# Research Ethics: A Handbook of Principles and Procedures

Approved by University Research Degrees Committee, September 2008

# **Research Ethics: A Handbook of Principles and Procedures**

## Introduction

1. Professional and academic communities are placing increasingly exacting responsibilities on their members to improve the ethical standards of research and practice within their disciplines, and journal editors may require evidence that research projects have secured formal ethical clearance before agreeing to publish their findings.

2. Research Ethics: a Handbook of Principles and Procedures has been produced in response to this growing awareness of ethically sensitive issues in research and scholarly activity. Under the aegis of Academic Board, its intention is to guide and, where necessary, regulate the scholarly activities of researchers at undergraduate, postgraduate and staff levels within the University and to promote a stronger appreciation of ethical considerations in research.

3. The Handbook comprises three parts:

**Part A** is a statement of ethical principles designed to articulate a common set of values to guide and support the professional conduct of academic research and research-related activities. It is based on the statement of ethical principles which has been in use in the University since 1995 and applies principally to all research involving human subjects and participants, as well as to research on live animals.

Section 6 of Part A clarifies the requirements for approval. All University activity that fits the definitions of research in clause 4 of this preamble, including internal consultancies where university staff and/or students are participants, is subject to the provisions of this Handbook.

**Part B** contains the procedures by which research proposals can be assessed and, where necessary, given ethical clearance.

**Part C** contains selected appendices which address the general and particular concerns of research in a variety of academic and professional fields. Its intention is to act as a context for the principles and procedures and to offer critical guidance. In particular, attention is drawn to Appendix 1 which is a discussion of some of the principal issues in research ethics, and Appendix 2 which contains a sample of questions that should guide the researcher in minimising risks and moving towards best practice in research.

4. For the purposes of this Code, the definitions used for the various types of research and scholarly activities are those articulated by the Roith Report (PCFC, 1990), which have gained wide acceptance within higher education:

**Basic Research**: experimental and theoretical work undertaken to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view; **Strategic Research**: applied research that is in a subject area which has not yet advanced to the stage where eventual applications can be clearly specified;

**Applied Research**: work undertaken in order to acquire new knowledge. It is, however, directed primarily towards practical aims or objectives;

**Scholarship**: work which is intended to expand the boundaries of knowledge within and across disciplines by in depth analysis, synthesis and interpretation of ideas and information and by making use of rigorous and documented methodology;

**Creative Work**: the invention and generation of ideas, images and artefacts including design. Usually applied to the pursuit of knowledge in the arts;

**Consultancy**: the deployment of existing knowledge for the resolution of specific problems presented by a client, usually in an industrial or commercial context;

**Professional Practice**: a variant of consultancy applied to certain well defined professions (for example, law, accounting, architecture, nursing, and social work).

5. The following statement of principles places a considerable emphasis on the personal responsibility of researchers to act ethically and to promote ethical behaviour in all aspects of research activities. It is also recognised that statements of principles and procedures cannot expect to cover every aspect of a complex area such as research ethics. For these reasons, the Research Ethics Sub-Committee - which will operate and monitor the procedures described in this Handbook - would welcome comments and suggestions for future enhancements from individuals, research units, or any other interested parties (Email: Malcolm MacLean and/or Sharon Brookshaw).

## **Part A: Principles**

## **1** Introduction

1.1 The primary responsibility for the conduct of ethical research lies with the researcher. It is a fundamental principle that staff and students engaged in research adopt a continuing personal commitment to act ethically, to encourage ethical behaviour in those with whom they collaborate, and to consult where appropriate concerning ethical issues.

1.2 The University acknowledges the importance of the professional codes of conduct of external agencies and organisations, and accords them primacy as a default position.

# **2** General Responsibilities

## 2.1 Towards research participants

Researchers have a responsibility to ensure as far as possible that the physical, social and psychological well-being of their research participants is not detrimentally affected by the research. Research relationships should be characterised, whenever possible, by mutual respect and trust.

## 2.2 Towards other researchers

Researchers should avoid, wherever possible, actions which may have deleterious consequences for other researchers or which might undermine the reputation of their discipline. Those directing research should bear in mind their responsibilities towards members of their research teams and should aim to anticipate and guard against the possible harmful consequences of the research for team members.

