

RESEARCH ETHICS POLICY

1. INTRODUCTION

1.1 OVERVIEW

The University is committed to advancing and safeguarding high quality academic and ethics standards in all its activities. When undertaking research, researchers are expected to consider and observe ethics principles and the University's mission and values. This Policy sets out the principles and conditions of the ethics review requirements of a research project. Operational requirements are set out in the Procedures for Research Ethics Reviews. The Policy been developed in consultation with University stakeholders and builds on and codifies existing practice, relevant legislation and guidance from professional and funding bodies. The Policy should be read in conjunction with other complementary policies, procedures and guidelines, including:

- Guidelines on Good Research Practice
- Procedures for Dealing with Allegations of Misconduct in Research
- Guidance and Procedures on Research Ethics Approvals
- Constitution and terms of reference for the Research & Innovation Committee, Research Degrees Committee and Research Ethics Committee
- The University's Health and Safety Policy
- The University's Single Equality Scheme
- Financial Regulations
- The Concordat to support research integrity
- Academic Integrity Policy

1.2 RESEARCH ETHICS

The University uses the HEFCE's 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 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.

The core concern of the ethics decisions taken at the University relates to research involving human participants. In broad terms, this is research which:

- directly involves people in the research activities, through their physical participation, eg. interviews, questionnaires, surveys, observational research, requiring 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).

Other areas of ethics consideration covered by the Policy include research where: there are serious health and safety implications for the participants or the researchers, animal experiments are involved, there is a risk of damage to the environment, the impact of the research may be emotionally damaging and where the research is politically or socially sensitive. It may also include research which involves organisations which 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 Department who is ultimately responsible for all activities performed in that Department.

The Policy recognises the University's distinct governance, culture and diversity, while supporting the achievement of its collective research objectives. The University's Research & Innovation Committee (R&IC) has overall responsibility for this Policy and research ethics reviews. Detailed operational arrangements are approved by the R&IC and set out in the Guidance and *Procedures for Research Ethics Approvals* available on the University's intranet.

2. PRINCIPLES OF RESEARCH ETHICS

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. 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/Department 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.

2.2 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 review bodies 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.

2.3 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 the case of 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 the lead researcher.

2.4 OBTAINING CONSENT

2.4.1 OVERVIEW

Consent is at the core of research ethics approval. 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.

2.4.2 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.

2.4.3 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. However, if the person falls under the protection of the 'Mental Capacity Act 2005, they cannot be included in a research study unless approval is given by the Social Care Research Ethics Committee (SCREC). Any relevant legal requirements, conventions or special policies should be observed.

2.4.4 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.

2.4.5 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.

2.4.6 ANONYMITY, CONFIDENTIALITY AND DATA PROTECTION

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.

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.

2.5 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.

2.6 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 Director of Department, Head of Service or other line manager 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 reviewer 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 re-reviewed.

3. PRINCIPLES OF ETHICS REVIEWS

3.1 OVERVIEW

The University's Guidance and Procedures for Research Ethics Approvals ("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/Department has access to a University recognised ethics review mechanism that is sufficiently flexible to accommodate the diverse research interests and needs in the University while sufficiently coherent in design and operation to ensure corporate consistency.

3.2 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 Department/School and may be reviewed 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.

3.3 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 review procedure of a body recognised by the University as providing an equivalent to its own

The procedure for recognising a review body, eg. at another University or overseas authority, is set out in the University's Guidance and procedures for Research Ethics Approvals. Bodies must be recognised by the University before an applicant seeks an alternative review.

3.4 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 ethics 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.

The outcomes of ethics reviews are:

- approved as submitted with guidance on the baseline for the decision (see below for changes to the baseline);
- approved subject to specified conditions
- rejected based on the principles in this Policy

Approval may be withdrawn or suspended in an ongoing research project where concerns are raised regarding its ethical aspects. Where the decision-making baseline changes in a research project after it has been approved, work in the affected area should be suspended and a referral made guidance and the project re-reviewed. Even where a change occurs which has not been anticipated and specified in the original decisions, where there is any concern or doubt, a referral must be made.

4. MINIMUM TERMS OF REFERENCE FOR ETHICS REVIEW BODIES

The University may exercise considerable flexibility and discretion in meeting the minimum terms of reference to best serve local needs, including using existing committee and structures so long as the minimum terms of reference are observed

i) The full membership of a committee is as follows:

- A Chair who is a senior and experienced researcher
- A Deputy Chair: an academic drawn from a School other than that of the Chair
- At least one academic member from each Department/School to provides a broad base of research experience and methodological expertise in the areas of research
- A lay member
- Co-opted members as required
- At least one male and one female member
- At least one member with experience of managing ethical issues

Not all members need be involved in every review. The quorum for decision-making purposes is determined by the form of ethics review and requirements of specific funders.

- ii) The Chair may appoint deputies to cover periods of absence, conflicts of interest or to chair sub-committees. The Chair 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.
- iii) The Chair 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. The task of screening may be delegated, but screening decisions are the ultimate responsibility of the Chair.
- iv) 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 membership.
- v) The reviews may be performed in a virtual environment.
- vi) There will be a procedure for appealing a decision.
- vii) There will be a procedure for recognising alternative ethics review bodies which must ultimately be approved by the Research & Innovation Committee.

- viii) Minutes of meetings will be kept and standard documentation on decisions and guidance will be used.
- ix) 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 Research & Innovation Committee.
- x) The Chair will submit the following to the Research & Innovation Committee for approval before operations commence:
- its own specific terms of reference based on these minimum requirements;
 - committee membership;
 - guidance on 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;
 - the criteria for assessing levels of risk and complexity and a description of the associated forms of ethics review;
 - copies of procedures and forms
 - plans for training and awareness-raising

After operations commence, an annual report will be made including an update of the above and a summary of 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.

Falmouth University

22 March 2011

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