## **HUMAN RESEARCH ETHICS**

# PROJECT APPLICATION FORM

## **How To Use This Form**

### 1. Consider and refer to relevant guidelines and regulations.

References to specific guidelines are provided, with hyperlinks, throughout this form. The primary guide for human research ethics in Australia is the *National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015*. Human research ethics applications at the University of Melbourne are reviewed and approved under the warrant of the *National Statement*. References to the *National Statement* are abbreviated (e.g. *NS* §2.1.)

### 2. Use plain English.

Use clear, non-technical language in your application. Be concise. Spell out the first instances of acronyms and abbreviations. Avoid jargon. Do not repeat information. Following these directions ensures effective review of your application. It will avoid unnecessary delays which result if applications are not clear and concise.

### 3. Consider ethical principles.

Your application will be reviewed according to the principles of ethical research outlined in the National Statement, namely:

- Research Merit and Integrity (<u>NS §1.1 §1.3</u>)
- Justice (<u>NS §1.4 §1.5</u>)
- Beneficence (<u>NS §1.6 §1.9</u>)
- Respect (<u>NS §1.10 §1.13</u>)

#### 4. Use the current version of the application form.

Ensure that you are using the current version by downloading this form each time you prepare a new application.

#### 5. Detailed instructions for specific questions are available online.

If you are unsure about how best to answer a particular question, consult the Human Research Ethics **Guidance Document**. That document provides detailed guidance on how to answer specific questions in this form.

#### 6. Where possible, avoid printing this form.

Consult your HEAG to find out if they still require hard copies of your application. If you must print this form, consider printing double-sided and in grayscale (black and white).

### 7. Save your completed application as a PDF and upload it to Themis.

Refer to your local Human Ethics Advisory Group (<u>HEAG</u>) for detailed instructions on how and when to submit your application.

## ANSWER ALL OF THE QUESTIONS IN THIS FORM

Ethics ID number: (assigned by Themis)	1749270.3	
Project Title: (as recorded in Themis)	Decision-Making in Source Memory	
Responsible Researcher: (as recorded in Themis)	SMITH, PROF PHILIP LEIGH	
Application Type:	χ Minimal Risk	
(mark with an "X")		Standard Project

# 1. Project Details

# 1.1 Project Summary

Summarise your research project in plain language.

[Limit: 300 words]

### A) Aims and Objectives

By collecting response time and accuracy data from a memory task described in the design, this study aims to distinguish between a threshold or a continuous model of how people remember the context of memories (source memory).

### B) Key Question(s)

Does source memory fail completely past a threshold, under which people guess at random, or is memory strength continuous?

### C) Research Design

Participants drawn from the (1) Melbourne School of Psychological Sciences undergraduate REP system and (2) recruited online via Prolific/Amazon Mechnical Turk will be asked to complete four experimental sessions. Each session is estimated to take between 45 to 50 minutes to complete. Each trial consists of seeing a word positioned on a circle, and then after a delay, participants will be cued with the word, and then indicate using a computer mouse where on the circle the cued word was located.

# **Specific Guidelines Checklist**

Type an "X" in the left-hand column beside all items that apply to your research project. Linked sections of the National Statement contain relevant guidelines and requirements that you need to address when completing your application.

