

SEN10D031

Title: Revisions to University Research Ethics Policy
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Issue

The policy approved by Senate in November 2005 (Ref SEN05A001) provides for a University Research Ethics Committee (UREC) which defines the University's ethics policy and operational principles. Changes to the structure of the Committee were approved by Senate in 2009. Since then, changes to legislation, funder requirements and a greater awareness of research integrity have resulted in the need to undertake a full review of the terms of the University Research Ethics Policy.

Recommendation

That the submitted University Research Ethics Policy, which was approved by the University Research Ethics Committee at a meeting on 5 May 2011, be approved by Senate.

Timing of decisions

Senate is asked to agree the recommendations at this meeting

Further Information

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Background

The development of the University Research Ethics Policy has been influenced by the requirements of

- the ESRC Framework for Research Ethics
- the RCUK Policy and Code of Conduct on the Governance of Good Research Conduct "Integrity, Clarity and Good Management"
- the UK Research Integrity Office Code of Practice for Research "Promoting good practice and preventing misconduct"
- the European Commission guidance on Ethics For Researchers

as well as the need to expand the guidance on the requirements of the Mental Capacity Act 2005 and the Human Tissue Act 2004.

In addition it has been made explicit that failure to comply with the Policy, by staff or students, may constitute research misconduct and be subject to disciplinary action.

Further developments

As a result of the Integration Project the administrative and support structures for the sub-committees of the University Research Ethics Committee, and the responsibilities at Faculty level, will require revision. The Annexes to the Policy are therefore supplied for information only, and will be submitted to Senate for consideration in due course.

UNIVERSITY OF EAST ANGLIA
RESEARCH ETHICS POLICY, PRINCIPLES AND PROCEDURES

1 INTRODUCTION

1.1 OVERVIEW

The 'Research Ethics Policy, Principle and Procedures' (the Policy) has been developed in close consultation with University stakeholders and builds on the '*Framework for Ethical Approval*' (approved by Senate in 2004) and existing good practice and local procedures in Faculties and Schools of Study, relevant legislation and the requirements of professional and funding bodies.

The University is committed to promoting high ethical standards in research and to safeguarding the dignity, rights and welfare of all those involved in research. The Policy should be read in conjunction with other complementary policies, including the University's '*Guidelines on Good Research Practice*' and with the University's '*Procedures for dealing with allegations of misconduct in research*', as well as specific ethics guidance issued by the University Research Ethics Committee and any associated sub-committees.

When undertaking research, it is the researcher's responsibility to consider and observe ethical principles and the University's Research Ethics Policy.

This policy sets out conditions for establishing the ethics review and approval requirements of research and other projects involving human participants and animals.

It also provides guidance on the review of projects which do not fit the definition of research but which may present ethical issues.

The original Policy was approved by Senate on 23 November 2005 on recommendation of the University's Research Executive. Revisions to the Policy were approved by Senate on 21 June 2006. Senate approved further revisions on 25 February 2009 *and the current version of the Policy on xxxxxxx*.

1.2 RESEARCH ETHICS

The University uses the 'Research Assessment Exercise 2008' definition of research for the purpose of this Policy, but recognises that it is also necessary to take account of specific legislative and funding body requirements. Additionally, there are forms of enquiry or investigation which may not strictly be defined as research, but which may carry risks to participants or infringe ethical principles or legal obligations, and need to be considered under the rubric of the University's Research Ethics Policy

The concept of ethics is taken to define systems of moral principles or values, principles of right or good behaviour in relation to others, integrity and the rules and standards of conduct binding together members of a profession. The concept of research ethics marries these two issues together. The concept can cover all types of research, from research involving animals and other living subjects to research involving the environment, and can be used to determine what types of research an organisation will support. The nature and source of funding may also independently play a role in the decision making process. Although ethics should always be a consideration in research, this does not mean that full ethics review by the University

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is always required; ethics review supports good research practice and is not an end in itself.

Many of the ethical decisions taken at the University concern two broad areas: human participants and animal research.

Research involving human participants (“participants”) is defined broadly to include research that:

- directly involves people in the research activities, through their physical (or virtual) participation. This may be interventional (eg. surgery, drug trials, interviews, questionnaires) or non-interventional research (e.g., surveys, observational research) and may require the active or passive involvement of a person;
- indirectly involves people in the research activities, through their provision of, or access to, information, personal data and/or tissue;
- involves people on behalf of others (e.g. legal guardians of children and the psychologically or physically impaired and supervisors of people under controlled environments (e.g. prisoners, school pupils)).

Animal Research is defined as any research involving any non-human animal. This includes research that is regulated by the Animals (Scientific Procedures) Act 1986 as well as research that is not covered by the Act.

Other areas of ethical consideration covered by the Policy include research that involves organisations which may have concerns about disclosure, research which may relate to illegal activities (such as downloading obscene material from the internet) and where the source of funding or other stakeholder in a research project introduces direct or indirect links with unethical activities or which conflict with the University’s mission and values.

1.3 APPLICABILITY

The University’s Policy is generic and applies to:

- all University researchers (staff and registered students) who are conducting or contributing to research activities either within or outside the University as an institution;
- all individuals who are not members of the University (including visiting academics and Fellows) but who are conducting or contributing to research activities which take place within the University as an institution;
- all investigations which may have ethical dimensions and put people or the University at risk.

