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**UNIVERSITY OF GLASGOW**

**PROCEDURES FOR UNIVERSITY COLLEGES IN RESPECT OF NON-CLINICAL RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN MATERIAL AND DATA**

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## **ETHICAL ISSUES ARISING FROM NON-CLINICAL RESEARCH WITH HUMAN SUBJECTS, HUMAN MATERIAL OR DATA**

### **INTRODUCTION TO GLASGOW UNIVERSITY PROCEDURES**

#### **1 SUMMARY**

**The University of Glasgow Ethics Committee was established by Senate in 2002 and charged with sustaining a University-wide awareness of ethical issues arising from non-clinical research involving human subjects, human material and data. The Committee is responsible for producing guidelines for the conduct of such research and for ensuring that all University Colleges and Centres linked to them either have in place proper procedures for the consideration and conduct of such research or provide a written explanation as to why such procedures are considered to be unnecessary for them. The University Ethics Committee will also consider and give guidance on research referred to it from Colleges and hear appeals on decisions made by Colleges. In exceptional cases the University Ethics Committee may itself make decisions on research.**

**NOTE: Where Schools Ethics Committees have been established in Colleges, these guidelines will apply to those School Ethics Committees where relevant.**

#### **2 RESPONSIBILITIES OF THE UNIVERSITY ETHICS COMMITTEE**

2.1 The responsibilities of the University Ethics Committee in respect of Colleges and College procedures for ethical review of research are as follows:

- (a) to develop policy and guidelines for and with Colleges;
- (b) to approve College procedures or statements;
- (c) to assist with the provision of appropriate training for College officers with specific responsibility for ethical review;
- (d) to consider and offer guidance on cases of uncertainty and to hear appeals against College decisions. In exceptional cases the University Ethics Committee may itself make decisions on research;
- (e) to consider annual reports from Colleges on the management of ethical issues in research, offering advice and making recommendations as appropriate on the operation of College-level procedures;
- (f) to make an annual report to Senate on the operation of procedures for ethical review of research with the University;
- (g) to report to Senate on any outstanding difficulties in respect of ethical review of research;
- (h) to seek clarification from external expert bodies, as necessary, on matters of ethical review policy and practice.

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### 3. PROCEDURES FOR COLLEGES

3.1 Under the guidance of the University Ethics Committee, each College is required:

(a) to *either* establish procedures for handling the ethical issues in research, or provide a written explanation as to why such procedures are considered to be unnecessary for that College (details in both cases must be submitted to the University Ethics Committee for approval);

(b) to appoint a named member of staff to act as the designated officer with responsibility for ethical review of research on behalf of the College;

(c) through the designated officer, to conduct an annual review of procedures within the College, report to the University Ethics Committee on the findings and keep ethical issues in research under continuous review;

(d) to consult as appropriate with external expert bodies;

(e) to refer cases to the University Ethics Committee that require advice or an opinion from that Committee. It is expected that referral to the University Ethics Committee for an appeal will be in exceptional circumstances only. The University Ethics Committee will not normally interfere with a College Ethics Committee decision to require revisions to the project, such to amend an information sheet or consent form. The University Ethics Committee is concerned with the general principles of natural justice, reasonableness and fairness of the decision made by the College Ethics Committee.

3.2 College procedures will be reviewed from time to time by the University Ethics Committee.

### 4. BASIS OF APPROVAL BY UNIVERSITY ETHICS COMMITTEES

4.1 A decision by any of the University's Ethics Committees to approve a research project does not imply an expert assessment of all possible ethical issues or of all possible dangers or risks involved nor does it detract in any way from the ultimate responsibility which researchers must themselves have for all research which they carry out and for its effects on human subjects. The University's Ethics Committees address themselves to ethical matters and are dependent upon information supplied by the researcher. This information is expected to be properly researched, full, truthful and accurate. Failure to follow the University's guidance on ethical review of research may result in disciplinary action.

4.2 A decision by any of the University's Ethics Committees, including a College or School Ethics Committee, to approve a research project does not constitute a precedent and each application will be judged on its own merits and in the light of present circumstances. For that reason, a decision may be made to approve research of a kind not previously approved. Equally a decision may be made not to approve research of a kind that was previously approved. In neither case does this imply that the Ethics Committee's decision nor decision-making process is flawed since proper ethical review cannot be reduced to a mechanical or formulaic approach.

4.3 A decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate and any such changes do not invalidate ethical approval that has been given. However, researchers are expected to make themselves aware of changes in policies or procedures and to adopt them as necessary.

## **ETHICAL ISSUES ARISING FROM RESEARCH IN RESPECT OF NON-CLINICAL RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN MATERIAL AND DATA**

### PROCEDURES FOR UNIVERSITY COLLEGES

#### 1 Introduction

1.1 The University Ethics Committee (UEC) is charged with creating a University-wide awareness of ethical issues arising from research. The UEC produces guidelines for the conduct of non-clinical research involving human subjects, human material and data and ensures that all University Colleges either have in place proper procedures for the consideration and conduct of such research or provide written explanation as to why such procedures are considered to be unnecessary for that College. In exceptional instances the UEC will also consider and give guidance upon specific cases, or other matters referred to it by College Ethics Committees, including appeals from decisions of College Ethics Committees.

1.2 This paper:

(a) sets out the nature of some of the ethical issues which might face University Colleges in research and raises questions for Colleges to consider in identifying their own positions. The University Ethics Committee does not believe it is possible to produce an exhaustive list of circumstances or instances that involve ethical issues. The following paragraphs deal with the major issues;

(b) sets out procedures to be followed by University Colleges and the University Ethics Committee

1.3 Within this paper the term "College" is used as shorthand for University units and should be taken to include academic College, Research Institutes, Schools and inter-College centres of the University. Research Institutes, Schools, centres and other units are expected to ensure applications for ethical review of research are dealt with through the procedures of the College to which they are cognate or linked. **Section 4.7 below provides for Schools to have their own ethics committees in certain circumstances.**

#### 2 Ethical Issues

2.1 Ethical issues arise when the conduct of research involves the interests and rights of others. Perhaps the most obvious cases concern people who act as "subjects" (or 'participants') in medical research involving innovative treatments. However humanitarian are the long-term prospects of the research, there may be immediate or impending threats to the participants' safety, comfort, privacy or convenience. The interests of others may equally be affected by research outside of a medical or clinical context. This research too requires full consideration of its ethical implications for those being asked to take part.

2.2 The adoption of an ethical position in respect of research requires that the researcher observes and protects the rights of would-be participants and systematically acts to permit the participants to exercise those rights. Ethical practice in such cases requires that participants, as a

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minimum, be properly informed, free to volunteer without inappropriate inducement, free to opt out at any time without redress, and be fully protected in regard to safety to the limits of best practice.

2.3 Ethical practice in the management of this work requires that a body independent of the research team examine the research design and the system for protecting participants' interests with a view to adjudicating on their ethical acceptability and their accountability.

2.4 As explained in 2.1, ethical issues arise in a much broader range of situations than the medical one. Any research that involves others as participants creates the possibility of an interference with the participants' interests or rights. Social research involving interviewing or observation especially where records (particularly on audio or video tape) are kept, may impinge on the confidentiality, privacy, convenience, comfort or safety of others. Such possibilities constitute ethical problems.

2.5 Ethical issues may also be raised by research which makes reference to named persons either living or with living relatives. Research which relates to the dead may accordingly raise issues of privacy and confidentiality.

