adequate to establish if data and records have been relocated or destroyed, relevant dates, and the authority on which this action was taken. The proforma [Register of Research Data & Records Stored in Department](#) in Section 13 may be used or adapted as required.
- Where there are multiple investigators or multiple projects it may be appropriate to establish a departmental master file identifying the projects, names, date and location(s) of data and records for the whole study.
- If research data and records need to be stored elsewhere (eg. because of confidentiality requirements), the relevant department (and student's supervisor, if relevant) must be advised of the location and access made available if required. The department should register the location of these data and records in the departmental register of research data and records.
- In some instances data has been obtained from limited access databases or in a contracted project it may not be possible to store the data in the department. In cases such as these a written description of the location of the original data or key information regarding the limited access database from which it was extracted should be kept as part of the research records for the project and recorded on the departmental register.

## **7. Security and Protection**

- Research data and records should be maintained securely to prevent unauthorised access, destruction, alteration or removal, accidental or intended damage or destruction. Refer to the [University's Records Management Policy and Procedures Manual](#)
- Confidential research data and records should be stored securely in lockable filing cabinets or a lockable room with controlled access. When confidential research data and records are stored electronically (for example on a personal computer) precautions should be taken to control access to the research data and records. Such precautions include password access and 'locking' datafiles. The signed consent forms for a particular project

should be stored separately from the collected research data for that project. Refer to the [University IT Security Policy](#) for information about secure storage and disposal of electronic data and records.

- Audio-visual data. If there is only one copy it may be advisable to make another copy and retain the original as a master copy.
- Electronic data and records. Refer to the [University's Records Management Policy and Procedures Manual](#). There is also advice in [Managing Your Electronic Mail](#).
- Web Pages. Refer to the University's [Web Archiving Strategy \(WAS\) Project](#) for information on how to archive web pages or data collected via the web.

## 8. Access to Research Data and Records

- Research data related to publications should be made available for discussion with other researchers, except where confidentiality provisions prevail (2.1.5 [Code of Conduct for Research](#)). Confidentiality provisions relating to research data and records will apply in circumstances where the University or the researcher has made or given confidentiality undertakings to third parties or where disclosure would involve the unreasonable disclosure of information relating to the personal affairs of any person (including a deceased person) or when confidentiality is required to protect the intellectual property rights (2.1.6 [Code of Conduct for Research](#)). Confidentiality provisions should be recorded on the departmental register.
- When data involving human participants has been collected for research, only the named researchers can have access to it without further permission from the approving human ethics committee.
- In the event of legal action, research data and records may be accessed by the University and its legal advisers to determine their relevance to any litigation and, if relevant, removed for use in the litigation.
- Research data is subject to subpoena including confidential research data and records.
- Researchers should be aware that under the Freedom of Information Act 1982 (Vic), the University is required to allow persons access to documents which are in the University's possession under defined circumstances. Further information may be sought from the [Office of the University Secretary](#) and on the University's website at [Freedom of Information](#).

## 9. Removal or Movement of Data and Records

- The original research data and records must be kept at the University, normally in the department where the research was conducted. This is because the University may need to respond to allegations of falsification of data. It is also required in all cases where the University has filed a patent application to protect commercially exploitable research outcomes.
- In the event of the researcher leaving the University, they may negotiate with the Head of Department to take copies of their research data and records for their own use, but original data and records are to remain in the department.
- If the researcher moves to another department within the University they may make a request to relocate the original data and records to their new department. In such cases the head of the original department is required to authorise the relocation. Refer to the proforma [Register of Research Data & Records Stored in Department](#) in Section 13. The departmental register of research data and records should include all details of the new location and the date when the records were moved.

## 10. Destruction of Records

- The destruction of research data and records should be authorised by the Head of Department on recommendation of the researcher. A record of the recommendation and approval must be maintained in the departmental register. Refer to the proforma [Register of Research Data & Records Stored in Department](#) in Section 13. This form may be used or adapted as required.