1.4 GOVERNANCE, RESPONSIBILITY AND OPERATIONAL ARRANGEMENTS

The University Research Ethics Committee (U-REC) defines the University’s Policy and operational principles, which are applied by U-REC and Sub-committees of the Research Ethics Committee (S-RECs).

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The University recognises that it is important for U-REC and its Sub-committees to be able to operate independently of any influence or bias inside or outside the institution, and has procedures to handle conflicts of interest.

As a condition of their employment, all staff are required to adhere to the policies, rules and procedures of the University. Individual researchers are individually responsible for adhering to the University Research Ethics Policy under the leadership of their Head of School, or Dean of Faculty, who are ultimately responsible for all activities performed in the School.

Students are governed by the General Regulations for Students which are available within the annual University Calendar or on the University website http://www.uea.ac.uk/polopoly_fs/1.130509!FWF38%20GEN%20REG%20FOR%20STUDENTS.pdf

The Policy recognises the University's distinct governance, culture and diversity, while supporting the achievement of its collective research objectives. Each Faculty will implement a system of ethics procedures which provides for registration of all research involving humans and animals in that Faculty, review by an appropriate Ethics committee where required, oversight by the Associate Dean for Research and reporting to the University Research Ethics Committee (U-REC).

The system is subject to the University's normal decision-making rules and procedures, including conflicts of interest. These procedures will be governed by the application of minimum terms of reference, principles and procedures defined by U-REC and set out in the Policy. Failure by a member of staff or a student to comply with Research Ethics Committee conditions may constitute research misconduct, and be subject to disciplinary action.

1.5 REVIEW

The University Research Ethics Committee (U-REC) will undertake periodic reviews of the Policy and report its key findings and recommendations to the University's Research Executive, and thereafter to Senate.

1.6 REFERENCES AND ACKNOWLEDGEMENTS

In informing the development of this policy, a broad range of publicly-available material and resources has been used from government departments, professional bodies and other universities, including:

- Association of Research Ethics Committees
- Council for Industry and Higher Education
- National Research Ethics Service (NRES)
- Department of Health
- Higher Education Funding Council
- Office of Research Integrity
- National Health and Medical Research Council (Australia)
- Research Councils UK
- Royal College of Physicians Guidelines on the Practice of Ethics Committees
- Royal Society for the Prevention of Cruelty to Animals
- University of Cardiff
- University of Sheffield
- Universities UK

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- ESRC Framework for Research Ethics
- The Information Commissioner's Office
- US Code of Federal Regulations 21CFR56.108

An electronic copy of this Policy and associated reference material is maintained on the Research and Enterprise Services website:

2 ETHICAL PRINCIPLES FOR RESEARCH

2.1 OVERVIEW

The Ethical Principles for Research provide the strategic framework to realise the Policy and are intended to protect both participants involved in research activities undertaken by University researchers, the researchers themselves and the University. The University's ethical review procedures provide the operational framework (see section 3).

The primary responsibility for considering ethics in research lies with the lead researcher, student supervisor or equivalent. Prior to, during and following the completion of research activities, researchers are expected to consider the ethical implications of their research and, depending on its nature, the socio-cultural consequences of it for the participants involved. This should be considered in the context of a range of other potential stakeholders, including fellow researchers, their School and the University, the research funder and the academic profession.

No one should be compelled, or compel others, to undertake or participate in a research activity that conflicts with their own individual ethical principles or beliefs.

2.2 PRINCIPLES

2.2.1 LEGAL RIGHTS, CONVENTIONS AND SPECIAL POLICIES

People participating in research have, at the very least, all the rights as defined by law (eg. the Human Rights Act 1998, the Data Protection Act 1998, the Mental Capacity Act 2005, and relevant European Directives and conventions).

The United Kingdom is not a signatory of all conventions relevant to research ethics and does have certain opt-outs from specific provisions of ones it does. However, as statements of widely accepted ethical standards, researchers, members of the University's Research Ethics Committees and reviewers may refer to such documents for guidance.

Where organisations involved in the research prescribe special policies in this context which are not necessarily legal requirements, these should be observed, in so far as this does not conflict with ethical standards.

2.2.2 THE UNIVERSITY'S MISSION AND VALUES

The nature and ethical standing of other stakeholders involved in a research project should be considered in the context of their fit with the University's mission and values.

2.2.3 CONFLICTS OF INTEREST

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Conflicts of interest arise where an individual may have a pecuniary, family or other personal interest in an activity which a member of the public, knowing the facts of the situation, could reasonably conclude might influence that individual's judgement. The University's standard rules and procedures on dealing with conflicts of interest apply equally to this Policy: any real or potential conflict of interest must be disclosed to the relevant Head of School or Service who will make a decision or refer to another authority as appropriate.

In the specific case of research ethics review, a conflict of interest may arise through links with the funder, such as consultancy, directorships or shareholdings. This may also occur in the course of research ethics approval, such as when a member of one of the University's research ethics committees has an interest in a project under review, or has a close personal relationship with the researcher.

The existence of a conflict of interest does not inevitably mean a researcher or member of a committee must be excluded. In all cases, however, any real or potential conflicts of interest must be fully disclosed on the ethics review application or to the chair of the committee respectively; it is left to the judgement of the committee or chair to take any necessary precautions to remove the conflict of interest.

