UNIVERSITY OF GLOUCESTERSHIRE

Research Ethics: A Handbook of Principles and Procedures

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Research Ethics: A Handbook of Principles and Procedures

1.0 Introduction

1.1 This handbook outlines policy and provides guidance for the development and maintenance of appropriate ethical approaches to the conduct, supervision and utilisation of research. As such, it underpins, supplements and enhances the principles and operational requirements flowing from the need to work within professional codes of conduct and relevant legislation.

1.2. In line with definitions adopted by the Quality Assurance Agency (QAA), 'research' "*comprises creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of [people], culture and society, and the use of this stock of knowledge to devise new applications*"[1]. The word is used in an inclusive way to accommodate the range of activities that support original and innovative work in the whole range of academic, professional and technological fields, including the humanities, and traditional, performing, and other creative arts. It is not used in any limited or restricted sense, or relating solely to a traditional 'scientific method'. The University recognises that a number of professional practices and sectors have their own codes of ethics; these codes and the University's Research Ethics requirements supplement each other and should be applied as necessary and fitting, both in professional and associated scholarly practices.

1.3 Research is generally understood as an enterprise invested with mutual respect and trust between researchers[2], participants[3], stakeholders[4], academic and public audiences. As such it is subject to ethical review to ensure that it is conducted in accordance with its responsibilities to individual participants and the wider public. Most particularly the ethical review of research is intended to:

- ensure that any foreseeable harm to the physical, psychological, social well-being, health, values and dignity of participants, researchers and other stakeholders is minimised; and that
- the rights of participants, researchers and other stakeholders are upheld, including participants' right to informed consent, privacy, confidentiality and anonymity.

[1] UK Quality Code for Higher Education, Chapter B11 (Research Degrees)
[2] Researchers: denotes all students and staff of the University of Gloucestershire who are undertaking research, and encompasses anyone involved in conducting research with the University of Gloucestershire, whether on or off the premises or in collaboration with University staff or students
[3] Participants: usually understood to be individuals or groups who directly provide the data for a study.
[4] Stakeholders: individuals or groups with a vested interest in the research, e.g.: family members, local communities, funding agencies, employers, the wider research community and society more generally

1.4 The ethical dimensions of research relate to issues of research integrity and as such involve more than these specific responsibilities to take account the interests of the public and the researchers to incorporate the credibility and standing of scholarly research. Some of these dimensions include:

- The collection, use, and interpretation of research data
- Methods for reporting and reviewing research plans or findings
- Relationships among researchers
- Relationships between researchers and those that will be affected by their research
- Means for responding to misunderstandings, disputes, or misconduct
- Options for promoting ethical conduct in research

1.5 At the University of Gloucestershire, ethical review is intended to be a constructive and collaborative enterprise that promotes valuable research in the interest of the common good. The University's Research Ethics Committee (REC) is responsible for reviewing applications for ethical approval. This document sets out the University's policy and practice on the ethical conduct of any research carried out under its name.

1.6 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.

1.7 Maintenance of ethical literacy in research and a system of research ethics based in best practice is fundamental to the development and enhancement of research integrity. Although not the same thing, an ethically sound approach to research is a key component of research integrity. The University of Gloucestershire is working to ensure that it achieves the highest standards of research integrity, and expects the same of all its staff and students.

1.8 *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.

1.9 The Handbook comprises three parts:

1.9.1 **Part A (Section 2.0)** 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.

1.9.2 Section 2.6 clarifies the requirements for approval. All University activity that fits the definitions of research in section 1.2 and 1.10, including internal consultancies where University staff and/or students are participants, is subject to the provisions of this Handbook.

1.9.3 **Part B (Section 3.0)** contains the procedures by which research proposals can be assessed and, where necessary, given ethical clearance.

1.9.4 **Part C (Section 4.0) c**ontains 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.