2.6 The above illustrations indicate that a great deal of research conducted by students and staff in a very wide range of disciplines will inevitably raise ethical issues. It therefore must involve a systematic regard for the rights and interests of those others as they may be affected by the research.

2.7 Ethical issues may be felt to be especially important where research involves people who may be need of additional protection. For example, research with children and those with learning disabilities may require additional safeguards to be taken to protect participants' well-being.

2.8 Legal issues may also arise in conducting research with human subjects or using data about them. For example, data protection legislation governs research with data concerning identifiable, living persons and legislation governs research with adults who are unable to give a legally valid consent to take part. The University's Ethics Committees are concerned with ethical rather than legal review of research. However, they will expect researchers to be aware of the legal issues that arise from their research and to demonstrate that they have taken proper steps to ensure they comply with legal requirements. This may include seeking legal advice, for example from the University's solicitors, in cases of doubt or difficulty. The responsibility for ensuring that legal requirements are met is that of the researcher and, in the case of students, the first named supervisor.

2.9 The University and its Colleges have the responsibility for ensuring that:

- (a) ethical principles are explicitly communicated;
- (b) ethical practices are followed.

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### 3. Colleges

3.1 Colleges vary widely in the scope and significance of the ethical issues affecting their work. The MVLS College regularly engages in research that requires the approval of an NHS ethics committee. Some Schools have significant numbers of research students whose studies involve human subjects. Some Schools house research projects involving the recruitment of people as subjects of research. Other Schools within Colleges may not engage in any of these activities.

3.2 Each College must consider the precise nature of potential ethical issues in the conduct of its research. The following questions are offered to guide such consideration:

- (a) Does the College carry out research with people, human material or human data as its subjects?
- (b) If so, does it have a forum for discussing and reviewing ethical issues related to this work?
- (c) What ethical or legal rights do the people affected by the research project have? How are their rights observed and protected?
- (d) Are any potentially vulnerable people involved (e.g. children, adults with learning disabilities, undergraduates in academically dependent relationships with researchers)? If so, are additional safeguards required?
- (e) Is there recognition of legal issues arising and are there mechanisms for ensuring legal requirements are met?
- (f) Are there discipline-specific guidelines or codes of practice dealing with ethical standards produced by professional bodies which the College is expected or required to observe?
- (g) Does research within the College involve sponsorship or external contracts? If so, what additional ethical issues are raised and how are they dealt with, for example, in respect of the publication of findings?
- (h) Do any College research activities raise issues of an ethical nature even if they do not raise the questions listed above? How are such issues handled?
- (i) Generally, how are ethical principles in the conduct of research taught? What evidence is there that they are learned?

### 4. Procedures

4.1 All Colleges must either have in place procedures for the consideration of ethical issues and for ensuring that any policy or guidelines developed through the University Ethics Committee are followed, or provide a written explanation as to why such procedures are considered to be unnecessary for that College. It is the responsibility of the UEC to approve all College procedures or written explanations.

4.2 The scale of a College's procedures will be determined by the extent to which ethical issues are raised and their frequency. Where a College's work rarely (if at all) raises ethical issues, a complex procedure would clearly be inappropriate and the College should state and explain this in writing. They must explain how research is monitored to ensure any ethical issues are recognised and how any ethical aspects of research would be dealt with. Where a College is extensively engaged in research that raises ethical issues formal procedures are required and it will be necessary to establish an ethics committee, or develop an existing one, within the College.

4.3 Taking into account the matters described in 3.2, each College must establish an appropriate mechanism to cover all aspects of its research as revealed in its review. Formal procedures, where developed, must be consistent with best practice in the subject area and, as a minimum, should conform with the requirements of professional bodies in that domain. Where appropriate, the approval of these bodies should be obtained.

4.4 The University policy of review of non-clinical research applies to individuals carrying out research for the University including, without limitation, all University employees, irrespective of whether their current place of work is within or outside University premises and all visiting researchers of the University irrespective of whether they are employed by the University, including persons with honorary positions, conducting research within, or on behalf of, the University. In the case of students, it covers research undertaken by a student currently registered for a degree within the College as a recognised part of his or her degree programme. However, it does not cover work carried out as part of the teaching of the programme, for example, students conducting established experiments as part of their learning. Ethical issues in respect of such matters continue to be dealt with through College teaching committees and the Education Policy and Strategy Committee

4.5 Each College must appoint an officer with specific responsibility for the management of ethical issues raised by the research work of the College. The designated officer should have clear terms of reference. These should include:

- (a) ensuring that there are effective mechanisms to bring any policy, guidelines or procedures developed with or through the University Ethics Committee and the College Ethics Committee to the attention of staff and students for whom the College is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;
- (b) keeping College ethical issues in research under review;
- (c) managing and monitoring the procedures in practice;
- (d) ensuring that appropriate records of applications, practices and decisions are made and kept;
- (e) reporting to the head of College as appropriate;
- (f) reporting to the College through an appropriate forum;
- (g) reporting on an annual basis (using the format provided in Appendix IV) on behalf of the College to the University Ethics Committee.
- (h) Membership of the University Ethics Committee. This entails attending meetings of the University Ethics Committee and dealing with the work of that Committee.

Even where it has been agreed that an Ethics Committee for the College is unnecessary, a designated officer must be appointed to carry out (a), (b), (f) and (g) above.

4.6 The University Ethics Committee is conscious of increasing administrative burdens in academic life and is concerned to avoid adding unnecessarily to this development. However, it is important that there can be appropriate confidence in the scrutiny process for those asked to take part in research carried out by staff and students. A consistent approach to ethical scrutiny across the University must therefore be in place and kept under review.

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Templates, forms and guidance for operating procedures of College Ethics Committees are included within this document or are available as links from the University Ethics Committee website. Links to further information and guidance on ethical aspects of research are also available from the website. Subject specific guidance for staff and students should be maintained by Colleges on their own part of the University website.

**4.7 Because of the volume of applications or for other operational reasons, Colleges may wish to have School ethics committees to deal with ethical review of research..**

**If there are reasons for establishing Ethics Committees at School level, these Ethics Committees are expected to have the same responsibilities as Ethics Committees at College level, save that instead of reporting directly to the University Ethics Committee, they will report to the College Ethics Committee. The School should appoint an ethics officer and an Ethics Committee with the general constitution and responsibilities outlined in this document for Colleges.**

**The College retains overall responsibility for ensuring the appropriate ethical review of its research. All staff and all PhD and Masters (Research and Taught) applications for ethical review must be examined by the full College or School Committee; systems for undergraduate research ethical approval may apply a lighter touch but must nevertheless contain independent scrutiny and not just that of the supervisor.**

4.8 Colleges should ensure that any applicants for project approval (or their supervisors) should withdraw from the Ethics Committee meeting when their cases are discussed and should not take part in decisions on their applications.

4.9 Where research work involving human subjects, human material or data is concerned, caution should be exercised to protect both the public interest and the University. Colleges must either incorporate responsibility for ethical issues into the terms of reference of an existing College ethics committee or set up a separate College Ethics Committee with explicit membership, terms of reference and operating procedures. Guidelines on these matters are attached as Appendix II. **The Guidelines apply as applicable to any School committees set up in line with the conditions above.**

4.10 Research work should not proceed without explicit, written approval. Copies of the formal written approval must also be retained by College or School where a School committee exists. Reference to a project having received “Ethics Committee approval” for a project in letters of invitation to participate in research or information to participants can only be made in relation to the project for which approval has been given. Any amendments to the research as it has been approved must also be approved by the appropriate Ethics Committee before the research proceeds.