Where a conflict of interest arises after approval, the case should be referred to the relevant committee for re-approval.

2.2.4 SAFETY AND WELLBEING

Researchers have a responsibility to protect participants and colleagues from any harm arising from research. As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those they encounter in their normal lifestyles.

Depending on the nature of the research, researchers have a responsibility to ask participants about any factors in the research, such as pre-existing medical conditions that might create risks to them if they participate, and they must subsequently be advised of any special action they should take to avoid risk. Before participating, people should be informed of procedures for contacting the lead researcher within a reasonable time period if, following participation, they experience stress, harm or have related concerns.

If, during research activities, a researcher obtains evidence of physical or psychological problems of which a participant is apparently unaware, the researcher has a responsibility to inform the participant if he or she believes that by not doing so the participant's future wellbeing may be endangered. However, if the issue is serious and the researcher is not qualified to offer assistance, then the appropriate source of professional advice should be recommended to the participant.

Any researcher who has concerns that information about illegal or dangerous activities has been discovered should contact the U-REC Chair or Secretary as soon as possible, to discuss whether formal legal advice is needed.

Participants should also be given the option to refuse to be given information discovered as a result of research.

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In general terms, interventional research should only take place where the foreseeable risks to the participants are outweighed by the potential benefits. In exceptional cases, participants may feel they have a right to consent to potentially harmful research e.g. a terminally ill person may choose to participate in a high risk clinical trial.

In the case of research methods which do not involve physical intervention, the content and procedure may nevertheless be highly sensitive and intrude on a participant's comfort and privacy. Included in this category are interviews, questionnaires, participant observation and ethnographic approaches. The initial judgment on whether or not questions are sensitive and likely to cause harm rests with a lead researcher, but should be considered by a Research Ethics Committee.

2.2.5 INFORMED CONSENT

Informed consent is the process whereby a prospective participant, prior to participating in research, is fully informed about all aspects of the research project which might influence their willingness to participate, in a language which the participant understands. In addition, the researcher should normally explain all other aspects of the research about which the prospective participants enquire. The basis of this is to provide free and voluntary consent. Information before consent is sought should be provided with sufficient time for it to be assimilated so as to avoid the possibility of coercion.

2.2.6 OBTAINING CONSENT

Normally, potential participants in research must give their informed consent prior to participation, and the lead researcher is responsible for ensuring that consent is obtained. Consent must be given freely and voluntarily and under no circumstances must coercion be used to obtain a person's consent to participate in research. There should be a recognition and consideration of any power differential between the researcher and participant in this context. Wherever possible, and proportionate to the nature of the research activity, an individual's consent should be obtained in writing. Where this is not possible oral consent should be obtained and recorded, ideally in the presence of at least one witness.

Prior to participation, researchers must make clear a participant's right to refuse to participate in or to withdraw from the research at any stage, irrespective of whether payment or other inducement has been offered. This also applies where participant data are identifiable.

Informed consent should also be seen as an ongoing process, with the researcher ensuring at each stage of the research that the participant understands the process and continues to give voluntary consent.

2.2.7 CONSENT AND VULNERABLE PARTICIPANTS

Some people participating in research may be more vulnerable to harm than others and this possibility requires special consideration.

From 1 October 2007, the Mental Capacity Act 2005 (which covers England and Wales) stipulates that research cannot include any people who lack capacity to consent to the research unless:

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- the research has the approval of a research ethics committee recognised by either the Secretary of State or the Welsh Assembly Government, as appropriate;
- the researcher considers the views of carers and other relevant people
- the research treats the person's interests as more important than those of science and society; and
- the researcher respects any advance decisions or expressed preferences of a person who lacks capacity and any objections the person makes during the research.

Any relevant legal requirements, conventions or special policies relating to participants not covered by the Mental Capacity Act should also be observed. This includes the provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004 which has separate requirements for participants who lack capacity to consent.

Researchers carrying out research in Scotland should refer to the provisions of the Adults with Incapacity (Scotland) Act 2000.

In Northern Ireland the final report of the Bamford Review on Mental Health and Learning Disability is being considered in reaching policy decisions on the way forward for this area of law. Such research is currently covered by common law.

2.2.8 CONSENT AND RESEARCH INVOLVING CONCEALMENT

Special consideration is needed in those exceptional circumstances where it may be desirable to avoid bias in participants' responses, by concealing or withholding particular information regarding either the fact they are the subject of research or the aims of the research. In such cases the Chair of the S-REC should consult the Chair and Secretary of the U-REC as part of the process of ethics approval.

2.2.9 CONSENT AND RESEARCH IN PUBLIC AND WITH GROUPS

Obtaining consent from every individual participating is not always possible or practical. In such cases, researchers should ensure that:

- such research is only carried out in public contexts;
- where possible approval is sought from relevant authorities;
- appropriate individuals are informed that the research is taking place;
- no details that could identify specific individuals are given in any reports on the research unless reporting on public figures acting in their public capacity;
- particular sensitivity is paid to local cultural values and to the possibility of being perceived as intruding upon or invading the privacy of people who, despite being in an open public space, may feel they are unobserved.