1.10 The definition of research includes the following:

1.10.1 **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;

1.10.2 **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;

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

1.10.4 **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;

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

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

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

1.11 The only activities that are likely to be ***excluded*** from ethical review are those not defined as research as follows:

- Routine testing and analysis of materials, processes, systems for the maintenance of standards;
- Routine audit, quality assurance reviews, performance reviews;

- The development of teaching materials that do not embody original research[5].

1.12 The following statement of principles places a considerable emphasis on the personal responsibility of researchers to act ethically and with integrity, 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 Committee (REC), 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.

2.0 Part A: Principles

2.1 Introduction

2.1.1 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.

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

2.1.3 The University's approach to research ethics is consistent with European Commission's *Twelve Golden Rules to Ethical Research Conduct*[6]:

2.1.4 You must ensure that your research:

1. Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits);

2. Follows the "Do no harm" principle. Any risks must be clearly communicated to subjects involved;

3. Recognises the rights of individuals to privacy, personal data protection and freedom of movement;

4. Honours the requirement of informed consent and continuous dialogue with research subjects;

5. Treats animals with respect and works under humane conditions before, during and after the research;

[5] *As extracted from Frascati Manual, 2002; REF2011; and ESRC, 2015*. Note that one-off or specially commissioned testing, audits and reviews are not *routine*.
[6] European Commission (2013) *Ethics for Researchers: Facilitating Research Excellence in FP7* Brussels, European Commission. p 24.

6. Designs animal research in accordance with the 3 Rs: Replacement, Reduction, Refinement;

7. Respects the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives (mission creep);

8. Treats societal concerns seriously - a researcher's first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity;

9. Tries to prevent being openly available for misuse or malignant dual use by terrorists or military organisations;

10. Recognises the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle;

11. Respects biodiversity and does not impose irreversible change that threatens the environment or ecological balance;

12. Builds on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned).

2.1.5 All research conducted under University of Gloucestershire auspices is expected to be consistent with these provisions, and researchers are expected to take account of them in their research design.

2.1.6 Six Principles governing research at the University of Gloucestershire:

1. Autonomy/respect – participants' ability to think, decide and act freely.

    i) Autonomous individuals are able to make independent decisions, while those with diminished autonomy are entitled to protection;
    ii) This principle of respect underpins core practices including informed consent, protection of vulnerable participants' rights to privacy, anonymity and confidentiality;

2. Beneficence – to do some good.

    i) Noting that benefits may be direct or indirect, and may including contributions to knowledge

3. Non-maleficence – to do no harm.

    i) Noting that the risk of harm is often balanced against other principles, especially beneficence, and

ii) that at best the risk of harm in research can be minimised, not guaranteed

4. Justice – fairness and equity.

    i) This usually requires and assessment of who benefits for the research, who bears the burdens or takes the risks, and

    ii) requires research designs that ensure equity of treatment of participants.

5. Fidelity – honesty, integrity, trust.

    i) All research is a collaborative venture, whether that is with participants, other researchers or other source material; fidelity therefore incorporates other principles such as integrity, trustworthiness and honesty.

6. Academic freedom.

    i) That is, the right of the researcher to design, conduct and disseminate their research freely and without interference including from funders, commercial companies, governmental or institutional pressures.

2.2 General Responsibilities

2.2.1 *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.

2.2.2 *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.

2.2.3 *Towards themselves*
Researchers should avoid, wherever possible, actions which may have deleterious consequences for themselves. In many research settings researchers are vulnerable to various forms of harm, including physical, psychological and reputational harm. Researchers with an occupational or professional presence in their research area need to be aware that they have specific obligations under both University policies and procedures and any professional requirements. The University's policy and procedures set a minimum expectation for ethical practice: in cases where obligations may

differ between the University and professional expectations, the higher, more stringent standard shall apply.

2.3 Informed Consent

2.3.1 Research should be based, as far as possible and practicable, on the freely given informed consent of those under study and is the principal means by which participant autonomy is recognised and given meaning. 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 the information below.