4.11 The University Ethics Committee recognises that in some instances (e.g. in medical research) research ethics committees already exist to consider research proposals and the Committee would not wish such work to be duplicated by Colleges. In such cases it would be necessary for the College to ensure that treatment was comprehensive (i.e. all relevant proposals were taken to the appropriate committee) and that the College, through its designated officer, played an active role in



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reviewing procedures and managing the link between the College and the external ethics committee.

4.12 It is not always easy to distinguish between non-clinical and clinical research. Non-clinical human research in this context is taken to be research which is generally not concerned with medical treatment of patients but which applies systematic procedures of investigation to human beings, whatever the nature of the research; whether, for example, it be physical, social or psychological.

**In Scotland (similar rules exist in the rest of the UK) ethical advice from the appropriate NHS Research Ethics Committee (REC) is required for research proposals involving:**

- a. patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions**
- b. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above**
- c. access to data, organs or other bodily material of past and present NHS patients**
- d. foetal material and IVF involving NHS patients**
- e. the recently dead in NHS premises**
- f. the use of, or potential access to, NHS premises or facilities**

**NOTE – From 1 September 2011, a revised version of the National Research Ethics Service Standard Operating Procedures (SOPs) for NHS Research Ethics Committees in the UK is in operation. There have been changes to the remit of NHS RECs and revised requirements for ethical review of research by NHS RECs. To check whether this affects the need to apply for ethical review for your research under either legislation or the policy of the UK Health Departments, please see the following link:**

**<http://www.nres.nhs.uk/news-and-publications/news/nres-sops-version-5/>** and in particular the following guidance from the link

- [Guidance on changes to the remit of RECs; and](#)**
- [Algorithm – does your project require REC review?](#)**

If requested to do so, an NHS REC may also provide an opinion on the ethics of similar research studies not involving the categories listed above, carried out for example by private sector companies, the Medical Research Council (or other public sector organisations), charities or universities.

The appropriate REC in each case is one recognised for this purpose by the NHS Board within the area of which the research is planned to take place. This will normally be one established by the NHS Board itself within its geographical area. For the purposes of ethical review of the research proposal, a research "site" is defined as the geographical area covered by one NHS Board, whether the research is based in institution(s) or in the community. Even when the research may physically take place at several locations within that geographical boundary, a favourable ethical opinion on the research protocol is required from only one NHS REC within that NHS Board boundary. Where the research is planned to take place at more than one "site" as defined above, different arrangements apply.

**<http://www.nres.npsa.nhs.uk/>** and **<http://www.nres.nhs.uk/news-and-publications/news/nres-sops-version-5/>** provide further details

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The University's Ethics Committees are not empowered to give permission for researchers to conduct research involving any of the above. Although it is expected that non-clinical research involving any of these categories would be rare, where such research is proposed the researchers must apply to the relevant NHS research ethics committee. Making such application is the responsibility of the researcher.

4.13 There may be some cases which would be described as clinical research but which NHS Research Ethics Committees will not ordinarily consider, for example, where the data collection is abroad. In these exceptional circumstances the College Committee will look at such proposals but may need to refer particular aspects of the research to those with appropriate, particularly clinical, expertise in the area. Researchers are asked to bear in mind that this may lead to some inevitable delays in the process while experts are consulted. Researchers should also note that research of this kind will be expected to have received ethical approval from a properly constituted and independent Ethics Committee in the country concerned, where such a committee exists to review the kind of research being proposed, before it can be considered by the College Ethics Committee. However, if Glasgow University is the only University involved it also requires approval from the College Ethics Committee before it can proceed. It is the responsibility of the researcher to check the requirements for ethical review in the country concerned, to make the appropriate applications and to provide evidence of ethical approval having been sought and given.

4.14 Where non-clinical research is being conducted abroad or data is being collected abroad, research will be expected to have received ethical approval from a properly constituted and independent Ethics Committee in the country concerned, where such a committee exists to review the kind of research being proposed, before it can be considered by the College Ethics Committee. If Glasgow University is the only University concerned, the research also requires approval from the College Ethics Committee before it can proceed. It is the responsibility of the researcher to check the requirements for ethical review in the country concerned, to make the appropriate application and to provide evidence of approval having been sought and given.

4.15 Where non-clinical research is being conducted by members of staff or students in more than one University, the research should undergo formal ethical review by and gain approval from a properly constituted and independent Ethics Committee in one of the Universities. The decision on which is the most appropriate University should take into account the University to which the lead investigator belongs and the formal ethical review structures in place in each University. If ethical approval is given by another University, it does not remove the responsibility of researchers at this University for complying with the ethical policies in conducting research adopted by Glasgow University. In particular researchers must ensure that they respect the interests and rights of human subjects involved in the research; that valid consent has been obtained and that the potential information to be gained by the research is not outweighed by any costs to the subject in time, effort, discomfort or potential risk. A copy of any ethical approval obtained from another University must be given to the College Ethics officer and research may not proceed until this is done.

4.16 Where non-clinical research is being conducted by members of staff or students in more than one College in the University, the research should undergo ethical review by only one College. The decision on which is the most appropriate College should take into account the College to which

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the lead investigator belongs and the type of research that is being conducted. This will usually give a good indication where the research should be considered. In case of doubt, College Ethics Officers in the relevant Colleges must be asked for their opinion and reach agreement. A copy of any ethical approval obtained from one Colleges must be sent to the College Ethics Officers in the other Colleges where researchers are based and research may not proceed until this is done.

4.17 Cases which cannot be satisfactorily resolved by the College Ethics Committee must be referred to the University Ethics Committee which will provide advice and guidance to the College Ethics Committee. The College Ethics Committee will then be expected to make a decision on the application. The procedure for referrals is attached as Appendix III.

The University Ethics Committee will not hear appeals from researchers against the decisions of College Ethics Committees until College level remedies have been exhausted. Colleges have a responsibility to ensure that there is an appropriate procedure in place for the consideration of revised or rejected submissions. The University Ethics Committee is particularly concerned with the general principles of natural justice, reasonableness and fairness of the decision made by the College Ethics Committee.

The University Ethics Committee will not hear appeals against the decisions of external ethics committees, which should provide their own appeals procedures.

## 5 Training

5.1 The University Ethics Committee will work with Colleges in sharing best practice through:

- dissemination of best practice
- assisting with organising briefing meetings or workshops
- requesting information and responding to feedback on best practice from Colleges and from external bodies

## 6 Monitoring and Auditing Procedures

6.1 The University Ethics Committee recognises that the definition and perceived significance of ethical problems may be subject to change and differences of opinion. In this light, Colleges, through their designated officers, must conduct an annual review of their position and report to the University Ethics Committee on the management of this aspect of the College's work, indicating, in particular, any suggested or agreed change in procedures. A format for such a report is attached as Appendix IV. The University Ethics Committee will consider these reports, offering advice and recommendations as appropriate and reporting to Senate. The University Ethics Committee will also report to the Senate on any outstanding or anticipated difficulties.

6.2 Where a College has decided that procedures for ethical issues are unnecessary for that College and has had its written statement approved by the Ethics Committee, the designated officer is responsible for keeping the situation under continuous review.

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6.3 Audit of the operation of College ethics procedures will be part of the role of the university Ethics Committee. The University Ethics Committee may request to see the minutes and individual applications at any time and will require a list of all submissions and the decision taken in respect of them as part of the annual report.

