2013

A Framework of Policies and Procedures for University Research Ethics Committees

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Foreword

This is an initial publication of a set of guidelines designed to help higher education institutions (HEIs) develop the quality of their policies and procedures for managing ethics issues in research involving human participants.

While recognising that there are valid reasons for diversity among HEIs in how these issues are managed, this document aims to encourage continued reflection, evaluation and development towards a set of common best practice standards. It also offers a means of evidencing the ways in which these standards are demonstrated in the specific practices of individual HEIs.

The focus is on the practice of formal review of ethics protocols through Research Ethics Committees (RECs), locating this core practice within the broader context of institutional approaches to the maintenance of high standards of research integrity. As such, it has been produced to complement, rather than supplant, other cross-sector initiatives such the Concordat on Research Integrity which seek to engage institutions in development practices to achieve such high standards.

It recognises that RECs and the process of ethics review has to be consistent with broader research standards as articulated in institutional policies and practices.

This document should also be seen as complementing the expectations of research councils and other funding bodies for the ethical conduct of research that they support. In common with these expectations, as expressed for example in the Framework for Research Ethics of the Economic and Social Research Council, and recognising that research ethics is a dynamic field of enquiry as well as practice, this document is an initial, rather than a final, statement. It is intended to stimulate reflection and in this spirit is expected to require review and revision as a result of its use.

Extensive consultation and liaison has underpinned the development of this document, in particular via the links with HEI research ethics committees and HEI research governance established through the University Research Ethics Forum and University Development Group of the Association of Research Ethics Committees and through joint actions with the Academy of Social Sciences and its member learned societies. There has also been engagement with funding bodies, the Health Research Authority and Universities UK which has further informed the development.

The Association of Research Ethics Committees (AREC) invites HEIs to express support of the principles and practices recommended herein and to demonstrate the embodiment of them in their own context through joining the AREC registration scheme.

Principles of research ethics

The principles underpinning the ethics review of research projects may seem self-evident, yet it is important that the world outside the institution should know what these are. There is no lack of models to go on, starting with the Declaration of Helsinki. First approved in 1964, it has been regularly updated, but it is medically orientated and the research disciplines requiring ethics review are now far wider than the medical world. Many professional bodies have produced their own codes of practice and researchers might usefully be advised to consult those relevant to their research. A selection is as follows:

- Association of Social Anthropologists of the UK and the Commonwealth, *Ethical Guidelines for Good Research Practice* (http://www.theasa.org/downloads/ASA%20ethics%20guidelines%202011.pdf);
- British Psychological Society, *Code of Ethics and Conduct* and *Code of Human Research Ethics* (http://www.bps.org.uk/what-we-do/ethics-standards/ethics-standards);
- British Sociological Association, *Statement of Ethical Practice* (http://www.britsoc.co.uk/about/equality/statement-of-ethical-practice.aspx);
- Economic and Social Research Council, *Framework for Research Ethics* (FRE) 2010: Updated 2012 (http://www.esrc.ac.uk/_images/Framework-for-Research-Ethics_tcm8-4586.pdf);
- Political Studies Association, *Guidelines for Good Professional Conduct* (http://www.psa.ac.uk/sites/default/files/GUIDELINES%20FOR%20GOOD%20PROFESSIONAL%20CONDUCT.pdf).

There is common agreement that the basic principles of ethical research are:

- *Autonomy*. The participant must normally be as aware as possible of what the research is for and be free to take part in it without coercion or penalty for not taking part, and also free to withdraw at any time without giving a reason and without a threat of any adverse effect.
- *Beneficence*. The research must be worthwhile in itself and have beneficial effects that outweigh any risks; it follows that the methodology must be sound so that best results will be yielded.
- *Non-maleficence*. Any possible harm must be avoided or at least mitigated by robust precautions.
- *Confidentiality*. Personal data must remain unknown to all but the research team (unless the participant agrees otherwise or in cases where there is an overriding public interest, or where participants wish their voices to be heard and identified).
- *Integrity*. The researcher must be open about any actual or potential conflicts of interest, and conduct their research in a way that meets recognised standards of research integrity.

Principles of governance arrangements

There are four principles that should underlie any set of governance arrangements, although how these principles are used might take different forms in different institutions. These four principles are:

- Independence
- Competence
- Facilitation
- Openness

1: **INDEPENDENCE**

Ensuring that conflicts of interest specific to universities are mitigated by sufficient external or impartial scrutiny and/or involvement

Demonstrating independence is one of the major challenges for URECs, as the traditional defence that 'academic freedom' is itself a guarantee of independence is not necessarily going to withstand public scrutiny. Universities can uphold this principle by:

a) ensuring that URECs include members from a wide range of disciplines; ensuring that URECs have members (and in some cases chairs) from outside the faculty or other academic unit covered by the committee.

b) providing a constitution which grants each UREC the freedom to make ethics judgements, but that also makes it accountable;

c) including 'lay' or external members in URECs;

d) having an overarching policy committee which may or may not undertake ethics review itself, but which sets consistent standards and has authority to intervene when necessary.