2.3.2 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. The research should also make sure to explain what happens to the data once the research project is completed.

2.3.3 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. This is a particular concern in projects where researchers play other roles, including but not limited to being a worker, in the research site. 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.

2.3.4 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 video cameras and audio and digital recording devices. Participants should also be made aware during the consent process whether the data set will be made publicly available and the implications of that availability: this is a requirement for many publicly funded projects, and in many disciplines, especially in the experimental sciences, is becoming considered best practice. In cases where data sets will be archived, in repositories or elsewhere, researchers should pay careful attention to issues of anonymity and confidentiality, including in respect of anyone who might be identifiable from the data set.

2.3.5 If there is a likelihood of data being shared with or divulged to other researchers, whether through archives, repositories or other means, the potential uses of the data should be discussed with the participants and their explicit agreement to such use should be obtained.

2.3.6 Researchers should be aware of additional data protection legislation and the responsibilities they have towards the collection, storage and use of data.

2.3.7 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. Where researchers are studying in locations where they also occupy other roles; the potential for misinterpretation by the participants should be considered. This may be significant where the researcher also has organisational power over the participants.

2.3.8 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.

2.3.9 In some cases when working with people with diminished autonomy, such as young children or people whose understanding is impaired in some way so that they are unable to give full informed consent, a system of informed assent may be possible: that is, in these cases agreement to participate does not need to be verbal or written, but it does need to be explicit and evidenced. Assent, that is non-verbal or non-written agreement to participate, may only be used in projects approved under the terms of categories identified in Section 2.6 of this handbook.

2.3.10 Researchers should obtain the informed consent of children and their parents in relation to schoolchildren who are *in loco parentis*.

2.3.11 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.

2.3.12 In cases where a researcher may have professional obligations, such as through professional registration provisions, additional to those expected by best practice in academic research, research participants should be made aware of those obligations.

2.4 Deceptive and Covert Research

2.4.1 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.

2.4.2 Any researcher considering deceptive methods in research must seek approval from the relevant School Research Ethics Panel (SREP) or Research Ethics Committee (REC) as appropriate (see sections 3.3 and 3.4). 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 over-ride the issues of free and informed consent. Where approval has been given, the potential implications arising from publication must be fully considered.

2.4.3 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.

2.4.4 Covert on-line research presents specific challenges to researchers related to, amongst others, confirmation of the identity of research participants and a culture of openness and confession in many on-line settings. At the time of writing this area is extremely fluid; projects should be developed in accordance with the most recent discipline and project specific guidance regarding both research design and research ethics.

2.4.5 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.

2.5 Confidentiality and Anonymity

2.5.1 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 current data protection and privacy legislation and should consider whether it is proper or appropriate even to record certain kinds of sensitive information.

2.5.2 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.

2.5.3 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.

2.6 Approval Requirements

2.6.1 Research subject to approval at University of Gloucestershire

2.6.1.1 All research involving human or live animal participants must demonstrate ethics approval by the relevant School Research Ethics Panel (SREP) or by Research Ethics Committee (REC). In many cases, approval may be given by gatekeepers as specified in section 3.2. Set against the principles expressed above, the following classes of research must be referred to the relevant SREP, REC or external body:

2.6.1.2 **Research which involves biomedical or clinical intervention** (with the exception of those approved under standard protocols - see Standard Protocols in the Exercise Physiology Laboratory);

2.6.1.3 **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;

2.6.1.4 **Certain classes of research where procedures vary from standard procedures** in particular, covert research and research where the data are not recorded in a manner that protects the anonymity of subjects or participants;

2.6.1.5 Research 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**. With the exception of children and young people (below), in all cases 'sensitivity' shall be a judgement determined by an assessment of:

i) the research questions
ii) the research design
iii) the recruitment procedures;

2.6.1.6 Proposals for research that involve **vulnerable populations**. With the exception of projects where participants are children and young people (see below), in all cases 'vulnerability' shall be a judgement determined by an assessment of:

i) the research questions
ii) the research design
iii) the recruitment procedures;

2.6.1.7 **Research where participants are under 18.** Guidelines for conducting research involving children and young people may be found in Appendix 1: University of Gloucestershire Guidelines for Working with Children and Young People.