Children and/or young people (< 18 years old) will be recruited as participants.	→ Refer to <u>NS §4.2</u> .
People in dependent or unequal relationships will be recruited as participants.  (There are pre-existing relationships between participants and researchers, or between participants and others involved in facilitating or implementing the research. E.g. student/teacher, patient/doctor, employee/employer.)	→ Refer to <u>NS §4.3</u> .
People in countries other than Australia will be recruited as participants.	→ Refer to <u>NS §4.8</u> .
<ul> <li>One or more of the following describes the research project:         <ul> <li>it will be about Aboriginal and/or Torres Strait Islander individuals or peoples, their health, or their culture(s), language(s) or histories;</li> <li>it will be about the impact(s) or effect(s) of some phenomenon or phenomena on Aboriginal and/or Torres Strait Islander individuals or peoples;</li> <li>it will specifically target Aboriginal and/or Torres Strait Islander people to be recruited as participants;</li> <li>it will be conducted in a geographic location where a significant number of</li> </ul> </li> </ul>	<ul> <li>→ Refer to NS §4.7.</li> <li>→ Refer to Values and Ethics.</li> <li>→ Refer to GERAIS.</li> <li>→ This application is ineligible for minimal risk review.</li> </ul>
the population are likely to be Aboriginal and/or Torres Strait Islander.  One or both of the following describes the research project:  it will specifically target women who are pregnant to be recruited as participants;  it will be focused on women who are pregnant and/or the human foetus (including human foetal tissue or human embryos).	→ Refer to <u>NS §4.1</u> .  → This application is ineligible for minimal risk review.
People who may be involved in illegal activities will be recruited as participants, and the research project could potentially expose such activities.	<ul> <li>→ Refer to <u>NS §4.6</u>.</li> <li>→ This application is <i>likely</i> ineligible for minimal risk reviews.</li> </ul>
People with cognitive impairment, intellectual disability, or mental illness will be recruited as participants.	<ul> <li>→ Refer to <u>NS §4.5</u>.</li> <li>→ This application is ineligible for minimal risk review.</li> </ul>
People who are highly dependent on medical care will be recruited as participants.	→ Refer to <u>NS §4.4</u> .  → This application is ineligible for minimal risk review.

## **Additional Modules Checklist**

Type an "X" in the left-hand column beside all items that apply to your research project. This checklist will help you determine if you need to complete any other modules in addition to this application form. Linked sections of the *National Statement* contain relevant guidelines and requirements that you need to address when completing this form and any applicable additional modules.

Χ	None of the above applies to this research project.	
	This research project will involve administration of ionising radiation.	→ Complete and attach the <u>lonising Radiation Module</u> .
	This research project will involve medical interventions, therapies or trials.	<ul> <li>→ Refer to NS §3.3.</li> <li>→ This application is ineligible for minimal risk review.</li> <li>→ Complete and attach the Interventions, Therapies and Trials Module.</li> </ul>
	This research project will involve human genetics.	<ul> <li>→ Refer to NS §3.5.</li> <li>→ This application is ineligible for minimal risk review.</li> <li>→ Complete and attach the Body Tissue and Genetic Research Module.</li> </ul>
	This research project will involve the collection and/or use of <b>human tissue/biological samples or materials</b> (e.g. blood, saliva, cheek swabs, hair, human embryonic or foetal tissue).	→ Refer to <u>NS §3.4</u> .  → Complete and attach the <u>Body Tissue and Genetic</u> <u>Research Module</u> .
	This research project will involve obtaining identifiable (or potentially identifiable) personal information (including health information) about individuals without their consent.	→ Complete and attach the <u>Privacy and Databanks Module</u> .
	This research project will involve accessing information from an existing databank (i.e. you will be accessing and making use of stored data that was previously collected – not for this specific project – by other parties).	<ul> <li>→ Refer to <u>NS §3.2</u>.</li> <li>→ Complete and attach the <u>Privacy and Databanks Module</u>.</li> </ul>
	This research project will involve the <b>collection of information for a databank</b> (i.e. your stored data will be made available to other parties for secondary use in future research projects).	<ul> <li>→ Refer to <u>NS §3.2</u>.</li> <li>→ Complete and attach the <u>Privacy and Databanks Module</u>.</li> </ul>
	This research project will involve the <b>creation of a databank</b> (i.e. your stored data will be made available to other parties for secondary use in future research projects).	<ul> <li>→ Refer to <u>NS §3.2</u>.</li> <li>→ Complete and attach the <u>Privacy and Databanks Module</u>.</li> </ul>

# 2. Background and Method

# 2.1 Background and Significance

Provide a summary of background information. Explain the significance of the proposed research in the context of this background. **Refer to** *NS* §5.2.5.