- If after five years (or required period) from the completion of the research project the research has not been published or otherwise publicly disseminated for any purpose to any other party, and the researcher declares an intention not to publish the data, the research data and records may be recommended for destruction.
- Research data and records collected, used and maintained by student researchers can be destroyed five years from the point of thesis submission provided there is no continuing value to the supervising staff member, department or University. If publication, or public release, of a work of research occurs after the thesis submission the research data and records should be retained for five years after the publication, or public release, of the work of research. The destruction of student researcher data and records left in the department should be authorised by the Head of Department and the signed record maintained in the department (refer Section 13).
- When confidential research data and records are destroyed it should be done in such a way as to ensure complete destruction of the information. Confidential research data and records in paper format should be shredded. Confidential research data and records in electronic format should be destroyed by reformatting or rewriting. ‘Delete’ instructions are not sufficient to ensure that all systems pointers to the data incorporated in the system software have also been destroyed. For audio-visual tapes a ‘magnetic field bulk eraser’ should be used to degauss the tape (i.e., remove the recording). At the time of destroying confidential data and records, researchers should ensure that they employ the most effective method since this may change over time with technological advances.

## 11. Special Requirements

### 11.1 Laboratory Notebooks

- Laboratory notebooks being the prime record of scientific research should document all aspects of the research process from the conceptualisation of a hypothesis or research problem, through to the formulations of research methodologies, the design of equipment and techniques used, the conduct of experiments and observational data.
- A laboratory notebook should be kept for all scientific projects.
- Separate notebooks must be kept for each project. This is particularly important when undertaking contract research simultaneously with publicly-funded research (eg. NHMRC or ARC grants) in the same or similar subject area to ensure that intellectual property rights remain clear.
- Refer to Section 14. [Instructions for Keeping Experimental Laboratory Notebooks](#).
- Scientific researchers may also find [\*Laboratory Notebooks – A Guide to Good Practice \(Reviewed January 2006\)\*](#) produced by Phillips Ormonde & Fitzpatrick Patent and Trade Mark Attorneys (Melbourne, Australia) to be a useful resource.

### 11.2 Patents

- Where a patent has been granted all research data and records must be retained for the life of the patent (whether granted in Australia or overseas).
- In the cases of commercially exploitable research, and research data and records that concern a patent application filed by the University, it is necessary for original research data to be retained at the University.
- The originals (ie. not copies) of all correspondence, deeds and contracts associated with the commercial exploitation of the patent must be returned to the University’s Patents and Royalties Officer.
- It is often difficult during the research process to identify if a project will result in a patent. For this reason it is advisable in relevant disciplines to maintain research data and records as if the project will produce patentable outcomes. Researchers are required to disclose inventions to the University. This will provide a means of assessing the potential value of the intellectual property.
- Researchers should be aware that there are specific recordkeeping requirements for patent applications in the United States. The standard of proof (for non USA applicants) required for demonstrating ‘first to invent’ is the same as that required as if the invention had occurred in the USA. Therefore recordkeeping in relation to the making and documentation of inventions must comply with US standards. One means of achieving this is

the maintenance of a data notebook in accordance with the [Instructions for Keeping Experimental Laboratory Notebooks](#) in Section 14.

### 11.3 Privacy

- The University Privacy Policy details how the University deals with personal and health information it collects to ensure that it complies with the Information Privacy Act (VIC) 2000 and the Health Records Act (VIC) 2001. This policy outlines the obligations of staff and students if they are dealing with health and personal information. The University takes its privacy obligations very seriously and a breach of the Privacy Policy may have serious consequences for the University and for staff.
- In some instances the University may be contractually bound to comply with Commonwealth privacy laws. This will be when information is received or collected under a contract between the University and a Commonwealth body or agency.
- University researchers who are collecting information from or about individuals for their research should also be aware of the requirements and implications of privacy legislation, both state and federal and any privacy policy of relevant organisations and how this may affect the data collection, storage, use and disclosure of the information they wish to collect.
- Researchers may need to consult:
- [University Privacy Policy](#)

The University of Melbourne Privacy Policy details how the University deals with personal and health information it collects to ensure that it complies with the Information Privacy Act (VIC) 2000 and the Health Records Act (VIC) 2001. In the privacy policy a reference to 'information' is a reference to both health information and personal information.