## **3 Informed Consent**

3.1 Research should be based, as far as possible and practicable, on the freely given informed consent of those under study. However, it is recognised that in some cases it may be necessary to employ covert methods should these constitute the only means to obtain the required data. In such cases, please refer to section 4 below.

3.2 It is the responsibility of the researcher to explain as fully as is reasonable and appropriate, and in terms meaningful to the participants: the aims and nature of the research, who is undertaking it, who is funding it, its likely duration, why it is being undertaken, the possible consequences of the research, and how the results are to be disseminated.

3.3 The power imbalance between researcher and researched should be considered. Care should be taken to ensure that the latter are not pressurised into participation. Research participants should be aware of their right to refuse participation at any time, including withdrawal from a research project at any stage, and should not be given the impression that they are required to participate. It should also be recognised that research may involve a lengthy data-gathering period and that it may be necessary to regard consent not as obtained once and for all, but subject to re-negotiation over time.

3.4 The researcher should explain how far research participants will be afforded anonymity and confidentiality and participants should have the option of rejecting the use of data-gathering devices such as tape-recorders, video cameras, and digital recording devices.

3.5 If there is a likelihood of data being shared with or divulged to other researchers, the potential uses of the data should be discussed with the participants and their agreement to such use should be obtained.

3.6 Where access to a research setting is gained via a 'gatekeeper' external to the University, researchers should also obtain the informed consent of research participants, while at the same time taking account of the

gatekeeper's interests. It should be borne in mind that the relationship between research participant and gatekeeper may well continue long after the research has been undertaken.

3.7 Where research participants are young children or other groups that may be made vulnerable in or by specific social conditions relevant to the research such as elderly, disabled or sick people, or people with learning difficulties whose understanding is impaired in some way so that they are unable to give full informed consent, it may be necessary to use a proxy in order to gather data. In this case great care must be taken not to intrude upon the privacy of the vulnerable participants. The researcher should consult relevant professionals, carers, parents/guardians and relatives, as appropriate. Researchers should attempt to obtain the informed consent of children and their parents and in relation to schoolchildren those who are *in loco parentis*.

3.8 In addition to obtaining the informed consent of those under study, researchers should attempt to anticipate and guard against the possible harmful consequences of their research for participants.

## 4 Deceptive and Covert Research

4.1 While it is recognised that there is a continuum of covert-overt research (and therefore difficulty in defining research simply as entirely covert or overt), researchers should endeavour, wherever possible and practicable, to avoid the use of deception in their research methods, as this violates the principle of informed consent and may invade the privacy of those under study, particularly in non-public spaces.

4.2 Any researcher considering deceptive methods in research must seek approval from the relevant Faculty Research Ethics Panel (FREP) or Research Ethics Sub-Committee as appropriate (see Part B, s3 & 4). The burden of proof will rest on the investigator to show that no alternative methods are possible, and that the data sought are of sufficient value to override the issues of free and informed consent. Where approval has been given, the potential implications arising from publication must be fully considered.

4.3 Covert research in non-public spaces (that is, where persons would not normally expect to be under observation), or experimental manipulation of research participants without their knowledge should be a last resort when it is impossible to use other methods to obtain the required data. It is particularly important in such cases to safeguard the anonymity of participants.

4.4 If covert methods are approved and employed, and informed consent has not been obtained prior to the research, every attempt should be made to obtain this post hoc.

# **5** Confidentiality and Anonymity

5.1 The anonymity and privacy of research participants should be respected and personal information relating to participants should be kept confidential and secure. Researchers must comply with the provisions of the <u>Data</u> <u>Protection Act</u> and should consider whether it is proper or appropriate even to record certain kinds of sensitive information.

5.2 Where possible, threats to the confidentiality and anonymity of research data should be anticipated by researchers and normally the identities and research records of participants should be kept confidential, whether or not an explicit pledge of confidentiality has been given.

5.3 Whilst the researcher should take every practicable measure to ensure the confidentiality and anonymity of research participants, s/he should also take care not to give unrealistic assurances or guarantees of confidentiality. Research participants with easily identifiable characteristics or positions within an organisation should be reminded that it may be difficult to disguise their identity totally without distorting the data.