2: **COMPETENCE**

Ensuring that membership of committees is informed by relevant expertise and decision making is consistent and coherent

Judging whether universities achieve good competency standards for their RECs is not simple.[1] There are several issues that need to be addressed by any institution seeking to uphold this principle:

a) Does the UREC have comprehensive standard operating procedures (see below) so that ethics opinions are reached consistently and fairly?

b) Do ethical review applications require details that provide all the information that a competent REC needs to have in order to make sound and coherent decisions?

c) Do UREC members get compensation, for example in the form of reduced teaching commitments, or other approaches which demonstrate that the university has a sustainable commitment to competent ethics review?

d) Does the university provide systematic training for UREC members?

[1] Moreover, the last comprehensive survey of university research ethics arrangements was undertaken as long ago as 2004. See Tinker, A. and Coomber, V. (2004) *UKREC: Their Role, Remit and Conduct* (London: King's College)

3: FACILITATION

Ensuring that procedures are administered efficiently and effectively, balancing duties of care with enabling and support of ethical research

While the primary responsibility of URECs is to protect the interests and welfare of those who participate in or are otherwise potentially affected by research, they are also an integral part of universities and have an additional role in facilitating good research. It is the experience of most URECs that they have to balance the two responsibilities. For instance, there is evidence of researchers complaining that RECs are irksome barriers.[2] Happily, there are also instances of researchers coming away from the ethics review process saying that it was a positive experience and that they benefited from the constructive criticism that they received.

Issues that should be considered in universities in order to uphold this principle are:

a) What is the degree of devolution for responsibility in making ethics decision? Are decisions taken at the local or central level? The benefits of a devolved approach are that a local committee has awareness of particular disciplines and ethical issues that might arise and is better placed to balance ethical judgement and also facilitate research. The downside of a devolved system is that independence might be compromised.

b) What checks and balances might be put in place to manage the balance between ethical duties and support of research activity?

c) How does the UREC and the university ensure that researchers are trained, in ethical issues and in the policies and mechanics of review? Researchers who are better trained are less likely to have to redesign projects because there are ethical concerns.

d) How does the UREC deal with ensuring timely and proportional review? Are different levels of risk handled efficiently? How are delays in response to application minimised? Dual ethics review should be avoided wherever possible.

[2] See, for example: Hammersley, M. (2006) 'Are ethics committees ethical?', *Qualitative Researcher* 2: pp. 4–8; Schrag, Z. M. (2011) 'The case against ethics review in the social sciences', *Research Ethics* 7:4, pp. 120-131

4: OPENNESS

Ensuring that decisions taken by RECs are open to public scrutiny and responsibilities discharged consistently

There is public expectation for RECs to be transparent and accountable, and the essential details of all research projects reviewed by NHS RECs, together with those RECs' ethics opinions, are publicly available. The consensus is that universities and researchers should act in co-operation with funding bodies, in deciding what, in the interests of transparency, should be made public, and what, in the interests of the researcher/university, should remain confidential. The decisions of a REC have to be transparent, but it also has to be accountable, through its governance structure. Most universities, whatever degree of devolution there is in the operation of ethics review, have a central committee that decides on policy and procedures and to which each ethics review committee in the institution is accountable,[3] but a web survey shows that not many publish details of their research ethics governance arrangements, and therefore the internal accountability is not properly carried through to public accountability.

This sets a number of challenges. Universities should consider the following in order to uphold this principle:

a) Research should be subject to rigorous peer review (or supervision in the case of students) but not normally open to public scrutiny before the results are published, so how is transparency to be achieved?

b) A researcher should be allowed to respond to any criticism or ethics review without the threat of having his or her career tarnished by adverse publicity, so how does a UREC ensure that this is avoided?

c) Original research involves intellectual property and universities have a duty to protect such property, whether it belongs to themselves or to individual members of staff, so how can the institution ensure openness whilst preserving property rights where due?

d) Are the research governance arrangements for the university clearly available to both internal and external parties? Would an interested member of the public be able to find out what governance was in place through a public-facing communication channel?

e) A regular review system of policies and guidance including an implementation plan should be in place. What reporting lines are in place and with whom does the responsibility for reporting lie?