7. Failure to follow the University's guidance on ethical review of research may result in disciplinary action. Where a College Ethics Committee or the University Ethics Committee become aware of research being conducted in breach of these policies and procedures or researchers who are not complying with them, in suitable cases the matter may be resolved by informal discussion with the researchers and remedial action being taken by them. However, where necessary either committee may refer the matter to the relevant staff or student disciplinary authorities for further investigation.

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## APPENDIX I

### GUIDANCE FOR COLLEGE PROCEDURES FOR THE CONSIDERATION OF ETHICAL ISSUES ARISING IN RESPECT OF NON-CLINICAL RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN MATERIAL AND DATA

1 The University requires all Colleges

*either*

(a) to maintain procedures for the consideration of ethical issues arising from non-clinical research involving human subjects, human material or data

*or*

(b) to provide a written explanation as to why such procedures are considered to be unnecessary for that Colleges.

2 The University requires all Colleges

*either*

(a) to submit to the University Ethics Committee for approval details of such procedures, and report any suggested or agreed changes to the approved procedures in their annual report to the University Ethics Committee

*or*

(b) to submit to the University Ethics Committee for approval a written statement as to why such procedures are considered to be unnecessary for that College and to keep the situation under continuous review

3. The University requires all Colleges to appoint a designated officer to:

- (a) ensuring that there are effective mechanisms to bring any policy, guidelines or procedures developed with or through the University Ethics Committee and the College Ethics Committee to the attention of staff and students for whom the College is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;
- (b) keeping College ethical issues in research under review;
- (c) managing and monitoring the procedures in practice;
- (d) ensuring that appropriate records of applications, practices and decisions are made and kept;
- (e) reporting to the head of College as appropriate;
- (f) reporting to the College through an appropriate forum;

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- (g) reporting on an annual basis (using the format provided in Appendix IV) on behalf of the College to the University Ethics Committee.
- (h) reporting on behalf of the college to the University Ethics Committee in the event that the latter requires a review of College ethical procedures.
- (i) Membership of the University Ethics Committee. This entails attending meetings of the University Ethics Committee and dealing with the work of that Committee.

4 Colleges that establish procedures for ethical review of research should ensure that their procedures are consistent with best practice in their subject domain and conform with the requirements of any relevant professional bodies. In addition, they should inform the University Ethics Committee of any changes in professional codes that might be of relevance to the broader University research community.

5 The University Ethics Committee recognises that, given that Colleges vary in the type of research undertaken, the ethical issues that will arise will vary considerably. However, there are certain categories of research for which some general guidance can be given. This is set out at Sections 7-8 below, along with the minimum action required of Colleges in each case.

#### 6 Activities which are Subject to Approval by External Bodies

In the case of activities which are subject to

*either*

- (a) approval by a statutory ethics committee

*or*

- (b) approval by the ethics committee of an NHS local health board, multi-centre research ethics committee

the College's designated officer is responsible for the management and monitoring of the procedures for referring research to such committees, for ensuring that there are appropriate mechanisms for ensuring that all staff and students of the College are aware of the need to refer research to these committees, for liaison with these committees as appropriate, and for reporting back to the College and the University Ethics Committee as necessary.

6.2 Where research is subject to approval by external bodies as described above, it shall not be necessary to obtain approval from the College Ethics Committee or University Ethics Committee in addition. However, the fact that ethical approval has been obtained must be notified to the College Ethics Officer who will ensure a record is kept of this approval. Researchers must ensure that they

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act in accordance with the approval given. Any proposed changes in the research must be dealt with by the procedures of the relevant body who gave approval.

## 7 The Involvement of Members of the University and the General Public in Research

7.1 The involvement of members of the University (staff and student) and of members of the general public in research must take place in accordance with routine procedures to protect participants' interests and to highlight ethical conduct. Particular consideration should be given to the recruitment, consent, confidentiality, safety and freedom of participants.

7.3 In respect of such research it is recommended that:

(a) all participants volunteer without inducement and give their written consent to participation. Reasonable expenses may be paid. Exceptionally, small tokens of appreciation for taking part in research may be given, provided they are not deemed to amount to an inappropriate inducement to take part;

(b) written consent is given in the light of full awareness of the objectives of the research, the procedures to be followed, and the anticipated outcomes particularly in respect of publication of findings;

(c) all participants be given a written description by the researcher of their involvement in the project, the demands to be made, their rights and how their rights and interests will be protected, particularly in respect of confidentiality, privacy and safety;

(d) all participants are made aware of their freedom to withdraw consent and discontinue participation at any time;

(d) appropriate documentation be designed to meet these objectives and to keep appropriate records, e.g. information regarding the project should be given in writing and records of the participants' agreement, usually a signed consent form, must be kept.

## 8 The Involvement of Children in Research

8.1 **Where children are involved in research, extreme care should be taken over ethical procedures and explicit authorisation for participation of children should always be obtained from the College Ethics Committee.**

8.2 **The Head of College and the designated ethics officer must ensure that there are appropriate mechanisms to bring to the attention of any staff or students for whom the College is responsible and whose work involves research with children that they must check and comply with any legal requirements, such as vetting procedures, before they proceed with such work. The responsibility for checking and complying with such legal requirements remains that of the researcher and this point must be specifically considered in all research involving children.**

**The University's procedures relating to working with children and other vulnerable groups must be adhered to. The details are available at**

<http://www.gla.ac.uk/services/humanresources/policies/p-z/protectionofvulnerablegroupsscheme/>

## 9 Statement on Confidentiality

The University is committed to rigorous and objective inquiry and supports academics in pursuing their research in an environment that affirms academic freedom. The University also acknowledges the importance of confidentiality as a guiding principle in research.

### 9.1 Duty of Confidentiality

A duty of confidentiality will exist between researchers and their subjects such that confidential information revealed to a researcher can only be disclosed to others if the party if the information has given specific authorisation or the researcher is under a legal obligation to disclose it. In some cases researchers may be under a professional obligation to disclose information to third parties. Whether information is confidential will depend on the circumstances but the key factor is whether or not the provider of the information would have considered it as confidential and would expect it to be treated as such. If the answer to both questions is “yes”, then the duty of confidentiality will arise. The duty also arises when the researcher has volunteered to keep confidential the information and/or the identity of the provider.

As a result of this duty there is a need for researchers to be aware of any circumstances, such as professional codes of practice, that preclude them from being able to give absolute assurances of confidentiality.

### 9.2 Obligations on Researchers:

Undertaken in the light of the above paragraph, researchers shall:

- (a) not convey personally identifiable information obtained in the course of research work to others, except with the express permission of the research subject unless *either* alternative arrangements have been agreed by a research participant (see (b) below) *or* where the researcher is subject to a legal obligation to disclose that information;
- (b) not give unrealistic guarantees of confidentiality and anonymity and be aware that legal challenge may preclude the honouring of such a guarantee. In some circumstances it may be necessary to inform research participants of obligations under law, such as the possibility that the researcher will be required to give evidence or reveal documents, which may make it impossible for certain information to be kept confidential without breaking the law. In other cases, it may be that the researcher’s professional obligations would require the disclosure of information, for example, where the welfare of a child is concerned. In such cases, the research subject needs to be made aware of the possibility of future disclosure in order to be able to decide whether to take part in the research. If the researcher has made it clear that information may be passed on as a result of legal or professional obligations and the subject nevertheless agrees to take part, the researcher may pass on that information even if the subject subsequently objects. However, passing on confidential information without the express permission of the subject is not to be undertaken lightly and legal and professional advice must be sought immediately if this is contemplated;
- (c) where possible, anticipate threats to the confidentiality and anonymity of research data. The identities and research records of those participating in research should be kept confidential whether or not an explicit pledge of confidentiality has been given. Researchers should also



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consider whether it is either necessary or appropriate to record certain kinds of sensitive information;

(d) take appropriate measures to store research data in a secure manner. Researchers should have regard to their obligations under the Data Protection Act 1998 and ensure that appropriate methods for preserving the privacy of data are used and allowing subject access to information where this is required;

(e) take care to prevent data being published or released in a form which would permit the actual or potential identification of research participants. In circumstances where it is difficult to protect the anonymity of informants and research participants, they must be informed of this fact before they are asked to take part or, if the possibility of publication had not arisen at that time, they must be re-contacted and their agreement obtained;

(f) ensure that the designated Ethics Officer is informed of any research proposal that might raise questions about guaranteeing participant confidentiality. If there are significant queries about this matter they should be brought to the University Ethics Committee for consideration and guidance;

(g) ensure that data collected is used only for legitimate academic purposes;

(h) be aware of the need to limit the University's potential liability in the event of a breach of confidentiality.

