

UNIVERSITY OF EAST ANGLIA

RESEARCH ETHICS POLICY, PRINCIPLE 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 University Schools, relevant legislation and professional and funding bodies.

The University is committed to advancing and safeguarding high quality academic and ethics standards in all its activities. 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 and Faculty Research Ethics Committee and any associated sub-committees.

When undertaking research, researchers are expected to consider and observe ethical principles and the University's mission and values. This policy sets out conditions for establishing the ethics review requirements of a research project.

The 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.

1.2 RESEARCH ETHICS

The University uses the 'Research Assessment Exercise' definition of research. The concept of ethics is taken to define systems of moral principles or values, principles of right or good behaviour in relating to others, 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 formal ethics approval by the University is always required; ethics approval 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 participation. This may be invasive (eg. surgery) or non-invasive research (e.g. interviews, questionnaires, 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 personal data and/or tissue;

- involves people on behalf of others (eg. legal guardians of children and the psychologically or physically impaired and supervisors of people under controlled environments (eg. 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 ethics 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
- all individuals who are not members of the University but who are conducting or contributing to research activities which take place within the University

1.4 **GOVERNANCE, RESPONSIBILITY AND OPERATIONAL ARRANGEMENTS**

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 Policy under the leadership of their Head of School, who is ultimately responsible for all activities performed in their School.

The Policy recognises the University's distinct governance, culture and diversity, while supporting the achievement of its collective research objectives. To accommodate this, a two-tier system of approval has been created, with ethics review managed directly by four Faculty Research Ethics Committees (F-RECs) and any constituent subject specific sub-committees, 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. The Policy applies to all Faculties but is designed to allow a degree of flexibility in recognition of the diverse and dynamic nature of the University research base through the application of minimum terms and conditions, principles and procedures defined by U-REC and set out in the Policy.

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.

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
- Central Office for Research Ethics Committees (COREC)
- Department of Health
- Higher Education Funding Council
- National Health Service
- Office of Research Integrity
- National Health and Medical Research Council (Australia)
- Research Councils
- Royal Society for the Prevention of Cruelty to Animals
- University of Cardiff
- University of Sheffield
- Universities UK

An electronic copy of this Policy and associated reference material is maintained on the Research and Business Services website: <http://www.uea.ac.uk/rbs/>

2 ETHICS PRINCIPLES FOR RESEARCH

2.1 OVERVIEW

The Ethics 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 ethics review procedures provide the operational framework (see section 3).

Research undertaken in accordance with recognised research ethics principles constitutes good research practice. 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 ethics 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 ethics principles.

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', 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 ethics 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, e.g. criminal records checks in hospitals or schools.

2.2.1 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. If it is expected that harm, unusual discomfort or other negative consequences might occur in the prospective participant's future life as a result of participating the lead researcher must, prior to the person's participation, obtain ethics approval via the University's procedures and the informed consent of any prospective participant.

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.

In general terms, invasive 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 be harmed, eg. a terminally ill person may choose to participate in a high risk clinical trial.

In the case of non-invasive research methods such as interviews and questionnaires, the content and procedure may be highly sensitive and intrude on a participant's comfort and privacy. The initial judgment on whether or not questions are sensitive and likely to cause harm rests with a lead researcher.

2.2.3 OBTAINING CONSENT

Normally, potential participants in research should give their informed consent prior to participation, and the lead researcher is responsible for obtaining that person's consent. 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, ideally in the presence of at least one witness.

Prior to participation, researchers should 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.

2.2.4 INFORMED CONSENT

Informed consent is where 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 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.

2.2.5 CONSENT AND VULNERABLE PARTICIPANTS

Some people participating in research may be more vulnerable to harm than others and this possibility requires special consideration. Where a prospective participant is unable to give informed consent to participate, a legal guardian or other appropriate person may give consent on their behalf. Any relevant legal requirements, conventions or special policies (see Principle 1) should be observed.

2.2.6 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.

2.2.7 CONSENT AND RESEARCH IN PUBLIC AND WITH GROUPS

Obtaining consent from every individual participating is not always possible nor 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.

2.2.8 ANONYMITY, CONFIDENTIALITY AND DATA PROTECTION

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

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

- any potential risks 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.

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, eg. 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 specific guidance is available from the University's Data Protection officer.

2.2.9 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.

2.2.10 ANIMAL RESEARCH

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 costs 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.

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. For certain purely observational protocols (e.g. bird watching), however, these principles may be less applicable. Before any animal research is undertaken an assessment of the research using the UEA Animal Ethics Information Form should 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.