[3] In 2008, the UK University Research Ethics Forum compiled a collection of posters summarising the governance arrangements for 19 universities. All had a central policy committee. See http://www.kcl.ac.uk/innovation/research/support/ethics/storeddocs/4TrainingAdvice/7UKURECsForum/15UKURECspostersJuly2008.pdf

GOVERNANCE WITHIN THE FRAMEWORK

The fundamental aim of the Framework is to define minimum standards for policies and procedures in research ethics review and to provide clear guidance on how institutions might meet these standards. The four principles of independence, competency, facilitation, and openness enable institutions to put governance arrangements in place on a sound basis, as well as ensuring comparability and a degree of measurability of standards across different institutions whose governance models may differ widely in specific structural or operational matters.

However, the way in which an institution assures itself, and any external scrutiny, that the principles are being upheld and standards are being met is flexible, as long as the following aspects of governance are considered:

(1) It is important to maintain the independence and integrity of committee decisions. Its decisions on individual projects must be respected. No member should be subject to pressure from interested parties (and remedies ought to be in place should this happen). No negative opinion should be overturned, except by another duly appointed UREC, and a positive opinion should be overturned only because of an academic or management issue outside the purview of the original UREC, or facts not brought to the attention of that UREC.

(2) Models of committee structures vary. Most universities have a hierarchy of URECs under an overall policy committee that reviews only special cases or appeals. Others have a parallel committee structure. There is no preferred model but the structure should be clear.

(3) URECs are not infallible and there should be an appeals procedure, for example which allows reference to another UREC. There should also be a procedure for dealing with complaints that an applicant has been treated unfairly or discourteously.

(4) The remit of URECs is normally limited to ethics review, but there is close connection with research governance and they may be run from the same office. Monitoring compliance with ethics requirements is a difficult issue, but researchers who fail to refer relevant projects for ethics review, who deliberately act against the requirements of a UREC or who treat those requirements contemptuously should be liable to investigation for misconduct in research.

(5) Where the administrators responsible for research ethics are located in the management structure of the university is entirely up to the individual institution, but they have a crucial role to play. On the one hand, they have to implement the decisions of an autonomous body and therefore protect its independence and, on the other hand, they must be accountable for how they perform their responsibilities to a line manager. It is suggested that job descriptions should recognise this dual responsibility.

Implementing the principles in the ethical review process

Ethical review processes in universities should seek to embody the principles outlined above and to, as far as possible, to operate within the spirit of the governance arrangements which are built upon them.

However, it is recognised that different universities will want to retain autonomy and flexibility in how the review process is managed. In what follows, those aspects of review that AREC consider to be **basic standards** are marked as '**required**' and should be in place for an institution aiming at demonstrating that its review arrangements meet those standards. Those aspects of review which aim to achieve **best practice** in the standards of institutional review arrangements are marked as '**recommended**.'

(1) *Policy document (required)*

Policy on the approach to research ethics review is here taken to mean a statement approved by one of the university's authoritative bodies. This might be a 'stand-alone' statement or it might be incorporated into something wider, such as a research conduct or research integrity policy. The statement should be simple, on the lines of requiring staff and students to submit relevant research projects for appropriate ethics review and to follow the ruling of the UREC and the consequences of not doing so.

Each university will have its own definition of a 'policy' and its own mechanism for how policies are approved, or may instead wish to call the formal research ethical document a procedure or a guideline, but whatever the nomenclature, a policy document about ethical review is a requirement in all institutions aiming to meet basic standards of review.

In setting-out such a policy document, the following are matters for consideration:

a) *Terms of reference of the committee (required)*

All URECs should have a Terms of Reference, which clarifies the remit and function of the committee, including the following:

The objectives and remit of the committee

The specific functions and duties of the committee

The reporting lines and responsibilities of the committee

The following is a model "Terms of Reference" for a UREC:

> The objectives of the committee are to maintain ethical standards of practice in research, to protect participants in research and researchers from harm, to preserve the participants' rights, to take account of legitimate interests of other individuals, bodies and communities associated with the research and to provide reassurance to the public and to outside bodies that these are being done. It is also the aim of the committee to facilitate, not hinder, valuable research, and to protect research workers from unjustified criticism.

Terms of reference

The terms of reference of the committee are:

1 to receive details of any research proposed to be carried out on human beings by members of the University staff, in cases where the researchers would be undertaking the research only in their capacity as University staff, and the research might reasonably be considered to raise ethics questions; and similarly to receive details of such research proposed to be carried out by registered students of the University where such research would be carried out in their capacity as students of the University;

2 to consider such research on behalf of the Senate of the University, and to approve it as proposed, or to approve it under certain defined conditions or specific requirements, or to refuse approval;

3 to advise, at its discretion, on the ethics of studies on human beings not satisfying all the criteria in 1 above.