## **6 Approval Requirements**

6.1 All research involving human or live animal participants must demonstrate ethics approval by the relevant FREP or by RESC. Set against the principles expressed above, specific approval is required for:

i) **research which involves biomedical or clinical intervention** (with the exception of those approved under standard protocols - see <u>Standard</u> <u>Protocols in the Exercise Physiology Laboratory</u> (95Kb Adobe PDF) ); All research related to the National Health Service (its personnel, plant, referrals etc) must abide by the NHS Research Governance framework. The relevant FREP or RESC will neither consider nor approve research proposals that should be submitted to the Local Research Ethics Committee (LREC) representing the NHS.

Further information can be found at: <u>http://www.nres.npsa.nhs.uk/</u>

Members of staff and students may, of course, use the relevant gatekeepers for advice prior to submission to the LREC or indeed subsequent to such.

ii) **deceptive research** which is defined as research where an investigator actively sets out significantly to misrepresent himself or herself, the nature of the research, and/or any other significant characteristics of the research;

iii) **certain classes of research,** in particular covert research, research where the data are not recorded in a manner that protects the anonymity of subjects or participants, where the research topic is one dealing with sensitive aspects of the subject's or participant's behaviour, or where proposals for research involve vulnerable populations (see <u>Appendix 5: British Psychological Society</u> <u>Code of Conduct</u> (405Kb Adobe PDF) for further guidance);

iv) **research where participants are under 18.** Guidelines for conducting research involving children and young people may be found in Appendix 3: Guidelines for Working With Children and Young People.

Procedures for gaining approval are contained in Part B.

6.2 Researchers must consult the appropriate University 'gatekeeper' whose role is described in the following sections covering procedures.

# Part B: Procedures

## 1. Introduction

1.1 Following the principles that underpin the University's general quality assurance systems, responsibility for ensuring that research is conducted in an ethical way lies at the closest point possible to its actual conduct. Responsibility for the ethical conduct of research, therefore, rests primarily with the person who is planning and undertaking a project, supported by the various arrangements for the scrutiny and approval of proposals which involves 'gatekeepers' including the relevant Faculty Research Ethics Panel (FREP) and Research Ethics Sub-Committee (RESC).

1.2 Every attempt has been made to develop a system of procedures sufficiently flexible to accommodate the needs of the various research communities within the University. Researchers who believe that the procedures do not adequately address their specific situation may consult directly with the Chair of RESC (Malcolm MacLean).

1.3 Where a member of staff is also a member of a professional organisation whose own published Code of Conduct in any way contravenes or conflicts with this Handbook, it is the responsibility of the member of staff to bring this to the attention of the FREP. The University recognises a default position in favour of researchers' obligations to their professional Codes of Conduct but must be informed of such conflict and be able to consider it before the investigation is approved for commencement.

# 2. The 'Gatekeeper' System

The relevant University gatekeeper acts as a conduit between the researcher and the possible use of RESC. The gatekeeper, who will have received appropriate training and have a strong grasp of precedence in local issues, will guide the researcher in areas of uncertainty. In particular, where a research proposal does not fall clearly into one of the categories expressed in <u>Part A, Section 6</u>, the gatekeeper will judge whether or not a proposal should be submitted to RESC or FREP for formal approval. In summary, gatekeepers are:

## Staff research

For members of Research Units and Institutes: the Head of Research Unit/Institute

For other members of staff: the relevant Associate Dean Research or equivalent

## Gatekeepers for applications to Research Council

Faculty Associate Dean Research/Head of Research unit or equivalent ⇒

FREP chair  $\Rightarrow$  FREP  $\Rightarrow$  RESC (with recommendation from FREP).

Gatekeepers for all other staff projects

Faculty Associate Dean Research/Head of Research unit or equivalent  $\Rightarrow$  FREP chair  $\Rightarrow$  FREP

Research degree students: the Faculty Research Director or equivalent

Gatekeepers for Research Student projects

Thesis advisor  $\Rightarrow$  Faculty Research Director/Research Degrees Tutor or equivalent  $\Rightarrow$  FREP chair  $\Rightarrow$  RESC

Thesis advisors are expected to guide students through the gatekeeping process.