The privacy and psychological wellbeing of people participating must be respected. Every reasonable effort should be made to ensure that members of a group understand they are being observed for research purposes. In such activities, researchers should at least obtain the consent of any group leader or others in positions of responsibility.

2.2.10 ANONYMITY, CONFIDENTIALITY AND DATA PROTECTION

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The collection, storage, disclosure and use of research data by researchers must comply with the Data Protection Act 1998 and any subsequent revisions. Researchers must make arrangements to carefully protect the confidentiality of participants and ensure the security of their data. All personal information collected should be considered privileged information. It should be dealt with in such a manner that it does not compromise the personal dignity of the participants or infringe upon their right to privacy and Data Protection rights.

Before consent is obtained, researchers should inform prospective participants of:

- any potential risks or circumstances that might mean that the confidentiality or anonymity of personal information may not be guaranteed;
- which individuals and organisations, if any, will be permitted access to personal information and under what circumstances such access will be permitted;
- the purpose for which personal information provided is to be used;
- the identity of the Data Controller (see Research and Enterprise Services website for link to UEA guidelines).

A researcher may not disclose the identity of a person nor disclose any information that could identify that person without having obtained, prior to the person's participation, the person's consent in writing. If it is necessary to identify participants explicitly, then the researchers should explain why this is the case and how confidentiality will be protected.

Researchers should be aware of the risks to anonymity, confidentiality and privacy posed by all kinds of personal information storage and processing which directly identify a person, e.g. electronic and paper-based files and communications. Measures to prevent accidental breaches of confidentiality should be taken, and in cases where confidentiality is threatened, relevant records should be destroyed. Provisions for data security at the end of a project must be made.

Further guidance, regarding specific exemptions relating to research, is available from the University's Information Policy and Compliance Manager.

2.2.11 ANONYMISATION

Wherever possible data should be collected, stored or handled in anonymous form. Where linkage between datasets is required, record numbers should be used as far as possible with special measures used to protect the key that would link a number to personal identifiers.

2.2.12 NHS RESEARCH

The National Research Ethics Service (NRES) and the United Kingdom Ethics Committee Authority (UKECA) working on behalf of the Department of Health in England, are responsible for defining the scope and operation of NHS Research Ethics Committees which are recognised by the University as providing an equivalent review to its own (see 3.2.3 Approval routes and recognition of other review bodies). Similar provisions apply in the devolved administrations.

2.2.13 HUMAN TISSUE ACT 2004

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Under the Human Tissue Act 2004, research in England, Wales and Northern Ireland requires ethical review in certain circumstances:

- where the research involves material consisting of or including human cells taken from the living or the deceased (unless it is held on premises with a licence from the Human Tissue Authority to store relevant material for research);
- where the research involves the use of material consisting of or including human cells taken from the living, and the donor has not given consent for use of the material for research (the researcher must also be unable to identify the donors of the material);
- where the researcher holds material consisting of or including human cells and intends to undertake DNA analysis, and the donor has not given consent for the analysis (the researcher must also be unable to identify the donors of the material).

See

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm>

for further guidance

Under the Regulations made under the Human Tissue Act ethical approval can be given by any ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA) under the Clinical Trials Regulations, or any ethics committee recognised by the Health Departments in England, Wales and Northern Ireland to advise on the ethics of research involving human tissue. This currently does not include University Research Ethics Committees.

The use of tissue from the deceased for research, and living donations for transplant, in Scotland, are covered by the Human Tissue (Scotland) Act 2006

See www.ukcrc-rgadvice.org/Documents/MRC_Human_Tissue_Summary-Scotland.pdf

2.2.14 ANIMAL RESEARCH

Some animal research is not regulated by the Animals (Scientific Procedures) Act 1986. This includes: (i) any research involving non-vertebrate species (except *Octopus vulgaris*); and (ii) the identification of any non-human animal by ringing, tagging or marking or any other humane procedure that causes only momentary pain or distress and no lasting harm. In general, this research will also be informed by the principles of replacement, reduction, and refinement (the Three Rs). For certain purely observational protocols (e.g. bird watching), however, these principles may be less applicable.

However, before any animal research is undertaken (including non-vertebrate species, and field work) an assessment of the research using the UEA Animal Ethics Information Form must be carried out. This will include an assessment of whether the research involves a regulated procedure and an assessment of the applicability and implementation of the Three Rs.

The Animals (Scientific Procedures) Act 1986 regulates any experimental or other scientific procedure applied to a "protected animal" that may have the effect of

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causing that animal pain, suffering, distress or lasting harm. A procedure so defined by the Act is referred to as a "regulated procedure". The Act defines a "protected animal" as any living vertebrate, other than man. The invertebrate species *Octopus vulgaris* was added by means of the Animals (Scientific Procedures) Act (Amendment) Order 1993. The use of animals in regulated procedures requires a certificate of designation, a project licence and a personal licence. Licences and certificates under the Act are issued by the Home Office to individuals. It is therefore, the individual (not the organisation) who is responsible and accountable to the Home Office for ensuring compliance with the terms and conditions of the licence or certificate.

The use of animals in regulated procedures is governed by the provisions of the Animals (Scientific Procedures) Act 1986 and informed by the "Three Rs": replacement; reduction; and refinement. Those planning research involving regulated procedures should ensure that all legislative requirements are met and consider the following questions.