2.6.1.8 **Research involving work outside the UK** where there is specific or identifiable risk to the researcher or other research participants. The degree of risk will be assessed in the light of the circumstances of each project, but will at all times includes cases where at the time of approval or at any stage during the research project the Foreign and Commonwealth Office (FCO) classifies the research location as High Risk or above.

2.6.1.8 **Research involving assent-based participation**, as defined in section 2.3.8 above. For University of Gloucestershire purposes, assent is when verbal or written agreement to participate is not feasible. Assent is therefore always implied and not stated.

2.6.1.9 **Research involving flora and fauna in natural environments.** Research involving hands-on or manipulative observation (e.g. trapping, handling) of species in natural environments, and/or involving protected species, and/or taking place in locations with a statutory designation. Such work may also be subject to licensing from relevant bodies (e.g. Natural England or other relevant regulatory body).

2.6.1.10 Procedures for gaining approval are contained in section 3.0.

2.6.2 Research subject to external institutional approval

2.6.2.1 All research related to National Health Service (NHS) users/patients/carers must abide by the NHS Health Research Governance framework Authority (HRA) provisions (further guidance can be found here: http://www.hra.nhs.uk/research-community/). Any research conducted on NHS property should be referred to the relevant local Research and Development team. It is no longer necessary to obtain full HRA approval for research involving staff. In the first instance, approval should be sought from Research Ethics Committee (REC).

2.6.2.2 Research involving Looked After Children (children in the social care system) may require approval from the Social Care Research Ethics Committee (SCREC) which falls within the Health Research Authority (HRA) system. In the case of projects where participants may be within the care system that do not require SCREC approval, research will be expected to use research designs that are consistent with the provisions governing the work of the SCREC. Applicants should, in the first instance, consult the Health Research Authority guidance.

2.6.2.3 Members of staff and students may, of course, use the relevant gatekeepers for advice prior to applying for HRA approval or if needed subsequent to such.

2.6.2.4 Research involving participants recruited because they are serving custodial orders in the criminal justice system will be required to seek approval from REC covering the relevant young offenders institution or prison. These apply also to community based custodial sentences. Applicants should, in the first instance, consult the National Offender Management Service (NOMS).

2.6.2.5 In cases where University staff or students are involved in a research project led from another UK or EU University and where the project has been given ethical approval by that University, no further University review will be carried out if evidence of that approval process and outcome is provided to REC.

2.6.2.6 In line with the Framework for Research Ethics adopted by several of the UK's research funding councils, REC reserves the right to review externally approved projects, require further information and/or ask for a full ethical review while adhering to the principle of non-duplication of research ethics review.

2.6.3 Review and approval provisions

2.6.3.1 Refer to sections 3.3 and 3.4 for the remit of REC and SREP.

2.6.3.2 Generally decisions will be made at the next scheduled meeting of the Research Ethics Committee (REC) or School Research Ethics Panel (SREP), unless the project is identified as meeting the criteria for Fast Track review (see section 3.1.4b)). Where the time-frame for decision-making needs to be extended applicants will be advised.

2.6.3.3 Applications will considered and become subject to one of three outcomes:

i) **Unconditional Approval**; the research can proceed as described.
ii) **Conditional Approval**; the research can proceed subject to the following amendments and enhancements to the ethical protocols. This would normally be subject to approval under delegated Chair's Action.
iii) **Approval Withheld**; the research cannot proceed until the amendments below have been made to the ethical protocol, the revised protocol will need to be resubmitted to REC/SREP for further review. Approval in this case cannot be obtained through delegated Chair's Action.

2.6.3.4 Applicants will be advised in writing via email of the outcome as soon as possible after the decision is taken; this shall normally be within 10 working days.