4 Following approval, to exercise powers to require the halting of research if substantive ethics flaws are identified during review until such time as any such flaws have been remedied to the satisfaction of the REC.

b) Job descriptions for committee members (recommended)

Job descriptions for UREC chairs and UREC members can help to clarify roles and responsibilities as well as demonstrate competence.

(2) *Training and development of members of the committee (required)*

The effectiveness of a UREC relies largely on the degree to which research organisations are able to build appropriate structures and create a culture that recognises the central place that ethics review occupies in good research practice. Ethics training plays a central role in this process; such training should be on-going and become an integral part of research practice.

Competent RECs require agreed minimum standards of training and competence on the part of their members, which may be achieved through programmes at institutional, faculty, departmental or research centre/unit level. The aim of the training should be to provide individuals with confidence in their abilities to conduct thorough and consistent ethics scrutiny of all types of research.

(3) *Standard Operating Procedures (recommended)*

In many areas governed by regulatory requirements, standard operating procedures (SOPs) have become crucial elements in demonstrating that the institution has a framework to meet compliance obligations. It is important that universities seeking to demonstrate a commitment to ethical research consider the development and implementation of a set of standard operating procedures (SOPs) for URECs. The model SOPs set out here demonstrate the way in which this could be achieved and covers the sort of issues that might be covered in an institution's own SOPs.

ARECs position is that **best practice would be for URECs to use SOPs**, but it is also acknowledged that this might be difficult for some institutions to develop. However, it should be borne in mind that a major advantage of using SOPs is that they allow for a degree of comparability across institutions of different types thus *demonstrating* more easily to external scrutiny that standards of ethical review are being maintained and, ultimately, that best practice in research ethics and integrity is being encouraged and supported by the institution.

(4) *Other procedures and guidelines (recommended)*

Procedures and guidelines that are of a more informal nature might be included in SOPs. However, some institutions might prefer to keep such informal procedures separate. Such procedures might include areas such as the conduct of meetings, the treatment of applicants meeting the committee, or where different URECs within one institution come to different opinions, as well as dealing with complaints.

Model Standard Operating Procedures (SOPs)

Set out below are some general issues that might be covered by SOPs. The purpose is to put into practice the principles and policies that have been discussed above. Some organisations, notably NRES[4] and the US OHRP[5], use SOPs as a way of defining very closely how a REC[6] should operate. Such a detailed document may be unnecessary for an individual institution but it is a useful prompt for REC chairs and administrators to think about issues that crop up from time to time. An Appendix has therefore been added which sets out, in NRES format, some issues that may require operating procedures.

(1) *The role of a Research Ethics Committee*

The SOPs should expand on the terms of reference of a REC. The role of a REC is normally:

- to review all research involving human participants conducted by individuals employed by or registered as students within that institution;
- to ensure that ethics review is independent, competent and timely;
- to protect the dignity, rights and welfare of research participants;
- to consider the legitimate interests of other individuals, bodies or communities associated with the research;
- to consider the safety of the researcher(s);
- to make informed judgements of the scientific merit of proposals, or to ensure that such judgements have already been made;
- to make informed recommendations to the researcher if the proposal is found to be wanting in some respect.

(2) *The constitution of a Research Ethics Committee*

The SOPs should set out the principles concerning membership of a REC, which should normally:

- be multidisciplinary;
- include both men and women;
- include at least one appropriately trained external member with no affiliation to the department, university or research institution;
- have members with a broad experience of and expertise in the areas of research regularly reviewed by the REC, and who have the confidence and esteem of the research community;
- include at least one member who is knowledgeable in ethics;
- include individuals who reflect the ethnic diversity of the local community;
- have members who represent a broad range of methodological expertise;
- be constituted so that conflicts of interest are avoided.

This would normally mean that a REC has at least 10 members and preferably 12.

[4] National Research Ethics Service (UK)
[5] Office for Human Research Protections (USA)
[6] in the USA, an Independent Review Board or IRB

(3) *Applications*

SOPs should set out:

- a requirement to use the prescribed form;
- who should complete, sign and validate the form prior to submission;
- the time within which a fully completed application is normally considered by the REC and provisions for 'stopping the clock';
- arrangements for requesting amendments;
- arrangements for dealing with appeals.

(4) *Fast-tracking ethics review and devolved review*

NRES now has a system of what it calls proportionate review in order to fast-track research projects that are considered low risk; in the USA, it is called 'expedited review'. An institution's SOPs should set out the arrangements for fast-tracking project review. Since this will usually involve devolving review to local ethics review panels or bodies, there need to be defined arrangements to ensure that such review is carried out in accordance with ethics principles.