Privacy Officer: The University's Privacy Officer is the University Secretary Mr Len Currie. He has overall responsibility for privacy issues but privacy is an important issue for all staff.

The Information Privacy Act (VIC) 2000 sets standards for the way Victorian government organisations, statutory bodies and local councils collect and handle personal information (except for health information). There are ten Information Privacy Principles which are the core of the Information Privacy Act. Non-government organisations that work for government under contract may also be covered, depending on the contract.

The Health Records Act (VIC) 2001 creates a framework to protect the privacy of individuals' health information. It regulates the collection and handling of health information. The Act applies to the health, disability and aged care information handled by a wide range of public and private sector organisations. This includes health service providers, and also other organisations that handle such information. Researchers are subject to the act when they collect or handle health information.

Privacy Act 1988 (Cth). Section 14 of the Privacy Act sets out eleven Information Privacy Principles (IPPs) to govern the conduct of Commonwealth agencies in the way those agencies collect, use, storage and disclose personal information. Section 95 of the Privacy Act (Appendix 2) provides a process to resolve any conflict that may arise between the public interest in privacy and the public interest in medical research.

Schedule 3 of the amended Privacy Act sets out 10 National Privacy Principles (NPPs) to govern the conduct of private sector organisations in the way those organisations collect use, store and disclose personal information. The NPPs apply to businesses with an annual turnover of \$3 million and all health service providers.

The two sets of Guidelines issued under both Section 95 and Section 95 A of the Privacy Act 1988 provide a framework in which medical research involving personal information collected or disclosed by Commonwealth agencies or private sector organizations, respectively, should be conducted to ensure that an individual's personal information is protected against unauthorised collection or disclosure. The responsibility for applying Section 95 guidelines and Section 95A guidelines lies with the relevant Human Research Ethics Committee.

### 11.4 Research Involving Human Participants

Special additional requirements exist in relation to data and records collected, maintained and used for the purpose of human research. Researchers conducting human research must operate within the framework of

[University guidelines](#) for conducting research projects involving humans and the [NHMRC National Statement on Ethical Conduct in Research Involving Humans \(1999\)](#).

#### **11.4.1 Consent Forms**

The informed consent of participants is a central principle in the conduct of research projects involving human participants. It is the responsibility of the investigator(s) to ensure that consent to participate is both informed and freely given by the participants of their research. Guidelines are provided in the University's Human Research Ethics Guidelines for Informed Consent.

Consent to participate cannot be seen to be either informed or given freely unless the potential participant has available to them a full description of the project in language they can understand, the nature of their participation and the implications in terms of risks and benefits of participating in the research, including information about what will happen to their information, how it will be used, stored and when it will be disposed of. In most research projects participants are given a plain language information sheet with information about the project and a consent form which outlines what the participants will do if they agree to take part and researchers agree. The signed consent form and the information sheet together are proof of the process of informed consent and should be kept together as evidence that the consent to participate was informed and freely given.

In the event of a dispute arising between the researcher and the participant during or after the completion of the project, for example claims that the consent was not informed or freely given or claims of personal injury (physical, psychological or social) as a result of participation in the project, the signed consent form and the information sheet together will be evidence of the process of informed consent. Like all research data and records they may be discoverable in the event of litigation.

It is the researcher's responsibility to maintain, and retain for an appropriate period (5 years minimum), consent forms and the information sheets. Consent forms for a project therefore should be retained for the same period of time as all other research records for the project. Signed consent forms should be stored separately from the data to protect the confidentiality of those who participated in the study. A copy of the plain language information sheet provided to participants should be stored together with the collected data e.g. completed survey forms, so that it is apparent which study the forms are associated with. Consent forms and research data are to be stored separately and securely, for example, in lockable filing cabinets or in password protected files.

#### **11.4.2 Clinical Trials**

Clinical trials require that records and data be retained for a minimum of fifteen (15) years from the date of termination of the study and preferably for the lifetime of the product.

There are specific recordkeeping requirements in relation to planning, conduct, analyses and assessment of clinical trials. These are outlined in the [Therapeutic Goods Administration Note for Guidance on Good Clinical Practice \(July 2000\)](#) which is an internationally accepted standard for designing, conducting, recording and reporting of clinical trials.