[Limit: 500 words]

#### A) Background:

The debate between dual-process and single-process models of source memory is relatively new, but has a long pedigree in other related fields as part of a wider, ongoing discussion regarding the nature of memory in general. In the working memory literature, evidence for both discrete slot-based and flexible resource models of memory capacity has been found, through manipulations of item number and distinguishability (van den Berg, Shin, Chou, George & Ma, 2012; Zhang & Luck, 2008).

This dynamic is analogous between interpretations of source memory accuracy. The dual-process model

describes a threshold for memory quality, below which responses are based on no evidence and hence constitute a secondary "guessing" process when memory fails, mirroring the mechanics of slot-based models of working memory when item number exceeds a given limit. Harlow and Donaldson (2013) argued for this dual-process model of source memory using the word circle paradigm described above. The distribution of accuracy data was found to have a narrow peak close around the correct response, with high tails at the end that Harlow and Donaldson (2013) interpreted as evidence of an underlying guessing process, dismissing the competing single-process account.

### B) Significance of This Research:

The present study responds to the findings of Harlow and Donaldson (2013) by replicating their study design, but rather than only record accuracy data, response time will also be recorded. The purpose of taking response time data is to assess fit with a circular diffusion model. Drawing from regularities in response time and accuracy in the simple diffusion model (Ratcliff, Smith and McKoon, 2015), this study aims to show that if variability in evidence quality (manifest in the diffusion model as 'drift rate') can account for the peaked, high-tailed distributions Harlow and Donaldson (2013) found, then there is no need for a dual-process model, when a single-process model suffices.

# 2.2 Research Design and Method

Provide details of your research design and your proposed method. **Refer to NS §5.2.5** §5.2.6.

Attach a copy of any measures, scales, questionnaires, survey instruments (including online surveys), interview questions/themes, and/or focus group topics/questions to be used.

### A) Participants (or Recruitment Targets, such as medical records):

No specific inclusion or exclusion criteria apply, and no specific population is targeted for recruitment.

### B) Recruitment:

Recruitment will be conducted using both Prolific/Amazon Mechanical Turk and the MSPS undergraduate REP program.

#### C) Participant Incentives:

Research Experience Program (REP) participants will be granted REP credit. All other participants recruited online will be paid \$6.50 USD per hour.

#### D) Participant Task(s):

In one trial, participants will be asked to remember a display consisting of a word positioned along a circle on a screen. Trials will occur in blocks of 10 stimuli. After a two-digit arithmetic distractor task with a duration of 30 seconds, participants will be cued with words that either occurred in the study list or not, and will be asked to indicate if the words was studied in the preceding study phase, and if so, where on the circle that word was presented using a computer mouse. Participants will complete 2 to 4 sessions, which are estimated to take between 45 to 50 minutes to complete.

### E) Data/Material Collection Technique(s):

Response accuracy and time will be collected online and stored on a computer located in a secure room in the Redmond Barry Building.

## F) Data Analysis:

Response time and accuracy data will be analysed using model fitting to the circular diffusion model.

# 3. Risks, Benefits and Monitoring

# 3.1 Potential Risks to Participants

Does your research project pose any potential risks to participants? What are those risks? How will they be negated, minimised or managed? **Refer to** *NS* §2.1.

Note that the risks you identify here should also be described in your Plain Language Statement (PLS). Attach a copy of any distress protocol or adverse event protocol (if applicable).

#### A) Potential Risks

There is minimal risk posed to the participant by the study, which consists of a measurement task using a computer mouse and a visual display. As part of this task, participants could potentially suffer from postural strain from sitting in front of the display, eye strain from viewing the display or hand strain from operating the computer mouse for an excessive duration.

### B) Risk Management Strategy

To address these potential risks, the study is designed with rest breaks in between periods of measurement to ensure participants do not engage in the task for long periods of time continuously.

# 3.2 Potential Risks to Non-Participants

Does your research project pose any potential risks to non-participants? (This could possibly include risks to researchers or independent contractors.) If so, how will these risks be minimised? **Refer to** <u>NS §2.1</u>.