10. Failure to follow the University's guidance on ethical review of research may result in disciplinary action. Where a College Ethics Committee or the University Ethics Committee become aware of research being conducted in breach of these policies and procedures or researchers who are not complying with them, in suitable cases the matter may be resolved by informal discussion with the researchers and remedial action being taken by them. However, where necessary either committee may refer the matter to the relevant disciplinary authorities for further investigation.

## **APPENDIX II**

### **GUIDANCE FOR THE ESTABLISHMENT AND OPERATION OF COLLEGE ETHICS COMMITTEES**

1 A College Ethics Committee must be established to consider, approve or otherwise issue guidance on non-clinical research involving human subjects, human material or data. Given the potentially sensitive nature of such research, it is imperative that College Ethics Committees have an established membership and terms of reference, and operate in strict accordance with approved written procedures. All College Committees are sub-committees of the University Ethics Committee.

2 Research involving non-clinical research with human subjects, human material or data should normally require the explicit approval by the relevant College Ethics Committee. Where children are involved, explicit approval of their participation should always be obtained. (See Appendix I, section 8 for guidance on this matter).

#### 3 Membership

3.1 A College ethics committee should have no fewer than six members, one of whom shall be the College designated officer. Given the need to ensure that the ethics committee is impartial, it is expected that at least one member must be a person from outside the College, preferably from outside the University. To be quorate, College Ethics Committee must have four members present. It is recommended that "reserve" members are able to be appointed to act in respect of proposals put forward by members of the committee, since those involved in a research submission must withdraw from the Committee while the submission is considered. In Colleges where research regularly involves taking of body material samples or research where there may be a risk to the participant's health a registered medical practitioner must be a member of the Committee. In all research involving taking body material samples or where there may be a risk to the participant's health an opinion on the research must be obtained from an appropriately qualified medical practitioner, generally a registered medical practitioner.

3.2 Membership of the College Ethics Committee shall be approved by a College Meeting (or equivalent).

#### 4 Terms of Reference

4.1 The College Ethics Committee's terms of reference should normally include the following:

- (a) to consider non-clinical research proposals (from both the College's staff and its students) involving human subjects, human material and data;
- (b) to either give written approval for such proposals in the form of minutes or provide written information as to why approval has not been given;
- (c) to consider revised submissions;

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- (d) to refer to the University Ethics Committee cases which cannot be satisfactorily resolved or about which there is uncertainty;
- (e) to operate procedures no less rigorous than those suggested or required by relevant professional bodies.
- (f) to inform the University Ethics Committee of any changes in the ethical codes of professional bodies in relevant discipline areas, in order that the University's procedures remain valid.

4.2 Details of the committee's terms of reference, membership and internal College reporting procedures must be submitted to the University Ethics Committee for approval.

## 5 Procedures

5.1 The College Ethics Committee should provide written information about its procedures and terms of reference for all relevant members of the College, and should carry out their work in accordance with those procedures. The College Ethics Officer should ensure that the College is fully aware of the ethical requirements of the College.

5.2 The College Ethics Committee should specify the format in which research proposals are to be presented for its consideration. As a minimum, proposals should incorporate the following information:

- (a) the title of the research project, the statement on research procedures to be undertaken;
- (b) full details of arrangements for participation of subjects including recruitment, consent and confidentiality procedures and copies of all documentation to be given to participants (such as information sheets and consent forms);
- (c) details of intentions in respect of the publication of findings;
- (d) any additional considerations, for example where research involves children.

5.3 Full records of the decisions of the College Ethics Committee should be minuted and the records should be kept by the Ethics officer.

5.4 The frequency and timing of meetings of the ethics committee will be determined by the reasonable requirements of the College. Where relevant research proposals are put forward on a regular basis, meetings should be time-tabled in advance and the dates circulated. Where ethical issues arise infrequently, the College Ethics Committee should be prepared to meet on an ad hoc basis.

Any applicants for project approval (or their supervisors) should withdraw from the ethics committee meeting when their cases are discussed and should not take part in any decision on the application.

5.5 The ethics committee should advise applicants on the revision of proposals and should have a procedure for the consideration of revised submissions. The ethics committee should have procedures for considering appeals against decisions of that committee.

5.6 These Guidelines apply to School committees set up in line with section 4.7 of the main guidance above (p8). School committees report to the College Ethics Committee.

## **APPENDIX III**

### **UNIVERSITY ETHICS COMMITTEE: REFERRALS BY COLLEGES**

1 The primary purpose of the University Ethics Committee is to issue general advice and guidance to Colleges on ethical issues arising from non-clinical research. The Committee has a responsibility to approve College procedures and to consider annual reports from Colleges on the management of ethical issues in research. Decisions in respect of research with ethical implications will normally be made by the College concerned, unless it is subject to approval by an external body (for example, by the ethics committee of a local health board or multi-centre research ethics committee).

#### 2 Referrals

2.1 The University Ethics Committee (UEC) will consider and give guidance on applications that cannot be satisfactorily resolved at the College level and on matters which require specific consideration due to the implications they may have for broader University activities. Referral of research applications to the UEC is the responsibility of the College Ethics Committee.

2.2 In respect of referrals the following shall apply:

- (a) The UEC will expect to receive a written statement of specific issues for advice or guidance, supported by the papers considered by the College Ethics Committee. The UEC will also expect a summary of the reasons for doubt or disagreement on each specific issue.
- (b) The Committee will, if necessary invite for discussion members of the College. The UEC Committee may also request attendance of the proposers of a research application and any member of staff involved in reviewing the application.
- (c) The UEC shall seek advice as appropriate and give guidance based on the information made available to it.
- (d) The procedures of the UEC shall be publicly available in writing.
- (e) The discussions of the UEC shall be strictly confidential, subject to legal data protection requirements.
- (f) The guidance given shall be recorded in writing and sent to the College Ethics Committee.

2.3 The University Ethics Committee will give guidance to the College Ethics Committee but it remains the responsibility of the College Ethics Committee to make a decision on the research application and to notify the researchers of the progress of the application and the outcome of review.

#### 3 Appeals

3.1 The University Ethics Committee will consider appeals from College Ethics Committee on the following matters:

- (a) Questions that arise out of applications for ethical approval that have broader implications for the University and therefore require a deeper consideration.
- (b) Appeals against decisions made by College Ethics Committees, but only once the local procedure for resolving difficulties has been exhausted.

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## **APPENDIX IV**

### **ANNUAL REPORTS BY COLLEGES TO THE UNIVERSITY ETHICS COMMITTEE**

1 Each College, through its designated officer(s), must conduct an annual review of its position in respect of ethical issues in non-clinical research and report to the University Ethics Committee on an annual basis.