### **11.5 Sponsored Research - Conditions of Award (Grant or Contract Research)**

Funding bodies may have specific requirements for retention of research data and records. Researchers should be aware of the conditions of any awards or contracts supporting their research.

Research funded by the ARC, for example, is subject to the [ARC Conditions of Award](#). Each scheme is bound by a Funding Contract/Agreement and includes clauses relating to the research data and records associated with the project or other activity. This information is detailed in those Contracts/Agreements under various headings including *Materials produced under this Agreement/Contract* and *Access to Premises and Records*. The ARC definition of 'material' includes documents, equipment, software, goods, information and data stored by any means.

For example: the following clauses are extracted from the [2004 Discovery - Projects Program Funding Agreement](#)

#### *18. Material produced under this Agreement*

*18.1 The Institution/Organisation shall establish and comply with its own procedures and arrangements for the ownership of all material produced as a result of any Project under this Agreement.*

*18.2 For any Material produced under this Agreement, the Institution/Organisation shall ensure that all Specified Personnel:*

- (a) take reasonable care of, and safely store any data or specimens or samples collected during, or resulting from the conduct of the Project;
- (b) make arrangements acceptable to the ARC for lodgement with an appropriate museum or archive in Australia of data or specimens or samples collected during, or resulting from their Project; and
- (c) include details of the lodgement or reasons for non-lodgement in the Final Report for the Project.

## 11.6 Archival Value

Consideration should be given to the long term preservation of research data and records of archival value. For example data and records that:

- document significant projects that made a major contribution to research;
- document projects that were controversial, subject to extensive debate or aroused wide interest;
- document projects that involve the use of major new or innovative techniques;
- document “first of a kind” process or product or significantly improve on an existing product or application;
- are the work of an eminent researcher such as a widely acknowledged authority in their field or a person who has in some other way achieved prominence;
- have value for research in other disciplines eg. history and philosophy of science, history and sociology.

Where research data and records are thought to be of archival value the researcher should consider depositing the research data and records in an appropriate archives institution.

The [Funding Agreements](#) for ARC Discovery Projects Program, Indigenous Researcher Development Program and Federation Fellowships Program contain specific references to the deposit of data, specimens or samples within appropriate archive for secondary use by other investigators.

Further advice on archival value and archival institutions can be obtained from [The University of Melbourne Archives](#) and [Records Services](#).

## 11.7 Discipline Specific Practices or Codes

Researchers should be aware of, and adopt, the relevant practices or codes within their research discipline that establish norms or best-practice for the retention of research data and records researchers.

*For example:*

ARC Grants and Fellowships states in section 15.8 that “any machine-readable data arising from a project involving research relating to the social sciences should be lodged with the [Australian Consortium for Social and Political Research Inc \(ASPRI\)](#) or any other appropriate archive for secondary use by other investigators. This should normally be done within two years of the conclusion of any fieldwork relating to the Project research. If a Chief Investigator is not intending to do so within the two year period they should include the reasons why in their final report.”

## 11.8 Research and Data Collection in Indigenous Communities

Researchers should be aware of and sensitive to the particular issues raised when undertaking research and conducting research in indigenous communities. In addition to the *Joint NHMRC / AV-CC Statement and Guidelines on Research Practice* researchers should consult the [NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research](#) (June 2003).

Where research is funded by the AIATSIS (Australian Institute of Aboriginal and Torres Strait Islander Studies) researchers should consult the [AIATSIS Guidelines](#).

## 11.9 Ethnographic Data

Special attention should be given to the long term storage of ethnographic data, recorded with speakers of small and potentially endangered languages. Such material should be properly described and archived so that members of the families and communities represented can have access to the material in the future. Consent to keep this data should be obtained from the appropriate people and their communities.

Researchers should investigate and utilise the repositories that exist in their field for the safe preservation of ethnographic data.

*For example:* [PARADISEC](#) (Pacific And Regional Archive for Digital Sources in Endangered Cultures) offers a facility for digital conservation and access for endangered materials from the Pacific region, defined broadly to include Oceania and East and Southeast Asia.