The potential risks to non-participants are minimal due to the psychometric nature of the study, as the role of the researcher in collecting response time and accuracy data does not carry any foreseeable wider consequences.

# 3.3 Risks, Benefits and Justification

In light of the risks and expected benefits of the research project, explain how the expected benefits of the research justify any risks it may pose. Refer to NS §1.6 - §1.7 and NS §2.1.

### A) Expected Benefits

The benefits to the participants arises primarily from the monetary reward for participation. The benefit of the research for society at large lies in the advancement of scientific understanding of the nature of source memory, and through this, the nature of memory as part of the wider literature.

### B) Justification of Risks by Expected Benefits

The risks of the study to all parties are minimal, and do not exceed inconvenience for the participant, which is still balanced by the monetary benefit for participation. On a wider scale, the described benefits to society are not outweighed by any foreseeable risks.

# 3.4 Management and Monitoring

How will researchers manage and monitor conduct of the research project? **Refer to NS §5.5.** 

## A) Management

The project will be managed by the responsible researcher and co-researcher to ensure compliance with regulations and legislation.

### B) Monitoring

This research will be undertaken by a graduate student. The student will be in regular contact via Zoom with the responsible researcher.

C) Independent Contractors

N/A

## 4. Consent

# 4.1 Obtaining Informed Consent

Type an "X" in the left-hand column beside as many of the following options as apply to your research project. Use the space provided below to explain how you will obtain informed consent from participants. If you seek a waiver of consent, or the use of opt-out consent, use the space provided to justify your request. Refer to NS §2.2, NS §2.3.

	consent, use the space provided to justify your request. Refer to NS §2.2, NS §2.3.				
х	Written consent will be sought from (or on behalf of) participants.	<ul> <li>→ Refer to <u>NS §2.2.6</u>.</li> <li>→ Attach a copy of your consent form(s).</li> </ul>			
	Verbal consent will be sought from (or on behalf of) participants.	<ul> <li>→ Refer to NS §2.2.5 - §2.2.6.</li> <li>→ Explain why you have chosen this form of consent, and how an individual's consent to participate will be recorded.</li> <li>→ Attach a copy of your consent script(s).</li> </ul>			
	Consent will be implied, rather than explicitly obtained.	<ul> <li>→ Refer to <u>NS §2.2.5 - §2.2.6</u>.</li> <li>→ Explain why you have chosen this form of consent.</li> </ul>			
	Third parties (e.g. parents/guardians of minors) will provide consent on behalf of participants.	<ul> <li>→ Refer to <u>NS §2.2.12</u>.</li> <li>→ Explain who will be providing consent on behalf of participants and why.</li> </ul>			
	Third parties (e.g. community elders, school boards) will be involved in whole of community participation decisions.	<ul> <li>→ Refer to <u>NS §2.2.13</u>.</li> <li>→ Provide details of which third parties will be involved, why they will be involved, and how this will be accomplished.</li> </ul>			
	This application seeks a waiver of consent.	→ Explain why you are seeking this option. Justify your request by referring to the conditions described in NS §2.3.10 - §2.3.11.			
	This application proposes to use <b>opt-out consent.</b>	→ Explain why you are seeking this option. Justify your request by referring to the conditions described in <u>NS §2.3.6</u> .			

Consent will be obtained using written forms. Competence to give consent will be established through participation in the SONA scheme from which participants are recruited.

4.2 Limited Disclosure	Do you propose to use limited disclosure, concealment or deception for this research project? (Answer Yes or No. If Yes, use the space below to explain.) Refer to NS §2.3.		
	YES or NO:	NO	

# 4.3 Future Use of Data, Materials, or Tissues

Do you intend for the data and/or materials and/or tissues collected for this research project to be reused in future research? **Type an "X" in the left-hand column beside as many of the following options as apply** to your research. **Use the space provided** to specify which data/materials/tissues will be reused, if any. **Refer to** <u>NS §2.2.14</u>.