Replacement

- Reasons why it is considered necessary to use animals *at all* to achieve the objectives of the work, and why non-animal methods or alternative approaches to the scientific questions are considered unsuitable.
- Whether non-animal methods are also used as part of the overall approach to the research or testing objectives, and, if so, how the different methods relate to and build on one another.
- The efforts made to search for replacement alternatives for animal studies.
- If the researcher has to imagine a world in which it was not possible to use animals in research at all, how might they attempt to address the research questions, and what would be the limitations of possible alternative approaches?

Reduction

- The process by which the numbers of animals has been decided, e.g. expert statistical advice.
- Whether expert advice might enable use of fewer animals, yet still provide meaningful results.
- On-going review to evaluate the need for as many animals as first predicted.

Refinement

- Reasons why it is considered necessary to use animals in the *particular ways* detailed in the study, and how the use(s) contribute to the objectives of the work.
- The particular adverse effects that will be, or are being, caused to the animals in the study, including detriment caused at any stage from birth to death of the animals, such as those resulting from: choice of species and strain of animal; source and transport of animals; housing and husbandry of animals; effects of procedures used (including how frequently each is performed), and care of the animals before, during and after each; end-points of the procedures; and the fate of the animals at the end of the procedures.
- Whether any of these aspects could be refined, so that harms to the animals are reduced.

2.2.15 PROJECTS WHICH DO NOT FIT THE DEFINITION OF RESEARCH

Each Faculty should have an explicit procedure for the governance of non-research projects (e.g. service evaluation, audit, consultancy involving human tissue, enterprise and engagement activities) which may involve research methods and may have ethical issues. This should state that investigators **MUST** submit such projects to be considered and recorded, which **MAY** include referral to one of the University's Research Ethics Committees for advice before and during the project. Assessment of a project must be carried out and documented before it starts. Where a project has received approval from the organisation being studied (e.g. NHS Trust audit committee) evidence of this should be accepted as sufficient review.

2.2.16 ARCHIVING TRIAL DATA

Trial data should normally be preserved and accessible for 10 years, but for projects of clinical or major social, environmental or heritage importance, for 20 years or longer, as specified in a final protocol.

Personal data should only be kept in accordance with the provisions of the Data Protection Act 1998.

Advice on procedures for records management, storage and destruction can be obtained from the Information Policy and Compliance Manager, and the Information Services Department.

3 THE UNIVERSITY'S ETHICAL REVIEW PROCEDURES

3.1 OVERVIEW

The University's Ethical Review Procedures ("Procedures") provide the operational framework for the Policy and Principles. All University members of staff and University-registered students (i.e. postgraduate research, postgraduate taught and undergraduate students) who plan to undertake research that falls under the scope of the Ethical Principles in the Policy must obtain ethics committee approval for the planned research prior to the involvement of the participants, via the appropriate ethical review procedure. This includes research and surveys undertaken by non-academic departments. The Procedures also apply to all individuals who are performing research which is funded or managed by the University, whether this is on or off University premises.

The Procedures operate to protect participants in research, the researchers themselves and the University. They are designed to ensure that, as a minimum, every University researcher and School has access to a University recognised ethics review mechanism that is sufficiently flexible to accommodate the diverse research interests and needs of Schools while sufficiently coherent in design and operation to ensure consistency.

3.2 ETHICAL REVIEW PROCEDURES

3.2.1 SCOPE

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All research proposals, projects or assignments must be screened to determine whether or not formal ethical approval is required. If research plans alter, review may have to be requested during the course of the research, and should go back to the original reviewing Committee.

The individual researcher is ultimately responsible for a research project's ethical aspects. The initial responsibility for deciding whether or not ethical approval is required lies with the Principal Investigator or the Supervisor of a student project in consultation with the student. The outcome of the initial review of student projects should be submitted to an appropriate S-REC in accordance with the Terms of Reference (Annex 3).

The decision not to submit a research study for formal review may be subject to audit by U-REC at a later stage.

Research activities put forward for formal ethics review:

- require ethics approval prior to commencement of the research activities;
- cannot continue if ethics approval has been withdrawn or suspended;
- may have to request review during the course of the research if the research plan alters;
- must comply with the conditions set by the University or other recognised body.

3.2.2 UNIVERSITY RESEARCH ETHICS COMMITTEE (U-REC)

The University Research Ethics Committee defines the University's Policy and operational principles which are applied by Sub-committees of the Research Ethics Committee (S-RECs). U-REC reports to Research Executive and Senate.

The minimum terms of reference for U-REC can be found at Annex 1, the minimum Faculty level responsibilities are at Annex 2, and the minimum terms of reference for S-REC at Annex 3. These may be amended as required to comply with changes such as new legislation or funder regulations.

3.2.3 APPROVAL ROUTES AND RECOGNITION OF OTHER REVIEW BODIES

The primary routes through which to apply for ethical approval are:

- the University's ethical review procedure;
- the ethical review procedure of the NHS National Research Ethics Service (NRES); or
- other recognised body.

In principle, the Policy seeks to avoid multiple reviews of the same research project by separate bodies through recognising the reviews of other bodies. The recognition of another body is at the sole discretion of U-REC on behalf of the University, and these will be notified in guidance to Faculties as and when they occur.