## **12. Where To Get Advice**

- Academic colleagues
- Fellow student researchers
- Student project supervisors
- Heads of Department
- Associate Deans (Research and Research Training)
- Departmental Managers
- Melbourne Research and Innovation Office (Tel: 8344-2000)
- School of Graduate Studies (Tel: 8344-8599)
- University of Melbourne Postgraduate Association (UMPA) (Tel: 8344 8657)

The University's [Records Services](#) coordinates a range of training and information sessions, and offers a consultancy service to departments seeking to establish or review their recordkeeping procedures.

**FORM 1:****Registration of Research Data & Records Stored in the Melbourne Graduate School of Education (MGSE)**

**Identification number:** ..... **Year:** .....

*(All stored data and records associated with this project should be labeled with this unique identification number and the year stored.)*

**Name of Principal Investigator** (academic staff member):

.....

**Names of all other researcher/s** (include student researchers where relevant):

.....

.....

.....

**Name of supervisor** (where applicable, ie. student researcher project):

.....

**Project title and description** (include sufficient detail to identify the type and nature of the research eg. animal or human research, classroom research):

.....

.....

.....

**Funding body/bodies** (if applicable):

.....

.....

**Date project commenced:** .....

**Date project completed or thesis submitted:** .....

**Description of data/records and format:** Include sufficient detail in this table to ensure that the full set of materials can be identified and retrieved. Format of data may include computer printouts, laboratory notebooks, files, maps, electronic data files, photographs, video and audio recordings, charts, models, disks, magnetic tapes.

**\*Detail any access /confidentiality restrictions:**

**Period of Retention:** .....

**Date of publication or public release (if applicable):** .....

Degree for which thesis was submitted and date of submission (if applicable):

**FORM 2:****Relocation of Data and Records Stored in the Melbourne Graduate School of Education (MGSE)**

**NOTE:** Original data and records may be relocated to another department within the University, but may not be removed from the University.

I request approval to relocate the research data and records for this project, currently held in the department, to:

.....  
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.....

(Give full description of location, i.e. building and room number or departmental office storage area location)

Reason for relocation: .....

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**Collaborators have been advised of the relocation.**

Principal Investigator: .....(signature) Date: .....

**Approval to relocate data and records stored**

Head of Cluster/Centre/Unit: .....(signature) Date: .....

Date relocated: .....

**FORM 3:****Disposal of Research Data and Records Stored in the Melbourne Graduate School of Education (MGSE)****Identification number:** ..... **Year:** .....*(All stored data and records associated with this project should be labeled with this unique identification number and the year stored.)***Name of Principal Investigator** (academic staff member):

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Complete all items in the following checklist. If the response to any item is "No", the issue must be resolved before any data and records are destroyed.

	Yes	No	N/A
5 years have passed since the publication, or public release, of the work of research OR 5 years have passed since completion of the research project and there is no intention to publish, or publicly release, the work of research.			
5 years have passed since the thesis was submitted (in case of project by student researcher) and there is no intention to publish, or publicly release, the work of research.			
Any additional time intervals established by external organizations for the retention of this type of data and records eg. Clinical trials, 15 years (NHMRC); psychological records, 7 years (APS), have passed.			
All specific requirements of funding bodies have been met.			
Archival value of records has been considered and appropriate actions taken to ensure the retention of potentially valuable materials.			
Any discipline specific codes or best-practices for the retention of data and records in the field of this research project have been adopted.			
Collaborators have been consulted.			
Confidential data and records will be destroyed by appropriate means and confidentiality protected throughout the disposal process.			

I recommend that the research data and records for this project, held in the department, be destroyed.

Principal Investigator: .....(signature) Date: .....

**Approval to dispose data and records for destruction**

Head of Cluster/Centre/Unit: .....(signature) Date: .....

Date disposed: ..... Destruction confirmation attached (circle one): **YES / NO**

## **14. Instructions for Keeping Experimental Laboratory Notebooks**

### **Purpose**

The laboratory notebook is used as a record of experimental data and ideas. It provides a complete record of laboratory work which can be understood and repeated by yourself and others. If used appropriately it will afford maximum patent right protection. A notebook should be kept for all scientific projects.