(5) *Monitoring*

Although URECs themselves will probably not be resourced to undertake proactive monitoring, all research organisations should establish appropriate procedures to monitor the conduct of research which has received ethics approval until it is completed, and to ensure continuing review where the research design anticipates possible changes over time that might need to be addressed. Monitoring should be proportionate to the nature and degree of risk associated with the research. It should include consideration of best-practice procedures for the secure holding and preservation (or destruction where appropriate) of the data.

Where an UREC considers that a monitoring report raises significant concerns about the ethical conduct of a study, it should request a full and detailed account of the research for full ethics review. Where it is judged that a study is being conducted in a way that is unethical, it should consider the withdrawal of its approval and require that the research be suspended or discontinued.

The SOPs should set out the detail of the monitoring arrangements.

APPENDIX 1: SOP Framework

The following is a framework set of SOPs developed by drawing from NRES procedures, with some references to the requirements of the US OHRP. It is not suggested that this should set a standard for determining the acceptability of an institution's ethics judgements, but it does give a prompt for thinking about some of the procedural issues that arise in ethics review.

'Standard Operating Procedures for Research Ethics Committees', produced by NRES (http://www.hra.nhs.uk/resources/research-legislation-and-governance/standard-operating-procedures/) (version 5.1, March 2012) is a comprehensive document of some 278 pages, covering the minutiae of operating procedures as well as guidelines interpreting relevant legislation. It is unnecessarily detailed for URECs but offers the most complete framework available in the UK, and it is arguably desirable to have parity across research ethics review in the UK. However, regard must also be paid to the US equivalent, the Common Rule, often referred to prosaically as 45 CFR 46, produced by the Office of Human Research Protections (OHRP) within the Department of Health and Human Services (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). This contains a number of procedures which any institution in receipt of US government funds for a research project involving human participants would be expected to follow.

1 Introduction

1.1 Purpose

The SOPs should set out their purpose, which, generally, might be:

- to meet the obligations of the university's own research ethics policies
- to have due regard for national and international guidelines, and in particular:
    - NRES SOPs;
    - 45 CFR 46;
    - EU Directive 2001/20/EC, as incorporated into UK law by the Medicines for Human Use (Clinical Trials) Regulations 2004. These Regulations do not apply directly to universities but it is generally held that the procedures required by the EU Directive ought to be applied to the review of all research involving humans.

It might also be useful to set out areas that are outside the scope of URECs:

- projects involving NHS patients and carers, except those research activities defined by NRES as not requiring ethics review within the NRES processes, such as audit or service evaluation;
- most projects involving participants with mental incapacity;
- research involving tissue that comes under the Human Tissue Act 2004;
- some types of research involving prisoners.

1.2 Terminology

It would be helpful to list in a glossary the terms commonly used within the institution to define or describe aspects of ethics review, and to define those words and phrases within the text. Examples might be:

Adverse reaction/event	An untoward and unintended response or event with the potential to cause harm.
Care organisation	The organisation responsible for the care of anyone participating in a study.
Chief Investigator (CI)	The investigator with overall responsibility for a research project.
CTIMP	Clinical Trial of an Investigational Medicinal Product. Such a project must go through a designated NRES committee.
Minor amendment	Amendment not requiring formal review by the REC.
Principal Investigator (PI)	The responsible Investigator for a research site. CI and PI have specific meanings within NRES but URECs are unlikely to have multi-site projects which need PIs as well as a CI.
Provisional opinion	A decision reached by a REC subject to the receipt of further information or clarification.
Sponsor	The person who ultimately takes responsibility for the initiation, management and financing (or arranging the financing) of a research project.
Substantial amendment	Commonly defined as an amendment which significantly affects: the safety or physical or mental integrity of research participants; the scientific value of the study; or the conduct or management of the study.

Universities might wish to vary or add their own definitions.

2. Applications

2.1 Applications should be made on a prescribed form. It is suggested that guidance should be given on what the form should include – for example investigator details, type of research, outline of project, methodology, statistical justification (if relevant), details about participants, risks and how these are mitigated, how informed consent is obtained and so on. There may be circumstances in which a shorter form is acceptable.

2.2 The application should be made by the CI. Each institution will wish to decide what status a CI must have – for instance, could a research student be a CI, or must it be a member of staff? Either way it should be clear who carries responsibility (a) for the application and (b) for the conduct and management of the research.

2.3 In general, when a main study is supplemented by a series of sub-studies, each with its own protocols, there should be one application for each sub-study.

2.4 Procedures should specify how a form is submitted and what constitutes a valid application. This might include the submission of:

- a completed *and signed* form;
- the study protocol
- information sheet, consent form, advertisement;
- research tools – questionnaires, interview schedules.

A checklist of supporting documents for each application would be helpful.