2.6.3.5 In reviewing applications for ethical approval, REC/SREP will:

i) Review and approve, or withhold proposals for proposed research projects;
ii) Review and approve, or withhold approval for amendments to previously approved research protocols where there have been changes to research design;
iii) Recommend amendments and enhancements where there are deficits in a submission;
iv) Require the halting of research where substantive ethics flaws are identified during review until such time as any such flaws have been remedied to the satisfaction of the REC/SREP;
v) Undertake a regular review of approved research at a time identified during the project approval or more frequently where deemed appropriate;
vi) REC shall report to the Research Committee (RC) the public minutes and to Research Degrees Committee (RDC) the

confidential minutes of each meeting of the REC, and an annual report outlining the work of the Committee in the preceding year. Each SREP shall provide an annual report to the Research Ethics Committee (REC);

vii) Oversee a database of all submitted proposals and annual reviews; and formally record the conclusion of research projects. For SREP, this database should include a record of all Undergraduate Taught and Postgraduate Taught dissertations or major projects approved, as well as other student research activities.

2.6.4 Researcher obligations

2.6.4.1 Researchers must consult the appropriate University 'gatekeeper' whose role is described in section 3.2 covering procedures.

2.6.4.2 In making a submission for ethical approval, applicants undertake not to begin the proposed research until it has been approved; to adhere to the project design and principles as approved and only make substantial amendments to the investigation pending the further approval of the Research Ethics Committee (REC).

3.0 Part B: Procedures

3.1 Introduction

3.1.1 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 School Research Ethics Panel (SREP) and Research Ethics Committee (REC).

3.1.2 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 REC.

3.1.3 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 REC. 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.

3.1.4 At both School and University level there are three types of research ethics review and approval process:

a) **Exempt**: where a project involves only library or desk-based research and does not generate new data derived from the recruitment or inclusion of human participants via any media, or has been otherwise approved under the provisions outlined in section 2.6.2 above;

b) **Fast track**: where a project seeking full review, including those with a mandatory review requirement as identified in section 2.6.1, is judged by the relevant gatekeeper to require referral to SREP/REC but to be low risk, a fast track review may be undertaken by the Chair (or vice-Chair) and one other independent of the project (at School level, from another Subject Community to the lead researcher; at REC from another School than the lead researcher). Cases being considered for fast track review must include a fully completed ethics application form (available on the University website), including the insurance risk assessment, signed and returned to the relevant SREP or REC officer; An application eligible for Fast Track review will only be considered once the full application has been submitted. The decisions about suitability for Fast Track review is that of the relevant gatekeeper, including REC/SREP Chair, only. It is not the decision of an applicant, or in the case of a student, their supervisors.

c) **Full Ethics Review**: all other projects where review is mandatory or where a gatekeeper determines that full review is required. In cases where a researcher is applying for a full ethics review, an ethics application must be fully completed, including the insurance risk assessment, and signed. In the case of submission to REC it needs to be returned to the REC Officer no later than 8 working days before the REC meeting where it will be considered. The application requires attention to all ethical issues raised by the project and should be presented in a way that non-specialist readers can understand and make judgement on both the research design and research process, including participant recruitment and all elements of data gathering and development. The application must include all consent and information documents and data collection tools and instruments. For

i) **Social Science projects**, include all questionnaires, interview schedules, observation preforms and participant recruitment information;

ii) **Laboratory based or experimental projects**: full details of experimental techniques and/or biomedical procedures, including human or non-human biological materials to be gathered.

3.1.5 In all cases where full ethics review is applied for, applications must show how they:

i) adhere to legislation and Codes of Practice relevant to the research area or discipline:

ii) are compliant with professional codes of practice relevant to the research area or discipline.