2 It is expected that the annual reports to the University Ethics Committee will include the following:

- (a) Details of any suggested or agreed changes to the approved procedures;
- (b) Summary of action taken by the College Ethics Committee including details of the number and title of applications considered (staff and student), the decision taken and any particular difficulties encountered or consequent action taken;
- (c) Where appropriate, the number of cases referred to external ethics committees;
- (d) Any issues for consideration by the University Ethics Committee.

3 The Ethics Committee will consider the annual reports, offer advice and recommendation as appropriate, and report to Senate on any outstanding difficulties.

4 A pro forma for reports will be provided. (See Annex 1)

## **APPENDIX V**

### **THE CONSTITUTION AND OPERATION OF THE UNIVERSITY ETHICS COMMITTEE**

1 The Glasgow University Ethics Committee (UEC) has been established by Senate and is charged with sustaining a University-wide awareness of ethical issues arising from non-clinical research involving human subjects, human material and data.

2 Terms of Reference

2.1 The UEC is concerned to protect:

- the dignity, human rights, health, safety and privacy of research subjects
- the health and safety of researchers
- the reputation of the University as a centre for properly conducted and high quality research.

Taking full account of these issues, the Committee aims to ensure as far as possible that the methodology of proposed research carried out by or on behalf of the University respects the interests and rights of human subjects involved in the research; that valid consent has been obtained and that the potential information to be gained by the research is not outweighed by any costs to the subject in time, effort, discomfort or potential risk.

The Committee is also available to assist researchers in exploring potential ethical issues which may arise as a result of a proposed project.

2.2 The Committee produces guidelines for the conduct of non-clinical research and ensures that all Colleges and units linked to them either have in place proper procedures for the consideration and conduct of such research or provide a written explanation as to why such procedures are considered to be unnecessary for them. The University Ethics Committee also considers and gives guidance on research referred to it from Colleges and hears appeals on decisions made by Colleges. In exceptional cases the University Ethics Committee may itself make decisions on research referred to it from Colleges.

#### Responsibilities of the University Ethics Committee

2.1 The responsibilities of the University Ethics Committee in respect of Colleges and College procedures for ethical review of research are as follows:

- (a) to develop policy and guidelines for and with Colleges;
- (b) to approve College procedures or statements;
- (c) to assist with the provision of appropriate training for College officers with specific responsibility for ethical review of research;

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(d) to consider and offer guidance on cases of uncertainty and to hear appeals against College decisions. In exceptional cases the University Ethics Committee may itself make decisions on research referred to it from Colleges;

(e) to consider annual reports from Colleges on the management of ethical issues in research, offering advice and making recommendations as appropriate on the operation of College-level procedures;

(f) to make an annual report to Senate on the operation of procedures for ethical review of research with the University;

(g) to report to Senate on any outstanding difficulties in respect of ethical review of research;

(h) to seek clarification from external expert bodies, as necessary, on matters of ethical review policy and practice

(i) to refer university students or staff through the University's research misconduct and/or disciplinary procedures if issues of concern arise from any aspect of the conduct of research

### 3 Membership

#### 3.1 The University Ethics Committee comprises

- Convener
- A lay member from outwith the University
- The SRC President or nominee
- The College Ethics Officers and deputies where applicable.

3.2 To be quorate, meetings of the University Ethics Committee must have six members present. Those involved in a research submission must withdraw from the Committee while the submission is considered, although they may attend if requested to give further information about the submission.

3.3 The term of office for members of the University Ethics Committee shall normally be three years with the possibility of a three year extension.

### 4 General Procedures

4.1 The frequency and timing of meetings of the ethics committee will be determined by the reasonable requirements of the University. The Committee shall meet no less than twice termly. These meetings will be time-tabled in advance and the dates circulated.

Where, ethical issues arise in circumstances where they cannot be considered at the next ordinary meeting, the University Ethics Committee may meet on an ad hoc basis. In exceptional circumstances when, for good reason, issues needing more rapid consideration arise, the Convener may act after consultation with no less than two other members of the UEC who are not members of the College or Colleges concerned. The Committee shall be immediately informed of decisions made on this basis. In addition, in order to facilitate the conduct of business, issues may be considered by the Committee by correspondence.

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4.2 If a member of the Committee is not able to attend the meeting he or she may submit written observations on any issue under consideration. Colleges may also nominate a substitute from the College Ethics Committee to attend a meeting which the College ethics officer is unable to attend.

4.3 The Convenor is empowered to make decisions in respect of the administration of the Committee, such as calling meetings of the Committee.

4.4 The discussions of the UEC shall be strictly confidential, subject to legal data protection requirements

4.5 Decisions should ideally be by consensus. Where agreement cannot be reached, decisions are by majority on a show of hands and in cases of equal votes, the Convenor shall have the casting vote.

4.6 The UEC and its Convenor are empowered to take advice when required from Senior University Officers, the University's Solicitors and any person within or outside the University with specialist knowledge on the issues in question.

4.7 The UEC shall be permitted to co-opt specialists to advise its members.

4.8 Full records of the decisions of the University Ethics Committee will be minuted and kept by the Clerk to the Committee.

## 5 Referrals

5.1 The University Ethics Committee (UEC) will consider and give guidance on applications that cannot be satisfactorily resolved at the College level and on matters which require specific consideration due to the implications they may have for broader University activities. Referral of research applications to the UEC is the responsibility of the College Ethics Committee.

5.2 In respect of referrals the following shall apply:

- (a) The UEC will expect to receive a written statement of specific issues for advice or guidance, supported by the papers considered by the College Ethics Committee. The UEC will also expect a summary of the reasons for doubt or disagreement on each specific issue.
- (f) The Committee will, if necessary invite for discussion members of the College. The UEC Committee may also request attendance of the proposers of a research application and any member of staff involved in reviewing the application.
- (g) The UEC shall seek advice as appropriate and give guidance based on the information made available to it.
- (h) The procedures of the UEC shall be publicly available in writing.
- (i) The discussions of the UEC shall be strictly confidential, subject to legal data protection requirements.
- (f) The guidance given shall be recorded in writing and sent to the College Ethics Committee.



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5.3 The University Ethics Committee will give guidance to the College Ethics Committee but it remains the responsibility of the College Ethics Committee to make a decision on the research application and to notify the researchers of the progress of the application and the outcome of review.

## 6 Appeals

6.1 The University Ethics Committee will consider appeals from College Ethics Committee on the following matters:

- (a) Questions that arise out of applications for ethical approval that have broader implications for the University and therefore require a deeper consideration.
- (b) Appeals against decisions made by College Ethics Committees, but only once the local procedure for resolving difficulties has been exhausted.

## 7. Clinical Research

In exceptional circumstances the University Ethics Committee will look at proposals concerning clinical research where it does not fall within the remit of an NHS Research Ethics Committees. It may refer particular aspects of the research to those with appropriate, particularly clinical, expertise in the area. Research of this kind will be expected to have received ethical approval from a properly constituted and independent Ethics Committee in the country concerned before it can be considered by the UEC. However, it also requires approval from the UEC before it can proceed.

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## ANNEX 1



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of Glasgow

### TEMPLATE

#### ANNUAL REVIEW OF COLLEGE ETHICS PROCEDURES FOR [YEAR]

College:

Name of College Ethics Officer:

(1) Please attach the Terms of Reference, procedures and membership of the College Ethics Committee.