2.5 Consideration should be given to setting a number of days within which the institution undertakes to complete an ethics review. It should not be more than 60 days as an absolute maximum from the validation date (normally the date on which all supporting documents have been received) and best practice would achieve shorter timeframes. Arrangements also for 'stopping the clock' should be noted.

3. The committee and meetings

Procedures should be set down to cover the following issues:

3.1 Constitutional matters

3.1.1 Formal terms of reference

3.1.2 Who appoints members and for what term

3.1.3 The chair and any deputies

3.1.4 Membership and diversity requirements (subject disciplines, expert, lay, etc.)

3.1.5 Quorums

3.1.6 Use of alternates, co-opted members and observers

3.1.7 Indemnity for members

3.1.8 Responsibilities of the administrator/co-ordinator

3.2 Business procedures

3.2.1 Meeting schedules – frequent enough to meet time deadlines

3.2.2 Declarations of interest and circumstances in which a member might withdraw temporarily

3.2.3 Confidentiality of discussions

3.2.4 Attendance by CIs, PIOs, supervisors, students

3.2.5 Decision-making normally by consensus, but in the event of a vote should there be a simple majority to approve a project, or a percentage higher than 50%?

3.3 Documentation

3.3.1 Documentation normally distributed to the committee

3.3.2 Documentation retained for viewing if required

3.3.3 Should all members receive the same documentation or should one or more 'primary reviewer' receive complete papers and others a summary?

3.3.4 All members should record return of documentation and the required retention period and storage arrangements be in place.

3.4 Minutes

These should show:

- members present
- those interviewed or present for other reasons
- summary points of issues discussed
- record of decisions
- frequency of continuing review
- record of voting (although this may seem superfluous, given that nearly every decision is by consensus, the OHRP may ask to see this in order to maintain the accreditation).

4. Giving an ethics opinion

4.1 Decisions available to the committee:

- approval (NRES prefers the term 'favourable opinion')
- conditional approval
- non-mandatory advice
- resubmit with revisions
- reject
- refer to another committee with or without advice

4.2 Letters arising from decisions

Institutions might wish to consider the following standard or optional items:

4.2.1 Approval letters

There might be stated methods of authenticating an approval letter (e.g. letterhead, email address) or more detailed prescription of what should be included in an approval letter, such as:

- Signature of Chair or designated person
- acknowledgement of those present at meeting
- period of validity of ethics approval
- warning about deviating from approved protocol
- mechanism for amendments
- requirement for continuing review/final report
- use of standard formulae, such as headed paper
- record of exchanges between committee members and the CI (this is now standard NRES practice, on the grounds that it supplements or clarifies the written evidence)
- any non-mandatory advice

4.2.2 Letters conveying conditional approval

- Revision, additional information or clarification required for the committee to be able to give final ethics approval

4.2.3 Letters conveying rejection or requirement for major revision

- Reasons for required revision or re-submission

- Appeals mechanism (each institution will have to decide whether appeals are limited to procedural matters, or whether appeals against a committee's judgement are permitted).

4.3 Mechanism for considering further information, clarification or revision

4.3.1 Circumstances where approval can be made by the chair or secretary (normally when the revision etc. is factual or simple)

4.3.2 Provision for an executive group to review

5. Amendments

5.1 Definition of minor and substantial amendments

5.2 Mechanism for dealing with substantial amendments
- circumstances for referral to full committee
- circumstances for referral to executive committee

6. Sub-committees

Within NRES there is provision for the establishment of one or more sub-committees from within the membership of the main committee. A UREC might well have such a sub-committee, but Universities are likely to have subsidiary tiers of associated or sub-committees based on faculties, schools, departments or particular subject areas. The numbers and complexities of these committees will mean that only a minority, if any, of their members can be drawn from the membership of the committee with overall responsibility for ethics review within the institution.

6.1 Executive sub-committee

This is defined here as a sub-committee drawn wholly from the main committee, to transact business on its behalf.

6.1.1 Function – to act on behalf of the main committee in specified areas:
- To review applications
- to review amendments to approved projects
- to consider revisions to conditionally approved projects
- to monitor progress reports
- to consider urgent new applications within defined circumstances

6.1.2 Authority

Sub-committees should have the full authority to act on behalf of the main committee in giving ethics opinions, but they may refer a matter up to the full committee.

6.1.3 Membership

Membership should never be less than two and preferably enough to allow for absences.

6.1.4 Virtual meetings

Provision might be made for sub-committees to hold virtual meetings rather than face-to-face ones.

6.2 Subsidiary committees

Each university will have its own methods of delegating authority to undertake the ethics review of research projects, as it is unlikely that any one committee would have the capacity to review all the relevant research projects within one institution.

6.2.1 Subsidiary committees should have common arrangements for governance, including function, terms of reference, authority, membership and reporting arrangements.