As follows:

1. The notebook must be bound so that pages cannot be added or removed.
2. Each page of the notebook must be numbered in sequence.
3. Each page must include a space for signatures by the researchers and at least one witness and the date on which the witness signed the page. The witness must be someone who is competent to understand the work but does not claim to be an inventor.
4. The entries in the notebook must be written in permanent ink. Erasures are not permitted. Do not use "white-out". To delete an entry draw a line through it so that the original entry is still legible. If any entry is modified, make a new entry which is signed, dated and witnessed. Changes made after the page has been witnessed should be initialled by both researcher and witness and dated the current date.
5. Additional items such as photographs, chromatographs, spectral data etc. may either be stapled or taped to the notebook and witnessed as above, or put in a separate file. The identification and location of the separate file should be referred to in the notebook along with cross-referenced numbers (eg experiment numbers, compound numbers, page numbers etc.). These objects should be witnessed in the same manner as the notebook pages. Once a page is finished and witnessed, do not make changes or add to it.
6. Do not skip pages. If a page is left blank, rule a diagonal line across the page and indicate that the page is intentionally left blank. Sign and witness in the usual way.
7. The notebook serves as a complete and continuous day-by-day running record of the activities of the researcher. Record sufficient information. All procedures, reagents, equipment, references, conditions must be recorded as the work is being done, as should be the reasons serving as a basis for decisions. Abandoned approaches or unsuccessful attempts should be included.
8. Record the date and sign your name at the bottom of each page.
9. The notebook and its contents are to be considered as a confidential document and of great value. Every care should be exercised in looking after it. The notebook remains the property of the University.
10. Reserve a page or two at the beginning of the notebook for a table of contents. Return the book to the authority responsible for its safekeeping when it is filled and is of no further day-to-day use by the researcher.
11. New ideas must be recorded and witnessed as soon as they occur to establish priority of inventions.

## **Useful Websites (as at 30 January 2012)**

Accounts Registration System (ARS) to access Themis:

<http://accounts.unimelb.edu.au/>

American Psychological Association ethical principles of psychologists and code of conduct: <http://www.apa.org/ethics/code2002.html>

Australian Association for Research in Education [AARE] – Code of Ethics:  
<http://www.aare.edu.au/ethics/ethcfull.htm>

Australian Code for the Responsible Conduct of Research:

<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>

Conducting Research in Catholic Schools:

- Victoria:  
<http://web.ceo.melb.catholic.edu.au/?sectionid=48&sectionid=48&mode=print>
- West Australia: [http://web4.ceo.wa.edu.au/rni\\_guidelines.asp](http://web4.ceo.wa.edu.au/rni_guidelines.asp)

Conducting Research in Government Schools:

- Victoria:  
<http://www.education.vic.gov.au/researchinnovation/research/schoolresearch.htm>
- Australian Capital Territory:  
[http://www.det.act.gov.au/publications\\_and\\_policies/publications\\_a-z/research\\_and\\_reviews](http://www.det.act.gov.au/publications_and_policies/publications_a-z/research_and_reviews)
- New South Wales: <https://www.det.nsw.edu.au/research/index.htm>
- Northern Territory: <http://www.det.nt.gov.au/corporate/research/>
- Queensland:  
<http://education.qld.gov.au/corporate/research/research-app.html>
- South Australia:  
<http://www.decs.sa.gov.au/research/pages/research/>
- Tasmania: <http://www.education.tas.gov.au/dept/reports/research>
- Western Australia: <http://www.det.wa.edu.au/>

**Consent Form Guidelines (with sample forms):**

<http://cms.research.unimelb.edu.au/humanethics/application/stepbystep/attachments/consentform>

**Deadlines for Submission of Ethics Applications to Graduate School:**

[http://www.edfac.unimelb.edu.au/research/ethics/ethics\\_deadlines.html](http://www.edfac.unimelb.edu.au/research/ethics/ethics_deadlines.html)