3.1.6 Following review, the provisions of section 2.6.3 shall apply.

3.2 The 'Gatekeeper' System

3.2.1 The relevant University gatekeeper acts as a conduit between the researcher and the possible use of Research Ethics Committee (REC). 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 section 2.6, the gatekeeper will judge whether or not a proposal should be submitted to REC or School Research Ethics Panel (SREP) for formal approval. As such, gatekeepers act with authority delegated by REC both as filters for projects to progress to SREP or REC review, and as approvers of projects that do not go forward for further consideration.

3.2.2 In summary, gatekeepers are:

Staff research, including applications to Research Councils

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

For other members of staff: the relevant School Research Ethics Lead ⇒ REC

Postgraduate research degree students:

Gatekeepers for Research Student projects

Thesis advisor ⇒ School Research Degrees Lead ⇒ School Research Ethics Lead ⇒ REC

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

Postgraduate taught students:

Gatekeepers for students in taught Postgraduate programmes

Dissertation Advisor/Module Tutor ⇒ School Research Ethics Lead ⇒ SREP

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

Undergraduate students:

Gatekeepers for students in taught undergraduate programmes

Dissertation Advisor/Module Tutor ⇒ School Research Ethics Lead ⇒ SREP

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

3.3 The School Research Ethics Panels

See section 2.6.3 for review and feedback requirements.

3.3.1 The principal aims of the School Research Ethics Panels (SREP) are three-fold. The first aim is to consider and, in accordance with the principles expressed in section 2.0 of this Handbook, grant permission for the undertaking of or refer back for further consideration, research investigations which fall in the categories listed in section 2.6.1. The second aim is to act as an advisory body to the School on matters related to research ethics. The third aim is to advise on appropriate training and staff development needs.

3.3.2 The details of SREP are as follows:

3.3.2.1 *Terms of Reference*

The Terms of Reference for SREPs are:

i) To consider research projects by students in undergraduate and postgraduate taught programmes for approval, referral to Research

Ethics Committee (REC), or referral back to the applicant in accordance with the principles expressed in this handbook on a regular basis, noting that;

a) all cross institutional, international, and collaborative projects should normally be accompanied by a recommendation from the SREP on whether the project complies with the University's research ethics principles if referred to REC;

b) all projects subject to the Health Research Authority (HRA) research ethics procedures shall be referred to the relevant HRA 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 School.

3.3.2.2 ***Membership***

The membership of the SREP shall be:

a) School Research Ethics Lead (Chair);
b) at least two School members who are experienced dissertation or thesis supervisors;
c) the SREP may co-opt members (e.g. Insurance officer, external advisor) for advice on specific proposals where necessary;
d) officer (provided by the School Administration team) (non-member).

3.3.2.3 ***Reporting Lines***

Reporting lines for the SREP are:

a) For staff development and policy issues: REC;
b) For post-graduate taught and under-graduate taught programmes: Head of School.

3.3.2.4 ***SREP Terms of Office***

Three years for all members.

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

The SREP 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 School-based gatekeepers at other levels.

Each SREP should organise sufficient meetings at times or otherwise establish a system for rigorous review of projects taking account of the principle of

externality to allow expeditious consideration of proposals and requests (NB: this may include a greater number and frequency of meetings or greater workload at the beginning of each academic year).

3.4 The Research Ethics Committee (REC)

See section 2.6.3 for review and feedback requirements.

3.4.1 The principal aims of the Research Ethics Committee (REC) are three-fold. Its first aim is to consider and, in accordance with the principles expressed in section 2.0 of this Handbook, grant permission for the undertaking of or refer back for further consideration, research investigations which fall in the categories listed in section 2.6.1. The decisions regarding research degree projects shall be notified to Research Degrees Committee (RDC). Its second aim is to act as an advisory body to the Research Committee (RC), and thus the University, on matters related to research ethics and integrity. Its third aim is to sponsor appropriate training and staff development.