6.2.2 Each committee should have full authority to provide ethics opinions, but may refer individual projects to the main committee. There may be provision for certain key members to have an overriding right to refer any project to the main committee.

6.2.3 Membership may be small but at least one member should be drawn from outside the subject area. Ideally every REC should have a 'lay' member but this may not be practicable.

6.2.4 There should be a mechanism for appeals from the subsidiary committee to the main committee.

6.2.5 There should be provision for virtual meetings.

7. Proportionate or expedited review

The fact that many student projects have to be prepared and conducted within a very short time means that occasions will arise when it is not feasible to wait until the next main meeting.

7.1 Criteria should be set out for those projects which may receive expedited review. These should include genuine urgency, minimal risk and proportionality in dealing with ethics issues.

7.2 Membership would be as set out in 6.1.3 above.

7.3 Arrangements for reporting decisions reached should be stipulated.

7.4 The use of electronic means of communicating among REC members and expediting review should be explored as potential facilitative mechanisms.

8. Appeals

Much under this heading depends on whether appeals are limited to procedural matters or whether appeals against an ethics judgement are permitted.

8.1 If applicants are given an unfavourable opinion or if they think the conditions imposed are unreasonable, they may either:

- submit a new application
- ask for the project to be reviewed by another committee.

8.2 In the latter case, arrangements need to be in place for lodging the appeal and placing the project on the agenda of the appeal committee.

8.3 An appeal against a decision made by a subsidiary committee would normally go to the main committee, although there may be provision for transferring to another subsidiary committee.

8.4 If the main committee deals normally only with policy matters, it can become the appeal body for such cases, but the rules of equity dictate that members of this appeal body should not have been involved in the original review.

8.5 If the main committee does ordinarily review projects, then special arrangements need to be in place for any appeal that might arise.

9. Monitoring research

9.1 As in the case of NRES advice to RECs, it is the assumption that URECs should not be responsible for the proactive monitoring of research. They should, however, continue to be responsible for keeping the original approval under review.

9.2 Duration of approval

9.2.1 Consideration may be given to limiting the time by which a project should commence once approval has been given. NRES advice is that a study which has not recruited a volunteer within 12 months needs the approval of the chair to extend the start date and of the committee itself for anything beyond 24 months.

9.2.2 Normally an ethics approval should be valid for the duration of the research, with provision for it to be extended as a minor amendment. However, it may be thought necessary to set a time limit of say, five years, beyond which any extension should be regarded as a new application.

9.2.3 If for whatever reason part of research has gone ahead before REC opinion has been received, then the CI/PIO should report the circumstances immediately to the REC who will weigh the impact in relation to the research as a whole and the potential damage to its integrity

9.3 Progress reports

9.3.1 Progress reports should be submitted at least annually.

9.3.2 A report, however, may be sought at more frequent intervals or at any time on request of the Committee. On this point OHRP expects RECs to keep a formal record of the reporting interval for each approved project.

9.3.3 The need for progress reports after the first annual report may be waived where it is clear that the active involvement of participants has been completed but the research is continuing for other reasons.

9.3.4 Progress reports can be monitored by the chair or nominated person and should not need formal review or approval. Any matter of concern can be referred to the committee or sub-committee.

9.3.5 Any decision arising from a progress report to suspend or terminate an ethics opinion should be taken by the committee, unless an overriding safety factor has to be considered.

9.3.6 Failure to provide a progress report after a reminder may constitute grounds for suspending an ethics approval.

9.4 Safety measures

9.4.1 If a CI suspends a research project for reasons relating to a participant issue, the matter should be reported to the REC without delay (3 days is specified by NRES).

9.4.2 There should be a protocol for the definition and reporting of Serious Adverse Events (SAEs).

9.5 Final reports

9.5.1 The CI should inform the REC of an early termination or a decision not to commence a project that has received a favourable opinion.

9.5.2 Each project should submit a final report to the REC, which should include information on whether the study achieved its objectives, the main findings and arrangements for publication or dissemination of the research results, including any feedback to participants. In many cases this final report will be made before or as part of the first annual report.

Acknowledgments

A lot of preparation has gone into this document and the Association of Research Ethics Committees would like to thank all those, both named and unnamed, who contributed to its formulation, writing and editing. The basic concept that universities should have a common set of principles and standards of ethical review for research was advocated more than ten years ago by Professor Anthea Tinker of Kings College London, which has generously hosted many meetings and seminars of UREC representatives, helping us to shape our ideas. We were encouraged to move forward with these ideas by David Anderson-Ford of Brunel University, co-convenor of the UK UREC Forum and subsequently Chair of AREC. For the formulation of the principles which underlie the Framework we must thank John Oates of the Open University. Various members of AREC's University Development Committee then contributed to the writing of the Framework, including Lorna Carter of Oxford University REC, Gella Richards of Roehampton University and Bridget Egan of Winchester University, while the final editing was undertaken by Birgit Whitman of the University of Bristol, Andrew Rawnsley of Teesside University, John Oates and Bridget Egan. Finally, we were all kept on track by Jackie Maull, Chief Executive Officer of AREC, who co-ordinated all our efforts and made sure we all had the right version of our various drafts at the right time.