The University recognises the NRES review procedure as equivalent to its own; where a proposal is reviewed under the NRES procedure, a University review is not required.

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Where an NHS REC decides it has no remit to review a project, for example, because there is no NHS involvement or the project is service evaluation, the researcher must report this to the School Research Ethics Officer or equivalent Faculty process, to undergo UEA Ethics review.

Should an applicant plan to seek ethical review via an alternative procedure (e.g. via an ethical review procedure from another University or overseas body) in the first instance, contact should be made with the Faculty Research Office for advice. This request may then be considered by an appropriate S-REC before being referred to the U-REC with a recommendation for a final decision.

3.2.4 THE UNIVERSITY'S ETHICAL REVIEW PROCEDURE

Within its broader interdisciplinary scope, which includes any ethical issue raised by members of staff and students, each Faculty may have specialist areas of research and deal with them through subject specific committees. Faculties may cross-refer cases to another Faculty where a particular specialism is covered by another S-REC. While the operational ethics review within a Faculty may take place within sub-committees, each with their own Chair, the Associate Dean for Research will take an oversight and management role. Minimum requirements for Faculty level responsibilities for Research Ethics Review are at Annex 2.

S-RECs are sub-committees of U-REC, work with the authority of U-REC and are independent of other governance processes. U-REC defines the minimum requirements for documentation to be used by S-RECs.

Approved S-RECs are constituted at Faculty, School or subject level, as considered most suitable, and subject to ongoing review. U-REC, and S-RECs consider research requiring ethical approval, following completion of the University Research Ethics Checklist. They may:

- refer research for approval by another committee,
- approve as submitted,
- approve subject to specified conditions,
- or reject research proposals

Decisions by the University's Research Ethics Committees are binding, and failure to comply with decisions may be regarded as misconduct in research. The Decisions of S RECs and U-REC may be appealed. (see 3.2.6 below)

Research involving biological hazards and/or genetic manipulation must also be considered by the Biological Hazards and GM Committee which reports to the University Health and Safety Executive.

3.2.5 FORMS OF ETHICAL REVIEW AND ASSESSMENT OF RISK

The form of ethical review is determined by an assessment of the potential risk associated with the research and the complexity of the ethical issues raised by the research proposal. Complexity here is defined by the need for diverse perspectives in order to reach a robust decision.

The University Research Ethics Checklist enables researchers to determine whether their research requires full review by an Ethics Committee.

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The University Research Ethics Checklist MUST be completed by the Principal Investigator or student supervisor for ALL research funded by the Economic and Social Research Council, which requires Light Touch review as a minimum condition.

Where minimal risk is involved and the level of complexity is low, a Light Touch review may be undertaken by a REC, and formal submission for ethical review will not be required.

Any funder or regulatory requirements for the form of review shall also be observed.

Guidance on the assessment of risk and complexity by the researcher is provided by S-RECs, subject to U-REC approval.

Where possible, standard protocols will be developed for commonly occurring situations, which will receive a full ethical review. This may limit the number of research proposals that need to receive a full ethical review, but a researcher conducting a project based on a protocol which already has approval will need to complete a University Research Ethics Checklist to demonstrate this.

3.2.6 APPEALS

An appeal against the decision of U-REC or an S-REC will initially be handled by informal arbitration, and conducted by the Chair of the reviewing REC, providing there is no conflict of interest. If this is unsuccessful the researcher may use the UEA Ethical Approval Appeals Procedure to make a formal application.

3.2.7 ADVERSE EVENTS

“any unanticipated problem involving risk to subjects that ultimately results in harm to the subject or others” [21 CFR 56 Sec 108(b)]

Every project proposal should state how unforeseen or adverse events in the course of the research will be managed.

The nature and severity of potential adverse events will form part of the risk assessment of the project. For example, the proposal might include provision for handling disclosure of criminal activity or directing participants to a source of counselling or support. Plans should also be made, as far as possible, to handle unforeseen events, by having a clear line of reporting for research staff, and ensuring familiarity with University and professional procedures.

Adverse and unforeseen events should be reported as soon as reasonably practicable, to the REC which reviewed the study. They should also be included in the Annual Report made by the Principal Investigator to the REC.

3.2.8 MONITORING OF UNIVERSITY ETHICAL REVIEW PROCEDURES AND RESEARCH

The U-REC has the authority to monitor the performance of the S-RECs as and when required and, as a minimum, will receive an annual report from each Committee on membership, key activities and findings over the preceding year.

In addition the U-REC will oversee the audit and monitoring of individual research projects.

3.2.9 COMPLAINTS

The participant information document for a research project must make it clear where any complaint regarding the conduct of the research should be addressed. In the case of student research this should be the supervisor, in the first instance. If the supervisor is unable to resolve the complaint, or in the case of research carried out by staff, the complaint should be directed to the Head of School.

The person investigating the complaint may wish to seek guidance from the REC which approved the project, and in any case must send a report on the complaint to the Faculty Associate Dean for Research and the reviewing REC at the completion of the investigation.

Annex 1: Minimum Terms of Reference for the University Research Ethics Committee (U-REC)

The University Research Ethics Committee (U-REC) defines the University's Research Ethics Policy and operational principles, which are applied by U-REC and its sub-committees (S-RECs), and reports to Senate.