Х		Consent (or waiver of consent) will be <b>specific.</b>	→ Data/materials/tissues will be used <i>only</i> for this research project (i.e. <b>no future use</b> ).
		Consent (or waiver of consent) will be <b>extended.</b>	→ Data/materials/tissues used in this research project may also be used in future projects that are <i>closely related</i> to this project, <i>or in the same general area</i> of research as this project.
		Consent (or waiver of consent) will be unspecified.	→ Data/materials/tissues used in this project may also be used in <i>any</i> future research.
N	I/A		

# 4.4 Conflict of Interest

Does your research present or involve any conflict of interest, whether potential, real, or perceived; or will the researcher(s) have dual roles in relation to the participants? (Answer Yes or No. If Yes, use the space below to explain.) Refer to NS §5.4, University of Melbourne Code of Conduct for Research §2.5, and Australian Code for the Responsible Conduct of Research §7.2.

YES or NO:	NO

# 4.5 Information for Participants

How will relevant information about the research project be provided to potential participants? Attach a copy of any advertisement (print or online), Plain Language Statement (PLS), consent form, letter, email, telephone script, and/or debriefing statement to be used. Refer to NS §5.2.23.

Participants will be made aware of information relevant to this study through the PLS (attached), which will be distributed through SONA.

Plain Language Statement (PLS): Your PLS must satisfy the requirements set out in the National Statement (NS §2.2.1 - §2.2.3, §2.2.6). The Research Ethics and Integrity's website has guidance on composing your plain language statement, as well as an example PLS template. A list of PLS requirements is also provided at the end of this form. Ensure that your PLS is written in plain language. Ensure that the information contained in your PLS is consistent with the information in your application.

**Consent Form:** Your consent form must satisfy the requirements set out in the *National Statement* (NS §2.2). The Research Ethics and Integrity's website has guidance on composing your consent form, as well as an example consent form. A list of consent form requirements is also provided at the end of this form. Ensure that your consent form is written in plain language. Ensure that the information contained in your consent form is consistent with the information in your application.

# 5. Dissemination and Data Management

# 5.1 Providing Results to Participants

How will the results of the research project be provided to participants in an accessible format? **Refer to** <u>NS §1.5</u>.

Results of the project will be made available to participants upon potential publication of the study through the posting of results on the university Learning Management System. Participants may also elect to provide an email on the attached consent form to which a summary of results will be sent.

# 5.2 Reporting Project Outcomes

How will outcomes of the research project be made public? Refer to NS §1.3.

Outcomes of the research will be potentially made public upon publication through a peer-reviewed journal, as well as potential conference presentations.

## 5.3 Data Management

How do you propose to manage the data collected in this research project? Specify what types of data will be collected, how they will be stored and in what format. How will access to the data be controlled and by whom? Discuss retention, security, and data sharing plans. What measures will be taken to protect participants' privacy, and their data?

Refer to <u>NS §1.11</u>, the <u>Australian Code for Responsible Conduct of Research §2</u>, and the <u>University of Melbourne Code of Conduct for Research §2.1</u>.

### A) Privacy and Confidentiality

All data collected will be de-identified and stored electronically on a password-protected computer accessible only to the named researchers. Data will be identifiable through physical forms which match participation numbers to identities.

## **B1) Security and Storage of Non-Digital Data**

Short term-storage of the physical identification forms will be stored in a locked filing cabinet in the office of the responsible researcher.

#### **B2) Security and Storage of Digital Data**

Data collected online will be stored in the hard drive of a computer located in the Redmond Barry Building and in a private git repository in the short term, and will be moved onto a USB for long-term storage. Both of these responsibilities will belong to the responsible researcher and co-researcher.

### C) Retention

Data will be kept for 5 years from the date of the last publication arising from the study, after which digital data will be electronically deleted, and physical identifying documents will be shredded.

## 6. Other Issues

# 6.1 Other Ethical Issues

Are there any other issues, not addressed above or in additional modules, which are relevant to the ethical review of your research project? Refer to the relevant sections of the *National Statement* identified in the Specific Guidelines Checklist, if applicable.