3.4.2 The details of REC are as follows:

3.4.2.1 *REC Terms of Reference*

3.4.2.1.1 The Research Ethics Committee (REC) is responsible to the Research Degrees Committee (RDC) for:

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

3.4.2.1.2 The Research Ethics Committee (REC) is responsible to the Research Committee (RC) for:

a) monitoring the appropriateness and effectiveness of procedures for granting or withholding ethical approval mechanisms for research;
b) reviewing and, if necessary, recommending revisions to *Research Ethics: a Handbook of Principles and Procedures*;
c) advice on policy issues related to research ethics as determined and requested by the Research Committee;
d) advice on policy issues related to research integrity as determined and requested by the Research Committee;
e) sponsoring staff development in the area of research ethics with appropriate partners within the University;
f) reporting outcomes of consideration of staff and student requests for approval of projects in accordance with the principles expressed in *Research Ethics: a Handbook of Principles and Procedures*.

3.4.2.2 *REC Membership*

a) Chair (nominated by the Dean of Academic Development)
b) Head of Postgraduate Research
c) One representative from each School who shall be the School Research

Ethics Lead
d) Finance and Planning Insurance Manager
e) Up to 2 external lay members appointed by the Dean of Academic Development in consultation with the Chair
f) The Committee may co-opt external members in cases where specialist biomedical and other technical expertise is necessary.
g) Officer: a member of the Governance and Secretariat Services team

3.4.2.3 ***Reporting Lines***

a) REC shall report outcomes of consideration of research degrees to RDC.

b) REC shall report all other matters to RC.

3.4.2.4 ***Terms of Office***

a) Three years for Chair and all other members.

3.4.2.5 ***Regularity of Meetings and Availability of Minutes***

The REC will meet on a regular basis and in response to applications submitted to it. Copies of all minutes of the REC will be forwarded to the RDC. Copies of Part 1 minutes will be reported to Research Committee. An annual report will be submitted to the Research Committee and RDC. Copies of all minutes will be held by the Officer for scrutiny.

3.4.3 It is an expectation that REC will be asked to consider any research proposal which falls under the categories listed in section 2.6.1 of this Handbook, using either Fast Track or Full Review procedures. Failure to submit such proposals for approval or, once submitted, violation of REC's decision to refuse permission for such research to proceed, may negate the University's insurance cover and also result in disciplinary action.

3.4.4 The University takes seriously research integrity and the reporting of research malpractice. Advice may be sought from the relevant gatekeepers, School representatives, or the Chair of REC. Additionally, staff and students are directed to the Whistleblowing Procedures.

3.5 Procedures for Securing Approval for Research Projects

3.5.1 ***Members of staff seeking ethics approval***

3.5.1.1 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. Gatekeeper decisions to approve staff projects should be reported to the REC Officer for noting at the next Research Ethics Committee (REC). This should include information on the names of the research team, the title of the research project and the date of approval.

3.5.1.2 Any proposal which falls under section 2.6.1 of this Handbook must be submitted to REC. Such proposals must be received by the REC Officer at least seven working days before the next scheduled meeting. Fast track review may be taken on matters that require greater expediency where it is appropriate to do so.

3.5.2 *Research degree students seeking ethics approval*

3.5.2.1 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 (Project Approval Form (PAF)), as is the supervisory team for each research degree programme. The School Research Degrees Lead's signature on the form confirms that both student and supervisors are aware of, and agree to abide by, those principles.

3.5.2.2 All proposals which fall under section 2.6.1 of this Handbook must be submitted to Research Ethics Committee (REC) for approval before the RD1 will be given final approval. The School Research Degrees Lead should liaise with the School Research Ethics Lead or the Chair of REC where there is any doubt whether a research proposal should be considered by REC.

3.5.3 *Postgraduate taught students seeking ethics approval*

3.5.3.1 The general framework for approval will apply to students following taught postgraduate courses. Additionally, all postgraduate taught 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. All postgraduate taught programmes must ensure that dissertation, major project or other research activities are conducted in a manner consistent with University research ethics policy and procedures. Course Leaders for free-standing postgraduate courses should ensure that an equivalent system is in place.