1. The membership is as follows:
 - A Chair: appointed by Senate
 - A Deputy Chair
 - Each Faculty may send a maximum of two Chairs of S-RECs (in rotation)The Associate Dean for Research or nominated Deputy where the Faculty has no reviewing REC
 - The University's Information Policy and Compliance Manager
 - At least one Lay Member
 - At least one male and one female member
 - The Secretary
 - Co-opted expert members as required
2. U-REC is responsible for the development and review of the Research Ethics Policy, principles and procedures.
3. U-REC identifies areas of best practice and disseminates these across the University. It is responsible for identifying and responding to strategic developments both within and outside the University. It may also instigate periodic audits of S-RECs, as routine, or where there are any causes for concern, e.g. adherence to terms of reference.
4. U-REC coordinates the provision of research ethics training for REC members, staff and students of the University.
5. U-REC approves core documentation used by S-RECs for reviewing research proposals.
6. U-REC may recognize an external ethics approval body as equivalent to the University's, to avoid unnecessary duplication of reviews, and will advise S-RECs accordingly.
7. U-REC will schedule three meetings per year, with the option of cancelling two if not required, or of carrying out business virtually. U-REC will report annually to the University Research Executive and Senate.
8. U-REC may carry out any of the functions of ethics review described in the Terms of Reference for S-RECs (Annex 3).
9. U-REC may meet on an extraordinary basis as circumstances dictate to ensure that S-RECs are able to meet their terms of reference, including:
 - approval of recommendations for the recognition of external ethics review bodies;
 - approval of recommendations for the classification of research as low risk for the purposes of Light Touch review;
 - hearing appeals against decisions made by S-RECs;

- providing definitive guidance on problematic cases or interpretations of ethics review requirements;
 - reviewing the remit and functioning of research ethics committees in light of changing research activity profiles; and,
 - considering any new statutory or professional responsibility and advising the relevant Committees or Officers of the University accordingly on the implementation of that responsibility.
10. U-REC will monitor the activity of S-RECs and will carry out periodic audits of the reviews and decisions of S-RECs.
11. U-REC will carry out periodic audits of research studies approved by U-REC and S-RECs. The audit programme will be determined by the requirements of legislation and funders, the risk assessment of individual studies, and concerns raised by adverse event reports or suspicion of research misconduct.

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Annex 2. Minimum Faculty level Responsibilities for Research Ethics Review

1. Each Faculty must keep records of all staff and student research in the Faculty requiring ethics review under the University Research Ethics Policy, and the outcome of that review, whether by the University or an outside body.
2. A Faculty may create subject or School-based sub-committees (S-RECs) to perform ethics reviews on its behalf. The Faculty should make the S-REC meeting schedules, guidance and approved forms readily available on its website.
3. Where a Faculty has no reviewing Ethics Committee the Associate Dean for Research, assisted by the Faculty Research Office, will have an oversight and management role for the research ethics responsibilities of the Faculty.
4. A Faculty which has no reviewing S-REC must provide information and guidance to its staff and students to enable them to have their research reviewed, as required by the University Research Ethics Policy.

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Annex 3: Minimum Terms of Reference for Sub-committees of U-REC (S-RECs)

These Terms of Reference may be supplemented as required to address new legislation or funder guidelines.

1. The full membership of each S-REC is as follows.
 - A Chair appointed by the relevant Head of School or Dean in consultation with the Associate Dean for Research
 - A Deputy Chair drawn from a School other than that of the Chair
 - At least one academic member from the research community served by the Committee. The number of members necessary will be determined by the need to provide collectively a sufficiently broad base of research experience and methodological expertise in the areas of research
 - At least one male and one female member
 - At least one member with experience of managing ethical issues
 - A lay member
 - Individuals seconded for their experience or specific methodological expertise, relevant to the research being reviewed

The S-REC should keep a record of the names, relevant experience and training of members.

All members need not be involved in every review. The type of research and the form of ethical review required will determine the number of members needed, and their status, but any approval decision must include at least one member independent of the School or subject in which the research is to take place.

An S-REC meeting which does not include a lay member is not appropriately constituted to undertake review of ESRC funded research.

2. The Committee may either co-opt members from other Committees or refer applications to another where a broader research experience or methodological expertise is required. Where the S-REC Chair has any doubt about the ability of the Committee to make a decision, this will be referred to the U-REC which will give definitive advice.
3. The Chair may appoint deputies to cover periods of absence or conflicts of interest. The Chair of the S-REC may not take decisions alone on cases where there is clear potential for conflict of interest or such a restriction is a condition of the funder.
4. The S-REC Chair is a member of the University Research Ethics Committee (U-REC) according to the U-REC Terms of Reference.
5. The Chair of the S-REC, or appointed deputy, will conduct an initial screening of any proposal submitted for ethical approval. The screening will determine the level of risk and complexity, which will determine which form of review will be applied. The task of screening may be delegated, but screening decisions are the ultimate responsibility of the Chair.
6. In the case of a taught student project (but not a research student project), the Chair of the Committee may delegate responsibility for assessment to the course

or programme director, and this decision will be reported to the S-REC for ratification.