**Postgraduate taught students**: the appropriate Course Leader or dissertation advisor (taking advice from the Chair of the FREP if necessary)

Gatekeepers for students in taught Postgraduate programme

Dissertation Advisor/Module Tutor  $\Rightarrow$  Course Leader  $\Rightarrow$  FREP chair  $\Rightarrow$  FREP

Dissertation advisors are expected to guide students through the gatekeeping process.

**Undergraduate students**: the appropriate Course Leader or dissertation Module Tutor (taking advice from the Chair of the FREP if necessary)

Gatekeepers for students in taught undergraduate programme

Dissertation Advisor/Module Tutor  $\Rightarrow$  Course Leader  $\Rightarrow$  FREP chair  $\Rightarrow$  FREP

Dissertation advisors are expected to guide students through the gatekeeping process.

# 3. The Faculty Research Ethics Panel

3.1 The principal aims of the Faculty Research Ethics Panel (FREP) are three-fold. Its first aim is to consider and, in accordance with the principles expressed in <u>Part A</u> of this Handbook, grant permission for the undertaking of or refer back for further consideration, research investigations which fall in the categories listed in <u>Part A, Section 6</u>. Its second aim is to act as an advisory body to the Faculty on matters related to research ethics. Its third aim is to advise on appropriate training and staff development needs.

3.2 The details of FREP are as follows:

# Terms of Reference

The Terms of Reference for Faculty Research Ethics Panels (FREP) are:

- i) the approval, referral to RESC, or referral back to the applicant of staff and student research investigations in accordance with the principles expressed in *Research Ethics: a Handbook of Principles and Procedures* on a regular basis, noting that;
  - a) all research council funded project bids shall be referred to RESC, normally with a recommendation on whether the project complies with the University's research ethics principles;
  - b) all cross institutional, international, and collaborative projects should normally be accompanied by a recommendation from the FREP on whether the project complies with the University's research ethics principles if referred to RESC;
  - c) all projects subject to the NHS research ethics procedures shall be referred to the relevant NHS research ethics panel, in consultation with the University Insurance Manager.
- ii) monitoring the appropriateness and effectiveness of procedures for granting or withholding ethical approval mechanisms for research;
- iii) facilitating and advising on staff development in the area of research ethics for staff and students within the Faculty.

# Membership

The membership of the FREP shall be:

- a. Faculty RESC member (chair);
- b. FREP member from another Faculty;
- c. at least two, and no more than three, Faculty members who are experienced dissertation or thesis supervisors;
- d. officer (provided by the Faculty);
- e. the FREP may co-opt members (e.g., Insurance officer, external advisor) for advise on specific proposals where necessary.

# **Reporting Lines**

Reporting lines for the FREP are:

- a. For research degrees: RESC;
- b. For staff , post-graduate taught and under-graduate taught programmes: Faculty Board;

# **Terms of Office**

Three years for all members.

The FREP shall, in consultation with RESC, consider requests for approval of modules for ethics purposes where research-like activities are uncontentious.

The FREP shall maintain a record of all projects given ethics approval, either on a case-by-case consideration by the Panel or under a system of approval of modules or by Faculty-based gatekeepers at other levels. Each FREP should organise sufficient meetings at times to allow expeditious consideration of proposals and requests (NB: this may include a greater number and frequency of meetings at the beginning of each academic year).

# 4. The Research Ethics Sub-Committee

4.1 The principal aims of the Research Ethics Sub-Committee (RESC) are three-fold. Its first aim is to consider and, in accordance with the principles expressed in <u>Part A</u> of this Handbook, grant permission for the undertaking of or refer back for further consideration, research investigations which fall in the categories listed in <u>Part A, Section 6</u>. Its second aim is to act as an advisory body to the University Research Degrees Committee (URDC), and thus the University, on matters related to research ethics. Its third aim is to sponsor appropriate training and staff development.