N/A

# **Attachments Checklist**

Review your answers above to determine which attachments (if any) are required for your application. **Type an "X"** in the left-hand column beside all items that apply to your research project. Attach a copy of the items you have selected.

nave selected.				
х	Plain Language Statement (PLS) for Participants			
х	Consent Form for Participants			
	Additional PLS(s) (e.g. for parents, teachers, schools)			
	Additional Consent Form(s) (e.g. for parents, teachers, schools; or assent forms for children)			
	Recruitment Materials (e.g. advertisement(s), posters, letter(s) or email(s) of invitation)			
	Questionnaire(s) and/or Survey Instrument(s)			
	Measure(s) and/or Scale(s)			
	List of Interview Questions and/or Themes			
	List of Focus Group Questions and/or Themes			
	Participant Distress Protocol			
	Adverse Event Protocol			
х	Debriefing Statement			
	Approval(s) of research by an HREC external to the University of Melbourne			
	Other External Approval(s) (e.g. schools, communities)			
	Full Protocol (for Medical Research)			
	Translations and/or Back-Translations (where languages other than English used)			
	Privacy and Databanks Module			
	Body Tissue and Genetic Research Module			
	Ionising Radiation Module			
	Interventions, Therapies and Trials Module			
	Other Documents (e.g. contracts, agreements) – specify which:			
	·			

#### Plain Language Statement (PLS) Requirements:

- 1. Clearly identify the University of Melbourne (i.e. by prominent placement of the University's logo) and the department(s)/school(s)/faculty(-ies) involved. If printed, the PLS should be on University of Melbourne letterhead.
- 2. Clearly identify the title of the project, and the name(s) and contact details of the Principal Researcher and Other Researchers. For student projects, specify the student's level of study.
- 3. Clearly explain the purpose of the research project.
- 4. Clearly explain what participants will be asked to do, and provide an estimated time commitment.
- 5. If participants will be photographed, audio- or video-recorded, clearly state as much.
- 6. Clearly explain any risks arising from participation, as well as any procedures or measures in place to minimise such risks.
- 7. Describe any expected benefits to the wider community. If applicable, also describe any expected benefits to participants.
- 8. List any payments, incentives or reimbursements to be made to participants.
- 9. State that involvement in the project is voluntary and that participants are free to withdraw from participation at any time. Explain any implications of withdrawal, including whether it will be possible for participants to withdraw any data already collected from or about them.
- 10. Describe the likelihood and form of dissemination of the research results, including publication.
- 11. Describe the arrangements in place to protect the confidentiality of participants' data, and advise participants of any legal limitations to such confidentiality. If the sample size for the project is small, advise participants that this may make them identifiable.
- 12. The project HREC number (which is the ethics ID number assigned by Themis) and the date and version number of the PLS must appear on the PLS. If the PLS is printed, put this information in the footer.
- 13. Explain what will happen to participants' data after the research project ends (i.e. how long it will be retained, whether it might be used again for future research and if so who would have access.)
- 14. Include the following statement: "This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: <a href="mailto:humanethics-complaints@unimelb.edu.au">humanethics-complaints@unimelb.edu.au</a> All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project."
- 15. If the research is externally funded, state the amount(s) and source(s) of funding for the research.
- 16. If there are any potential conflicts of interest for any of the researchers, sponsors (if applicable) or institutions, disclose these potential conflicts of interest.
- 17. If any participants will be in a dependent relationship with any of the researchers, state that decisions about participation will not affect the dependent relationship. (E.g. students' grades will not be affected if they decline to participate or withdraw from the project at any stage).

#### **Consent Form Requirements:**

- 1. Clearly identify the University of Melbourne (i.e. by prominent placement of the University's logo) and the department(s)/school(s)/faculty(-ies) involved. If printed, the consent form should be on University of Melbourne letterhead.
- 2. Clearly identify the title of the project, the name(s) and contact details of the Principal Researcher and Other Researchers. For student projects, specify the student's level of study.
- 3. If participants will be photographed, audio- or video-recorded, clearly state as much.
- 4. 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. Also state that the purpose of the project is research.
- 5. Describe the arrangements in place to protect the confidentiality of participants' data, and advise participants of any legal limitations to such confidentiality. If the sample size for the project is small, advise participants that this may make them identifiable.