Timothy Stibbs

Chair of AREC

Appendix 2: Self Assessment

QA framework: self-assessment (to be done web-based)	
1 = Standard not met	**2 = Standard partially met**
3 = Standard almost met	**4= Standard fully met or exceeded**

Domain 1: Principles of Research Ethics			
Standards	**Score: 1- 4**	**Evidence** **What documentation embodies the principles of research ethics?**	**Plan for enhancement** **What action is planned to improve the process? By when should it be complete?**
1. Autonomy			
2. Beneficence			
3. Non-maleficence			
4.Confidentiality			
5. Integrity			

Domain 2: Principles of governance arrangements			
Standards	**Score: 1- 4**	**Evidence**	**Plan for enhancement** **What action is planned to improve the process? By when should it be complete?**
1. Independence a. Do reviewing committees include members from a wide range of disciplines? b. Do committees have members from outside the Faculty or academic unit covered by the committee? c. Do the constitutions of RECs grant freedom to make ethical judgments, while being consistent with accountability? d. Do committees include 'lay' or external members? e. (if faculty/ departmental committees in place) Is there an over-arching strategic committee that functions as the appeals committee? f. Are arrangements for appeal in place?			

2. Competence a. Does the UREC have a clear process in place to ensure that ethical opinions are reached timely and consistently? b. Does the UREC have a standard form that asks all the questions that a competent REC in that Faculty of Academic Unit needs to have answers for? *c.* Does the university demonstrate that it has a commitment to competent ethical review by recognising UREC members for their contribution to the University by citizenship recognition or allocated hours in the working week?			

3. **Facilitation** Ethics review infrastructure must be clear within the institution. a. How is the independence and integrity of committee decisions maintained? b. What is the mechanism for appeal? c. What procedure deals with complaints that an applicant had been treated unfairly or discourteously. d. How are RECs linked to the Research Governance structures?. e. How is compliance with ethical requirements monitored? f. How is non-compliance addressed? g. Job descriptions or TOR for Research Ethics Officers			

4. Openness, *Transparency and Accountability* a. How are the ethics policies and processes of review made available to the public? b. How is individual intellectual property safeguarded? c. Is the policy and process regularly reviewed? d. How is confidentiality about any disputes or appeals maintained?			

Domain 3: Policies, Procedures and Guidelines / SOPs			
Standards	**Score: 1- 4**	**Evidence**	**Plan for enhancement** **What action is planned to improve the process? By when should it be complete?**
Policy Does the institution have a robust ethics policy (either a stand-alone policy, or incorporated into a Research Conduct or Research Integrity policy)			
Standard Operating Procedure The institution has a framework to meet compliance obligations. **The SOP or guidance framework should cover the following:** a. The role of a Research Ethics Committee b. The constitution of a Research Ethics Committee c. Applications **d.** Fast tracking Ethical Review **e.** Devolved Review			

Domain 4: Training and development			
Standards	**Score: 1- 4**	**Evidence**	**Plan for enhancement** **What action is planned to improve the process? By when should it be complete?**
Training provision What arrangements are in place for a. training of ethics committee members b. training of other academic staff in the institution			

Table 1. Glossary for AREC Framework of Policies and Procedures

ABBREVIATION	Full text and first time appears in framework document
AR	Adverse Reaction (p18)
AREC	Association of Research Ethics Committees (p4)
CI	Chief Investigator (p18)
CTIMP	Clinical Trial of an Investigational Medical Product (p18)
EU	European Union (p17)
HEIs	Higher Education Institutions (p3)
IRB	Independent Review Board (USA) (p15)
NHS	National Health Service (p10)
NRES	National Research Ethics Service (p15)
OHRP	Office of Health Research Protections (USA) (p15)
PI	Principal Investigator (p18)
PIO	Principal Investigating Officer (p19)
QA	Quality Assessment (26)
REC	Research Ethics Committee (p3)
SAE	Serious Adverse Event (p24)
SOPs	Standard Operating Procedures (p14)
TOR	Terms of Reference (p29)
UK	United Kingdom (p3)
UREC	University Research Ethics Committee (p7)
UUK	Universities UK (10)
USA	United States of America (p15)