7. S-RECs may perform their work in a virtual environment providing papers are distributed to members in sufficient time to allow responses and discussions. A meeting of the full membership of the Committee in person will take place at least once a year.
8. The S-REC approves research as submitted, approves subject to specified conditions or rejects research proposals on the basis of the University's Research Ethics Policy, and principles and procedures defined within it.
The S-REC also provides guidance and advice on ethical issues to those undertaking research.
The S-REC does not make decisions about the quality of the research itself, which is the responsibility of the Faculty's research governance function.
9. The University Research Ethics Checklist should be used by researchers and S-RECs to manage the process of initial application for ethical review. An exception may be made for research which clearly requires NHS REC review (see point 16) providing the Faculty can demonstrate that such projects are not escaping the University REC procedures.
10. Light Touch review may be undertaken where the complexity of the case is judged to be low and the risk minimal. Initial information should be obtained from the researcher by completion of the University Research Ethics Checklist. The ethics approval process may be handled through Chair's Action, taking account of the potential for conflict of interest, unless legislation or funder requirements necessitate a fully constituted Committee.
11. In exceptional circumstances Expedited Review may be used outside the usual S-REC meeting schedule to provide a full review at short notice to research of importance. This may consist of a virtual or actual meeting, carried out by one or more members of the S-REC, but not by a member of the department due to carry out the research. The decision should be ratified at the next S-REC meeting.
12. For Faculties without a reviewing Ethics Committee, the researcher must submit basic details of the project as required by the Faculty procedure. The basic details will be recorded, and the researcher will be advised about suitable Committees within the University to review the study. The Faculty will issue a standardised response confirming registration and requiring the researcher to submit a copy of his or her S-REC approval to the Faculty.
13. Where it is clear that the research requires NHS REC (or Social Care REC) consideration the submission to the Faculty will only need to be basic details of the study to enable registration. This will be reviewed by the Faculty which will issue a standardised response confirming registration, that review by the University REC is not needed, and requiring the researcher to submit a copy of his or her NHS REC favourable opinion. The researcher should continue with the NHS REC application, and does not need to wait for the Faculty response
14. Where it is not clear whether NHS or Social Care REC review is appropriate the researcher should make a full submission to the Faculty. The Faculty may then require the researcher to consult the NHS REC for further advice and to report back whether NHS/SC REC review is needed or not. If the NHS/SC REC decides

the project is outside their remit the researcher must seek approval from a University REC.

15. Where research requiring ethical review is to be done outside the UK the researcher should provide the S-REC with evidence that ethical review has been undertaken by an approved Institutional Review Board or Research Ethics Committee in that country. If such approval cannot be obtained, the researcher must submit the project for review by the S-REC
16. The S-REC will issue a formal notice of review to the researcher, indicating whether or not approval has been given. This should require researchers who are given approval to provide an annual report including any adverse events.
17. Applications from external researchers should be referred to the Chair and Secretary of UREC in the first instance, for initial review and referral to an S-REC if appropriate, or confirmation of approval by a recognised external body.
18. Service based research (non-academic Departments wishing to improve services or investigate problems) may require ethical review and should be discussed with the U-REC Chair
19. Appeals against an S-REC decision will be dealt with by informal arbitration led by the S-REC Chair unless there are conflicts of interest. A final appeal may be made direct to the U-REC, which will make a definitive decision.
20. Minutes of meetings will be kept and standard documentation on decisions and guidance as approved by the U-REC will be used. Copies will be kept locally which will meet any audit or monitoring requirements, and a summary report on all ethics decisions will be supplied annually to the U-REC. No documentation should be destroyed without reference to U-REC for advice.
21. The S-REC may withdraw or suspend approval of an ongoing research project as a result of serious concerns regarding its conduct or ethical issues.
22. The S-REC should ensure that each research study proposal makes provision for handling complaints by research participants. In the case of students, the supervisor's name and contact details should be given in the participant information. In the case of a member of staff, the Head of School's name and contact details should be given (see Policy 3.2.9)
23. On approval by U-REC, S-RECs may recognise an external ethics approval body as equivalent to the University's to avoid unnecessary repeat reviews.
24. Each S-REC will keep a watching brief on any new statutory or professional responsibility that may affect its work and make changes as appropriate, with the relevant approval by the U-REC.
25. Each S-REC will submit the following for approval to the U-REC on an annual basis:
 - Committee membership, including the scope of research experience and methodological expertise within the Committee;
 - details of procedures to be published on Faculty web pages, including forms, for submitting applications, Light Touch review of proposals, full review of proposals and appeals;

- frequency of meetings and deadlines for submission; and some indication of the time scale for reaching the different categories of decision;
 - plans for training and awareness-raising for members, staff and students.
26. Each Faculty will ensure Committee members have appropriate up-to-date training and information on ethics issues, to include:
- the University's Research Ethics Policy and associated guidance; and,
 - establishment and maintenance of a web site of links to specialist sources of information on ethics, with a link from the U-REC website.

In addition, the Faculty will:

- lead and contribute to awareness raising and staff development events
 - liaise with the U-REC, other RECs or specialist committees within the University or outside, e.g. NHS Research Ethics Committee
 - keep a record of training provided.
27. In conjunction with the U-REC, each Faculty will ensure staff and students are aware of the University's ethics approval requirements and the disciplinary consequences of non-compliance.