

UNIVERSITY OF EAST ANGLIA
RESEARCH ETHICS POLICY, PRINCIPLES AND PROCEDURES

1 INTRODUCTION

1.1 OVERVIEW

The 'Research Ethics Policy, Principles 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

Revisions to the Policy approved by Senate:

21 June 2006

25 February 2009

This version of the Policy approved by Senate on 15 June 2011.

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).

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

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.

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:

- 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

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

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

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

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.

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.

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.