4.2 The details of RESC are as follows:

## Terms of Reference

The University Research Ethics Sub-Committee is responsible to the University Research Degrees Committee for:

i) the approval or referral of staff and student research investigations in accordance with the principles expressed in *Research Ethics: a Handbook of Principles and Procedures* on a regular basis

ii) monitoring the appropriateness and effectiveness of procedures for granting or withholding ethical approval mechanisms for research;

iii) reviewing and, if necessary, revising Research Ethics: a Handbook of *Principles and Procedures*;

iv) advice on policy issues related to research ethics as determined and requested by the Research Committee;

v) sponsoring staff development in the area of research ethics with appropriate partners within the University.

#### Membership

Chair (nominated by URDC): (<u>Malcolm MacLean</u>) Dean of Research or nominee (<u>David James</u>)

Nominated Faculty representatives of: Media, Arts & Technology (<u>William Large</u> and <u>Stuart Wilding</u>), Business, Education and Professional Studies (<u>Tracy Jones</u> and 1 tbc), Applied Sciences (<u>Malcolm MacLean</u> and <u>Claire Cooke</u>)

Finance and Planning Insurance Manager (<u>Elaine Barwell</u>), Gloucestershire Research and Development Support Unit (tbc), Officer: Research Administrator (<u>Sharon Brookshaw</u>)

The Sub-Committee may co-opt external members in cases where specialist biomedical and other technical expertise is necessary.

# **Reporting Lines**

The RESC shall report to URDC.

## Terms of Office

Three years for all nominated members.

Regularity of Meetings and Availability of Minutes

The Research Ethics Sub-Committee will meet on a regular basis and in response to applications submitted to it. Copies of all minutes of the Research Ethics Sub-Committee will be forwarded to the University Research Degrees Committee. An annual report will be submitted to the University Research Degrees Committee. Copies of all minutes will be held by the Officer for scrutiny.

4.3 It is an expectation that RESC will be asked to consider any research proposal which falls under the categories listed in <u>Part A, Section 6</u> of this Handbook. Failure to submit such proposals for approval or, once submitted, violation of RESC's decision to refuse permission for such research to proceed, may negate the University's insurance cover and also result in disciplinary action.

4.4 The University takes seriously the reporting of research malpractice. Advice may be sought from the relevant gatekeepers, Faculty representatives, or the Chair of RESC. Additionally, staff and students are directed to the <u>Whistleblowing Procedures (PDF)</u> (168Kb Adobe PDF).

# 5. Procedures for Securing Approval for Research Projects

## 5.1 Members of staff seeking approval

5.1.1 The primary responsibility for the ethical conduct of research lies with the researcher. In cases of uncertainty, however, members of staff seeking approval may liaise with the relevant gatekeeper in order to ensure that their research does not contravene the principles expressed in this Handbook. For members of Research Units and Institutes, the relevant Head of Research Unit or Institute will act as the gatekeeper. Staff who are not members of Research Units are responsible for seeking guidance from their Associate Dean Research or equivalent. A pro forma for recording decisions and advice from relevant gatekeepers should be obtained from the Postgraduate Research Centre (Sharon Brookshaw).

5.1.2 Any proposal which falls under <u>Part A, Section 6</u> of this Handbook must be submitted to FREP. Such proposals must be received by the Officer at least five working days before the next scheduled meeting. Chair's action may be taken on matters that require greater expediency but such decisions will be taken in consultation with at least one other FREP or RESC member as appropriate.

# 5.2 Research degree students seeking approval

5.2.1 The general framework for approval will apply to research students as well as staff. Additionally, all research students will be offered appropriate education and training in Research Ethics through the University's Research Student Seminar Programme. All research degree students are required to signal their adherence to the University's principles on the registration form (RD1), as is the supervisory team for each research degree programme. The Faculty Research Director's signature on the form confirms that both student and supervisors are aware of, and agree to abide by, those principles.

5.2.2 All proposals which fall under <u>Part A, Section 6</u> of this Handbook must be submitted to RESC for approval before the RD1 is considered by the University Research Degrees Committee. The Faculty Research Director should liaise with the Chair of RESC or FREP where there is any doubt whether a research proposal should be considered by RESC.