3.5.3.2 All proposals which fall under section 2.6.1 of this Handbook must be submitted to the School Research Ethics Panel (SREP) for approval. The Academic Course Leader should liaise with the School Research Ethics Lead where there is any doubt whether a research proposal should be considered by SREP.

3.5.4 *Undergraduate student seeking ethics approval for research in a taught programme*

3.5.4.1 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 as part of the assignment submission process. 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 Academic Course Leader.

3.5.4.2 All proposals which fall under section 2.6.1 of this Handbook must be submitted to the School Research Ethics Panel (SREP) for approval. The Module Tutor or Course Leader should liaise with the School Research Ethics Lead where there is any doubt whether a research proposal should be considered by SREP.

3.5.5 Reporting back to applicants

3.5.5.1 The provisions of 2.6.3.4 shall apply.

3.6 Appeals Procedure

3.6.1 All investigators have the right to appeal against the judgement of the School Research Ethics Panel (SREP) or Research Ethics Committee (REC). There are two grounds for such appeal:

a) where the researcher feels that the SREP or REC 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 SREP or REC.

3.6.2 A researcher may not appeal against the decision of REC purely on the grounds that they disagree with the decision.

3.6.3 A researcher has the right to appeal in writing against a decision made by the SREP or REC within ten working days of the notification of that decision. Appeals against a SREP decision must be directed to the Head of School. Appeals against a REC decision must be directed to the University Dean of Academic Development.

3.6.4 Appeals Against the SREP

3.6.4.1 The REC Chair in consultation with the relevant Head of School will convene a sub-committee meeting of REC with the proposer to review the proposal and the grounds for the SREP's decision. This meeting will normally be held within ten working days of notification of the appeal. There will be at least two REC members who are not part of the relevant school, in addition to the Chair in attendance.

3.6.4.2 At this stage the REC Sub-Committee 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.

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

3.6.5 Appeals Against the REC

3.6.5.1 After consultation with the University's Dean of Academic Development, the RDC Chair will convene a meeting of a sub-committee of RDC with the proposer to review the proposal and the grounds for REC's decision. This meeting will normally be held within ten working days of notification of the appeal. There will be at least two RDC members in addition to the Chair in attendance.

3.6.5.1 At this stage the RDC 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.

3.6.5.2 Following an unsuccessful appeal, and where the researcher is dissatisfied with the decision of the RDC, 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 ten working days of receipt of RDC'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 RDC's decision-making process. The proposer will be notified in writing within five working days of Academic Board's hearing. There is no further right of appeal if the appeal is not upheld.

4.0 Part C: Appendices

University of Gloucestershire Research Ethics Resources

4.1 Appendix 1: University of Gloucestershire Guidelines for Working with Children and Young People in Research

4.2 Appendix 2: Standard Protocols in the Sport & Exercise Laboratories

4.3 Appendix 3: Laboratory Manual Statement: Human Tissue Act 2004

4.4 Appendix 4: University of Gloucestershire Data Protection Policy

4.5 Appendix 5: The Use of Online Transcription Services in Research

Professional Bodies Guidelines and Codes of Practice

4.6 Appendix 6: Research Governance Framework for Health and Social Care

4.67 Appendix 7: Statement of Ethical Practice for the British Sociological Association

4.8 Appendix 8: The British Psychological Society: Code of Ethics and Conduct

4.9 Appendix 9: British Educational Research Association (BERA) Ethical Guidelines for Educational Research

4.10 Appendix 10: The Oral History Society Code of Practice

4.11 Appendix 11: Market Research Society Code of Conduct

Other Useful Resources

4.12 Appendix 12: UK Universities Concordat to Support Research Integrity

4.13 Appendix 13: Procedures for Protecting Survey Respondents

4.14 Appendix 14: Conducting Covert Research

4.15 Appendix 15: The Medical Research Council

4.16 Appendix 16: WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

4.17 Appendix 17: http://www.ethicsguidebook.ac.uk/