**Human research ethics training:**

<http://www.msgr.unimelb.edu.au/programs/skills/workshops.html#ethics>

**Melbourne Graduate School of Education: Human Ethics Advisory Group**

**[MGSE HEAG] site:**

[http://www.edfac.unimelb.edu.au/research/ethics/human\\_ethics.html](http://www.edfac.unimelb.edu.au/research/ethics/human_ethics.html)

**Melbourne Research Office - Human Research Ethics Application Types:**

<http://cms.research.unimelb.edu.au/humanethics/application/stepbystep/applicationtypes>

**Melbourne Research Office - Human Research Ethics Reporting and Monitoring:**

<http://cms.research.unimelb.edu.au/humanethics/managingprojects/annualreports>

**National Statement on Ethical Conduct in Human Research (2007):**

<http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

**Plain Language Statement Guidelines (with sample statements):**

<http://cms.research.unimelb.edu.au/humanethics/application/stepbystep/attachments/statements>

**Themis Human Research Ethics Module:** <http://themis.unimelb.edu.au/>

**Themis Human Research Ethics Quick Reference Cards:**

[http://www.themis.unimelb.edu.au/support/help/ref\\_cards\\_research.html#humans](http://www.themis.unimelb.edu.au/support/help/ref_cards_research.html#humans)

**University of Melbourne - Human Research Ethics Brochure:**

<http://www.research.unimelb.edu.au/brochures/pdf/pub38web.pdf>

**University of Melbourne – Melbourne Research Office, Human Research Ethics Website:** <http://cms.research.unimelb.edu.au/humanethics>

**University of Melbourne Code of Conduct for Research (Regulation 17.1.R8):**

<http://www.unimelb.edu.au/ExecServ/Statutes/r171r8.html>

**Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research:**

<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>

## **Human Research Ethics Contacts & Committee**

### **MGSE HEAG Administrator (note new address and fax number)**

Tim Mattingsbrooke - Research Ethics Officer, Melbourne Graduate School of Education: Human Ethics Advisory Group (MGSE HEAG)

Phone: 83448662

Fax: 83448213

Email: [timm@unimelb.edu.au](mailto:timm@unimelb.edu.au)

Address: Melbourne Education Research Institute (MERI)  
Melbourne Graduate School of Education  
Level 9, 100 Leicester Street  
University of Melbourne Vic 3010  
Australia

### **HAPS HESC Secretary**

Jacky Angus – Secretary, Humanities & Applied Sciences Human Ethics Sub-Committee (HAPS HESC)

Phone: 83442074

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**Melbourne Graduate School of Education: Human Ethics Advisory Group  
[MGSE HEAG] Committee (as at 30 January 2012)**

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Dr Janet Scull (Deputy Chair)

Prof Raymond Adams

Dr John Munro

Mr Brad Astbury

Mrs Jennifer Nicholls

Mr Peter Bentley

Mr Nigel Palmer

Mr Peter Brennan

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Ms Mary Leahy

Ms Yuanlin Zhao

Ms Vicki Mckenzie

Ms Lyn Campbell (External Community Representative)

Ms Sally Windsor (Student Representative)

Mr Tim Mattingsbrooke (Administrator)

Ms Kathy Stewart (Assistant Administrator)

## **Prescribed MGSE Letterhead all Consent Forms and Plain Language Statements**

On the follow pages are examples of **two versions** of the accepted MGSE Letterhead. Please use one of there letterhead versions for all **Consent Forms** and **Plain Language Statements**; and any other appropriate associated documentation within your Human Ethics application.

Both these letterheads can be found on the MGSE Human Ethics website at:  
<http://www.edfac.unimelb.edu.au/research/ethics/Letterhead%20for%20Ethics%20PLS%20&%20Consent%20Forms.doc> or you can contact the MGSE HEAG Administrators: Tim Mattingsbrooke via email: [timm@unimelb.edu.au](mailto:timm@unimelb.edu.au) or Kathy Stewart via email [k.stewart@unimelb.edu.au](mailto:k.stewart@unimelb.edu.au) and they will attach both versions of the letterhead by return email.

***NOTE: Please be consistent in using one version of the MGSE Letterhead within your Human Ethics application!***

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## Your Notes