#### (2) REVIEW OF PROCEDURES OVER PAST YEAR

(a) Have you amended or considered amending your ethics procedures in the light of specific cases that have arisen at the College / School level during this period (yes / no)?

If yes, how?

(b) Have you made amendments to your procedures in the light of University level guidance (yes/no)?

If yes, how?

(c) Have you made amendments to your procedures in the light of guidance within your discipline and/or relevant professional Group (yes/no)?

If yes, please outline these changes.

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(3) Please provide two examples illustrating that decisions made by the College Ethics Committee have been acted upon **(and attach all relevant supporting documents including forms and details of the decision making process including emails, letters etc)**

(4) Please provide a summary of issues that you have placed before the University Ethics Committee for consideration. (Please comment about any matters arising out of decisions of the University Ethics Committee).

(5) Are there any comments you wish to make about Ethical policy and procedure at the University of Glasgow?

Signed-----  
Date-----

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## **ANNEXE II**

### **TEMPLATE FOR INFORMATION TO BE PROVIDED BY COLLEGES TO STUDENTS AND STAFF**

#### **Ethical Approval of Research with Human Subjects, Material or Data within the College of X at Glasgow University**

Scope of the Guidance

##### **Who does it apply to?**

This guidance applies to all staff and students in the College of X undertaking research in their capacity as members of the University of Glasgow.

In the case of students, it covers research undertaken by a student currently registered for a degree within the College as a recognised part of his or her degree programme. However, it does not cover work carried out as part of the teaching of the programme, for example, students conducting established experiments as part of their learning, or course monitoring questionnaires. Ethical issues in respect of such matters continue to be dealt with through College teaching committees and the Senate Education Committee.

In respect of non-student research, the University policy of review of non-clinical research applies to individuals carrying out research for the University including, without limitation, all University employees, irrespective of whether their current place of work is within or outside University premises and all visiting researchers of the University irrespective of whether they are employed by the University, including persons with honorary positions, conducting research within, or on behalf of, the University.

##### **What research does it cover?**

This guidance covers all research involving human participants or human data or material. It applies whether the research is funded or not and whatever the source of funding. The ethical review process does not include research where the information about human subjects is publicly and lawfully available, e.g. information published in the census, population statistics published by government departments; personal letters, diaries etc held in public libraries.

##### **Background**

Previous procedures for ethical review of research in College X.

In 2002, following a review of the existing University procedures for considering research, it was decided by Senate that a more consistent approach should be adopted throughout the University. From October 2002 the University requires that all research involving human participants or human data or material is subject to formal ethical review.

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### **Scope of Research involving Human Subjects, Material and Data in the College X**

[Outline of the types of research carried out by the College]

1. The College conducts research which involves healthy volunteers who may be adults or children. Research may also be undertaken on tissue or fluid samples taken from healthy volunteers. Surveys and questionnaires on issues such as lifestyle, housing and working environments, attitudes and preferences may also form part or the whole of research projects.
2. Research may be undertaken by undergraduate or postgraduate students as part of their degree work. It may also be undertaken by members of staff either as part of individual or team research work within the University or as externally contracted or funded work.

### **Outline Procedures for Considering Ethical Issues**

#### **COLLEGE ETHICS OFFICER**

The College of X has designated an officer responsible for the management of ethical issues in research in the College. The responsibilities of the Ethics Officer are as follows:

- (a) ensuring that there are effective mechanisms to bring any policy, guidelines or procedures developed with or through the University Ethics Committee and the College Ethics Committee to the attention of staff and students for whom the College is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;
- (b) keeping College ethical issues in research under review;
- (c) managing and monitoring the procedures in practice;
- (d) ensuring that appropriate records of applications, practices and decisions are made and kept;
- (e) reporting to the Head of College as appropriate;
- (f) reporting to the College through an appropriate forum;
- (g) reporting on an annual basis (using the format provided in Appendix IV) on behalf of the College to the University Ethics Committee.
- (h) Membership of the University Ethics Committee. This entails attending meetings of the University Ethics Committee and dealing with the work of that Committee.

The contact details for the Ethics Officer are given below.

#### **COLLEGE ETHICS COMMITTEE**

A College Ethics Committee has been established to advise on ethical issues in research in the College and to assess for approval research proposals involving the issues outlined above.

#### **Constitution and Membership of the College Ethics Committee**

Number of members (no less than six), any specific reason for appointment (e.g. as lay members, medical qualification), number for meeting to be quorate (no less than four).

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### Terms of Reference

The College Ethics Committee's terms of reference are:

- (a) to consider non-clinical research proposals (from both the College's staff and its students) involving human subjects, human material and data;
- (b) to either give written approval for such proposals in the form of minutes or provide written information as to why approval has not been given;
- (c) to consider revised submissions;
- (d) to refer to the University Ethics Committee cases which cannot be satisfactorily resolved or about which there is uncertainty;
- (e) to operate procedures no less rigorous than those suggested or required by relevant professional bodies.
- (f) to inform the University Ethics Committee of any changes in the ethical codes of professional bodies in relevant discipline areas, in order that the University's procedures remain valid.

### Application Procedure

The procedures for considering these ethical issues are as follows:

1. Research proposals involving volunteer subjects will be submitted to the College X Ethics Committee through the designated Ethics Officer.
2. The College Ethics Committee will specify the format in which proposals should be submitted. Much of the information will be entered onto a proforma although additional information may be required. (See Appendix A)
3. The College Committee will consider the application in accordance with the procedures set out Appendix A. They will inform the applicant of the decision and any amendments that need to be made or reasons for not giving approval of the research.
4. If the research application has not been approved by College Ethics Committee this decision may be appealed to the University Ethics Committee.
5. The University Ethics Committee hearing the application either as the initial review body or on appeal will follow the procedures set out in the document Constitution and Operation of the University Ethics Committee.

### Operating Procedures

How decisions are made e.g. after discussion and by consensus or majority vote with the Convenor having the casting vote.

### Members of the College Research Ethics Committee

Names, title, School, contact numbers

Ethics Officer

### Contact

Who to contact in the College - To submit applications to

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To seek further information/advice

Timing of the College Meetings

Dates, times, venues

Timing of application of submissions to the College Committee

Dates by which applications must be submitted in order to be considered at the next meeting.

Procedures (if any) to deal with applications between meetings.

Whether the convenor along with other members of the Committee will be able to consider applications in between meetings and on what grounds. Whether business may be conducted through correspondence as well as by formal meetings.

Links to College specific guidance – e.g. RCP for psychology

**Links to general guidance on research ethics**

Link to University Ethics Committee

(Appendix A below)

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## **APPENDIX A**

### **INFORMATION FOR APPLICANTS ON ETHICS COMMITTEE SUBMISSIONS IN COLLEGE X**

#### **Introduction**

Before you can start any research project involving human participants, material or data in the College, you have to get approval from the Ethics Committee. This is a group of people within the College who meet at regular intervals to discuss research submissions and to decide whether to allow the research to proceed. Our terms of reference are simple: to receive research proposals from students and staff of the College and to consider any ethical issues that might arise from the execution of this research.

We can make three main kinds of decision on the proposal. Either the project is approved as it stands, or it is accepted subject to specified alterations, or it is rejected. You will receive a letter as soon as possible after a decision has been made telling you what we have decided and (if relevant) why we have made the decision and what you now have to do. Please note, if your project is approved subject to specified alterations, you may NOT proceed to start the research until these changes have been approved by the Convenor.

In all cases (whether your submission is approved immediately or following revisions), **please make sure you retain your Ethics approval letter**. You will be asked to include it with your project (not in the form of an Appendix, but loose inside the front cover, so that it can be checked for approval, and then removed to ensure anonymity for the marking phase).