2.2.11 NHS RESEARCH

The Central Office for Research Ethics Committees (COREC) working on behalf of the Department of Health in England, is responsible for defining the scope and operation of NHS Research Ethics Committees which is recognised by the University as providing an equivalent review to its own (see 3.2 2 Approval routes and recognition of other review bodies).

2.2.12 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, eg. the type of business a funder is engaged in, as opposed to the nature of the research which is being funded. The U-REC will issue and maintain guidance on which stakeholders should not be associated with, or under which circumstances this may proceed, following consultation with relevant areas of the University.

2.2.13 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.

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.

3 THE UNIVERSITY'S ETHICS REVIEW PROCEDURES

3.1 OVERVIEW

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

The Procedures operate to protect participants in research, the researchers themselves and the University and are designed to ensure that, as a minimum, every University researcher and academic School has access to a University recognised ethics review mechanism that is sufficiently flexible to accommodate the diverse

research interests and needs of academic Schools while sufficiently coherent in design and operation to ensure corporate consistency.

3.2 ETHICS REVIEW PROCEDURES

3.2.1 SCOPE

All research proposals 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.

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. This decision is subject to endorsement by the Head of School and may be reviewed at a later stage.

Research activities put forward for formal ethical 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 APPROVAL ROUTES AND RECOGNITION OF OTHER REVIEW BODIES

There are two primary routes through which to apply for ethics approval:

- the University's ethics review procedure; or
- the NHS ethics review procedure 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 F-RECs as and when they occur.

The University recognises the NHS's ethics review procedure as equivalent to its own; where a proposal is reviewed by the NHS, a University review is not required.

Should an applicant plan to seek ethics review via an alternative procedure (eg. via an ethics review procedure from, for example, another University or overseas body) in the first instance, contact should be made with the F-REC for advice. This will then be referred to the U-REC with a recommendation for a final decision.

3.2.3 THE UNIVERSITY'S ETHICS REVIEW PROCEDURE

F-RECs approve as submitted, approve subject to specified conditions, or reject research proposals conducted by the University's staff and students on the basis of the Policy and Principles and the minimum terms of reference defined by the U-REC (see Annex 1). The U-REC also defines the minimum requirements for documentation to be used by F-RECs. F-RECs may exercise considerable flexibility and discretion in meeting these minimum terms of reference to best serve local needs.

Within its broader interdisciplinary scope, which includes any ethical issue raised by members of staff and students, each F-REC may have specialist areas of concern and deal with them through subject specific sub-committees. F-RECs may cross-refer cases to another Faculty where a particular specialism is covered by another F-REC. Where they exist, much of the ethics review business within the scope an F-REC is likely to take place within specialist sub-committees, with the F-RECs taking an oversight and management role.

Research involving biological hazards and/or genetic manipulation must also be considered by the Biological Hazards and Genetic Manipulation Sub-Committee which reports to the Health and Safety Advisory Committee.

3.2.4 UNIVERSITY RESEARCH ETHICS COMMITTEE (U-REC)

The University Research Ethics Committee defines the University's Policy and operational principles which are applied by F-RECs. The minimum terms of reference for U-REC can be found at Annex 2.

3.2.5 FORMS OF ETHICS REVIEW AND ASSESSMENT OF RISK

The form of ethics 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. Where minimal risk is involved and the level of complexity is low, expedited review may be undertaken. Any funder or regulatory requirements for the form of review shall be observed. Guidance on the assessment of risk and complexity is provided by F-RECs, subject to U-REC approval.

3.2.6 MONITORING OF UNIVERSITY ETHICS REVIEW PROCEDURES

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

Annex 1: Minimum Terms of Reference for Faculty Research Ethics Committees (F-RECs)

Faculty Research Ethics Committees (F-RECs) approve as submitted, approve subject to specified conditions or reject research proposals on the basis of the University's Research Ethics Policy, and principles and procedures defined within it. F-RECs may also withdraw or suspend approval of an ongoing research project due to serious concerns regarding its ethical aspects. F-RECs also provide guidance and advice on ethical issues to those undertaking research. F-RECs do not make decisions about the quality of the research itself.

F-RECs may exercise considerable flexibility and discretion in meeting these minimum terms of reference to best serve local needs.