# 5.3 Postgraduate taught students seeking approval

5.3.1 The general framework for approval will apply to students following taught postgraduate courses. Additionally, all Postgraduate Modular Scheme students will be offered appropriate education and training in research ethics in their Research Methods module(s). Course Leaders are responsible for ensuring that all students are aware of, and agree to abide by, the principles expressed in this Handbook, through their respective Course Guides. In the Postgraduate Modular Scheme, all students and dissertation supervisors are required to signal their adherence on the registration form P3. Course Leaders for free-standing postgraduate courses should ensure that an equivalent system is in place.

5.3.2 All proposals which fall under <u>Part A, Section 6</u> of this Handbook must be submitted to FREP for approval. The Course Leader should liaise with the FREP Chair where there is any doubt whether a research proposal should be considered by FREP.

# 5.4 Undergraduate Modular Scheme students seeking approval

5.4.1 The general framework for approval will apply to students following undergraduate programmes. Additionally, all students will be offered appropriate education and training in research ethics in their Research Methods Module or its equivalent. Course Leaders are responsible for ensuring that all undergraduate students are aware of, and agree to abide by, the principles expressed in this Handbook, through their respective Course Guides. All undergraduate students are required to signal their adherence to the principles expressed in this Handbook on their assignment cover sheets. Where a given project or element of coursework may entail ethically sensitive issues, it is the responsibility of the Module Tutor to liaise with the student and relevant Course Leader. 5.4.2 All proposals which fall under <u>Part A, Section 6</u> of this Handbook must be submitted to FREP for approval. The Module Tutor or Course Leader should liaise with the FREP Chair where there is any doubt whether a research proposal should be considered by FREP.

## 6. Appeals Procedure

6.1 All investigators have the right to appeal against the judgement of the FREP or RESC. There are two grounds for such appeal:

a) where the researcher feels that the FREP or RESC has been unfair in its consideration of a proposal and/or has not properly understood it;

b) where there have been any irregularities in the procedures adopted by the FREP or RESC.

6.2 A researcher has the right to appeal in writing against a decision made by the FREP or RESC within ten working days of the notification of that decision. Appeals against a FREP decision must be directed to the Faculty Associate Dean Research or equivalent. Appeals against a RESC decision must be directed to the University Dean of Research.

## Appeals Against the FREP

6.3 The RESC Chair in consultation with the relevant Faculty Associate Dean Research or equivalent will convene a meeting of RESC with the proposer to review the proposal and the grounds for the FREP's decision. This meeting will normally be held within ten working days of notification of the appeal. There will be at least two RESC members in addition to the Chair in attendance.

6.4 At this stage the RESC may:

a) uphold the original decision to refer the proposal;

b) uphold the appeal of the researcher and approve the original proposal;c) uphold the appeal of the researcher but refer the decision until appropriate revisions have been made to the proposal.

6.5 Following an unsuccessful appeal, and where the researcher is dissatisfied with the decision of the RESC, he or she has the right to submit a final appeal to the University's Research Degrees Committee (URDC). This appeal must be lodged through the Chair of the URDC within five working days of receipt of RESC's final decision. A panel of not less than three members of the URDC, who have not previously been associated with the proposal, will make a final decision which will be based solely on the procedural propriety of RESC's decision-making process. The proposer will be notified in writing within five working days of URDC's hearing.

# Appeals Against the RESC

6.6 The URDC Chair will convene a meeting of URDC with the proposer to review the proposal and the grounds for RESC's decision. This meeting will normally be held within ten working days of notification of the appeal. There will be at least two URDC members in addition to the Chair in attendance.

6.7 At this stage the URDC may:

a) uphold the original decision to refer the proposal;

b) uphold the appeal of the researcher and approve the original proposal;c) uphold the appeal of the researcher but refer the decision until appropriate revisions have been made to the proposal.

6.8 Following an unsuccessful appeal, and where the researcher is dissatisfied with the decision of the URDC, he or she has the right to submit a final appeal to the University's Academic Board. This appeal must be lodged through the Chair of Academic Board within five working days of receipt of URDC's final decision. A panel of not less than three members of the Academic Board, who have not previously been associated with the proposal, will make a final decision which will be based solely on the procedural propriety of URDC's decision-making process. The proposer will be notified in writing within five working days of Academic Board's hearing.