# **Declaration by the Responsible Researcher**

The information contained in this application is, to the best of my knowledge and belief, accurate.

I have read the University's current human ethics guidelines. I accept responsibility for the conduct of the procedures set out in the attached application in accordance with: those guidelines, with the <u>University's Code of Conduct for Research</u>, and with any other condition laid down by the University of Melbourne's Central Human Research Ethics Committee (CHREC), its Human Ethics Sub-Committees (HESCs), or by the Human Ethics Advisory Group (HEAG) which will review this application. I have attempted to identify all risks related to the research that may arise in conducting this research. I acknowledge our obligations as researchers and the rights of the participants stipulated in the <u>National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015</u>. I certify that the research team has the appropriate qualifications, experience and facilities to conduct the research described in the attached application, and to deal with any emergencies and contingencies related to research that may arise throughout the life of the project.

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

I, the Responsible Researcher, agree to:

- start this research project <u>only</u> after obtaining final approval from the HESC (if this is a standard project), or the HEAG (if this is a minimal risk project);
- carry out this research only where adequate funding is available to enable the research to be carried out according to good research practice and in an ethical manner;
- provide additional information as requested by the CHREC, HESC, or HEAG;
- provide progress reports to the CHREC, HESC, or HEAG as requested, including annual and final reports;
- maintain the confidentiality of all data collected from, or about, research participants and maintain security procedures for the
  protection of their privacy;
- submit an amendment if any modification to the research design or protocol is proposed (including any change of researchers)
   and to proceed with the research only after the amendment has been approved by the HESC (if this is a standard project) or by
   the HEAG (if this is a minimal risk project);
- notify the HESC (if this is a standard project) or the HEAG (if this is a minimal risk project) in writing immediately if any adverse event occurs during the course of the research;
- notify the HESC (if this is a standard project) or the HEAG (if this is a minimal risk project) in writing immediately if any
  complaints are received about the research;
- comply with an audit of the research undertaken, if requested by the CHREC, HESC, or HEAG;
- use only the data/tissue samples collected for this research, and for which HESC/HEAG approval has been given.

I certify that all members of the research team have read this application and the <u>National Statement on Ethical Conduct in</u> <u>Human Research (2007) - Updated May 2015</u> and that they have agreed to comply with the provisions of the latter.

Responsible Researcher Name	Signature	Date

# **Declaration by Human Ethics Advisory Group (HEAG)**

For HEAG use only.  Enter the date the application was received, then type an "X" in the left-hand column beside each item as applicable.			
Date Application Received:			
Technical review has been completed by the HEAG.  The merit of the proposed research project set out in this application has been reviewed on technical grounds.  Refer to NS §1.1.			
Ethical review has been completed by the HEAG.	The HEAG has reviewed the proposed research project set out in this application for compliance with the principles of Human Research Ethics.		
The <b>Minimal Risk</b> review process is appropriate for the proposed research project set out in this application.	→ Complete Declaration A (below)		
The <b>Standard Project</b> review process is appropriate for the proposed research project set out in this application	→ Complete Declaration B (below)		

# Declaration A (Minimal Risk):

The HEAG has reviewed this project. The HEAG considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed. **The HEAG grants approval for this research project to commence.** The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research described in the attached application in a manner that complies with the University's policy on the management of research data and records, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a researcher in this project, the declaration should be signed by another authorised member of the HEAG.]

Name of HEAG Chair/Authorised Member	Signature	Date

# Declaration B (Standard Project):

The HEAG has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed. **The HEAG regards this project as ready to submit to the HESC.** The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research described in the attached application in a manner that complies with the University's policy on the management of research data and records, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a researcher in this project, the declaration should be signed by another authorised member of the HEAG.]

Name of HEAG Chair/Authorised Member	Signature	Date