1. The full membership of each F-REC or subject-based sub-committee is as follows.
 - A Chair: Associate Dean for Research or deputy
 - A Deputy Chair drawn from a School other than that of the Chair
 - At least one academic member from Schools of the Faculty which collectively provides a broad base of research experience and methodological expertise in the areas of research
 - A lay member drawn as appropriate from the University's pool of volunteers
 - At least one male and one female member
 - At least one member with experience of managing ethical issues
 - Individuals seconded for their experience or specific methodological expertise, relevant to the research being reviewedAll members need not be involved in every review. Quoracy for decision-making purposes is determined by the form of ethics review.
2. An F-REC may handle all ethics reviews itself or may create subject-based sub-committees to perform ethics reviews on its behalf. In the latter case, an F-REC may sit exclusively in an oversight and management role of such sub-committees.
3. The Chair may appoint deputies to cover periods of absence, conflicts of interest or to chair sub-committees. The Chair of the F-REC or of any sub-committee 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 potential funder. The F-REC Chair is a member of the University Research Ethics Committee (U-REC).
4. The Chair of the F-REC or sub-committee will conduct an initial screening of any proposal submitted for ethics approval. The screening will determine the level of risk and complexity, which will determine which form of review will be applied. Forms of review are determined by F-RECs and operated after endorsement by U-REC. The task of screening may be delegated, but screening decisions are the ultimate responsibility of the Chair.
5. In the case of a taught student project (but not a research student project), the Chair of the F-REC or sub-committee may delegate responsibility for assessment to the course or programme director, but approval cannot be granted by the director alone.
6. Expedited review may be undertaken where the complexity of the case is judged to be low and the risk minimal. The ethical approval process may be handled through Chair's Action, taking account of the potential for conflict of interest, or

may be conducted by a subset of the full F-REC or sub-committee membership. In all other cases, the full F-REC or sub-committee membership must be involved in the decision-making process.

7. The F-REC and any sub-committees may perform their work in a virtual environment. A meeting of the full membership of the F-REC in person will take place at least once a year.
8. The F-REC or sub-committee may either co-opt members from other F-RECs or refer applications to another where a broader research experience or methodological expertise is required. Where there is any doubt about the competence of an F-REC make a decision, this will be referred to the U-REC which will give definitive advice.
9. Each F-REC will have an appeal option. A final appeal may be made direct to the U-REC, which will make a definitive decision.
10. 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.
11. On approval by U-REC, F-RECs may recognise an external ethics approval body as equivalent to the University's to avoid unnecessary repeat reviews.
12. Each F-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.
13. Each F-REC will submit the following for approval to the U-REC on an annual basis:
 - its own specific terms of reference based on these minimum requirements;
 - committee membership, including the scope of research experience and methodological expertise within the F-REC and any sub-committees;
 - a set of questions concerning the nature of the research that will provide guidance to staff and students with regard to whether or not ethical approval may be required in a particular case;
 - a statement setting out the criteria for expedited review and the forms of review that may be undertaken;
 - details of procedures, including forms, for a) submitting applications, b) expedited review of proposals, c) full review of proposals and d) appeals, including likely frequency of meetings and deadlines, where they exist; and,
 - plans for training and awareness-raising.
14. Each F-REC will ensure 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 linked to the U-REC's website.

In addition, the F-REC will:

- lead and contribute to awareness raising and staff development events; and,

- liaise with the U-REC, other F-RECs or specialist committees within the University or without, e.g. NHS Research Ethics Committee.
15. In conjunction with the U-REC, each Committee will ensure staff and students are aware of the University's ethics approval requirements.
 16. Each F-REC will make an annual report to the U-REC that summarises all activities taken in connection with these terms of reference, including a summary report on all ethics decisions taken during the year and general issues raised during the F-REC's work.

Annex 2: Terms of reference for the University Research Ethics Committee (U-REC)

The University Research Ethics Committee (U-REC) defines the University's ethics policy and operational principles which are applied by Faculty Research Ethics Committees (F-RECs).

1. The membership is as follows:
 - A Chair: appointed by Research Executive
 - The Chairs of F-RECs
 - The University's Data Protection officer
 - At least one male and one female member
 - Co-opted members as required
2. U-REC meets at least annually to receive reports of the F-RECs and to prepare an annual combined report to the Research Executive.
3. U-REC may meet on an extraordinary basis as circumstances dictate to ensure the F-RECs are able to meet their minimal 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 expedited review;
 - hearing appeals against decisions made by F-RECs;
 - providing definitive guidance on problematic cases or interpretations of ethics review requirements;
 - reviewing statements made by Schools on use of 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.
4. 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 without the University. It may also instigate periodic audits of F-RECs where there are any causes for concern, eg. adherence to minimum terms of reference.
5. U-REC approves core documentation used by F-RECs for reviewing research proposals.
6. U-REC is responsible for the development and review of the Ethics Policy, principles and procedures