The Committee consists of a Convenor and [x] members. We meet [x] times during term but consider individual applications during vacations. The Committee will post a notice at the beginning of the academic year, detailing the last dates for submission for consideration. All undergraduates and any postgraduate must get approval before starting work. Staff must also submit their own research plans for ethical consideration, whether the work is funded or unfunded, if the research is being carried out in their capacity as members of University staff or using University facilities. The University policy of review of non-clinical research applies to everyone carrying out research for the University including all University employees, whether their current place of work is within or outside University premises. It also applies to all visiting researchers of the University whether or not they are employed by the University, including persons with honorary positions, conducting research within, or on behalf of, the University.

#### **How the Committee decides**

We are guided by [any professional Code of Conduct. Copies of this document are available for consultation/ on the website]. In addition we are guided by general principles of ethical research with human subjects [link to University Ethics Committee site and references there].



### **Working with people**

We want to know that the safety and wellbeing of research subjects is assured, that the applicant is aware of any possible ethical issues in carrying out the research and that steps have been taken to ensure that best practice is followed. We also draw your attention to the section below entitled 'recruiting participants'. It is very important that people are aware that you respect their confidentiality and that, where possible, rigorous steps will be taken to preserve anonymity (such as the use of double-blind techniques).

### **Working with children**

You must satisfy yourself that there is a need to involve children and be able to justify this to the Committee. You should ensure that you have familiarised yourself with the relevant legal position, where it is intended to conduct research with children.

Those applicants who intend to work with children in schools must obtain written approval from the Head, the Local Education Authority or other person who is *in loco parentis*. The method of informing and, where appropriate, obtaining consent from parents to their child's participation must be clearly explained and agreed with the Head of the School and must follow best practice in this regard. You must check and comply with any legal requirements, such as vetting procedures for working with children, before you proceed with such work. The responsibility for checking and complying with such legal requirements is yours.

Where consent is given by parents it is still important to try and obtain real consent from the child; assuming the child is old enough to understand this principle. For older children, they would normally be expected to give their signed agreement to take part in the same way as adults. Even where children are younger, where the child is capable of understanding, the researcher should explain to the child that what they are doing is entirely voluntary and that they can refuse to take part if they wish.

### **Working with potentially vulnerable adults**

You must satisfy yourself that there is a need to involve potentially vulnerable adults, for example those with severe learning disabilities, and be able to justify this to the Committee. You should ensure that you have familiarised yourself with the relevant legal position, where it is intended to conduct research with adults who may not be able to give a legally valid consent to take part in research.

Where the proposed research subject is in a dependent relationship to the researcher (for example, where the research subject is a student) the researcher must make it clear that a decision to take part or not to take part in the project will in no way affect the individual's relationship with the researcher and the researcher must ensure that this is the case.

### **Recruiting participants**

The doctrine of valid consent operates here. That is, participants should enter into the research freely and willingly and know and understand what they are agreeing to when they take part. They should be told they have the right to withdraw from the research at any time. Wherever possible,

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anonymity and confidentiality should be maintained. If the experimental design necessitates some deliberate deception then participants should be told the purpose of the experiment and why information was withheld or why they were misled after the experiment is finished.

### **Electronic Recruiting**

On the question of recruiting participants via e-mail and the Web ('electronic recruiting') we have decided that (a) in principle we see no reason to veto this method (b) we anticipate potential problems where the computer network would be overloaded (c) the number of electronic recruiting proposals should be carefully monitored.

Electronic recruiting is acceptable within the following limitations:

- The University's Policy on Student Surveys must be adhered to. The Policy is available from <http://www.gla.ac.uk/services/senateoffice/academic/studentpolicies/policy/>
- Any mailing to an identifiable group of people (e.g. to all of the students in a College or a class) should be brief and succinctly explain the nature of the research and the criteria for participation.
- Clear indication that this is a request for help from a researcher should be given at the beginning and that the reader, if not interested, should 'hit the delete button'.
- If the reader of the e-mail is interested in participating then he or she should be asked to contact the researcher directly (not a group reply), or referred to a Web page where the research information is located.
- Under no circumstances should University Office telephone numbers be given as contacts for student research. Under no circumstances should file attachments to group messages be used.
- The GU postmaster must be asked for permission to send e-mails to group addresses. As well as complying with data protection principles this will also provide a means of monitoring the use of email across campus for research of this kind.

The researcher should check that they are complying with data protection principles in the use of personal information.

### **Issues to Consider when Providing Information to Potential Participants**

By far the greatest number of amendments that Ethics Committees ask to be made concern the information that will be given to participants. You must take time over this aspect as it is essential to explain what you are asking people to do and the possible implications so that they can make a proper decision for themselves whether they wish to take part.

You must clearly explain the following matters in terms that an ordinary person, rather than a specialist in your field, can understand:

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- that you are inviting them to take part in a research project
- who you are – a student/your post in the University and, where relevant, your experience in conducting research of this kind
- the nature, risks (if any), benefits (if any), duration and purpose of the research project. This must include clear information about what the subject will be asked to do, where the research will be carried out, any risks to the subject's health and safety and the steps that will be taken to minimise those risks
- that participation in the project is entirely voluntary
- if the project is funded (and if so, by whom)
- if the research project is part of a student's coursework
- what the information gathered is intended to be used for including whether it is intended to publish the results
- the arrangements concerning confidentiality of and access to information about the research subject
- what, if any, arrangements are in place for compensation in the event of an something going wrong
- how the research subject can obtain further information about the project (such as by the provision of work contact numbers/email for the researcher. Home contact numbers should not be given nor should university office numbers be given where the researcher is a student.)
- whom the research subject can contact if they are concerned about any aspect of how the research was conducted. This should not be you or your research supervisor. It will normally be the head of Section or School.

If participation in a research project is likely to be of no direct benefit to the subjects, you should explain this in the information sheet

You should give the research subject a copy of the information sheet to keep.

### **Consent Forms**

It would normally be expected that proposed research subjects would be asked to give their agreement in writing on a consent form. Ideally, the information sheet should be separate from the consent form and the Committee will wish to receive a copy of both. You should ensure that, before written consent is given, the proposed subject has been given the opportunity of reading the information sheet and asking questions about the research. For this reason, sufficient time must be

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provided between the request to take part and the signing of the document. Subjects' signatures do not normally need to be witnessed.

Exceptionally, it may be unnecessary or inappropriate to seek written consent although this will need to be clearly justified to the Committee. For example, in cases where you are, for example, handing out questionnaires that do not ask probing questions and it is clear from the front sheet what is going to be asked then we can assume that the act of accepting the questionnaire implies consent by the respondent. There may be other situations too where provision of an information sheet would be sufficient.

Where, for good reason, written consent is not sought, you must still ensure that you give proposed research subjects sufficient time to read the information about the research and ask questions.

In most cases however, you will have to supply us with a consent form.

### **Confidentiality of information obtained during research**

You must familiarise yourself and comply with current legal requirements for storage of and access to data about research subjects. You must consider the method of keeping personal data about research subjects and how to anonymise information about them, where appropriate.

You are referred to the guidance on confidentiality given in the document Procedures for University Colleges in Respect of Non-Clinical Research Involving Human Subjects, Human Material and Data.

### **Payment to Research Subjects**

If people taking part in your research are to be offered any payment or incentive to do so over and above appropriate expenses, you must explain this in your application. Any form of payment or incentive to take part will need to be clearly justified to the Committee.

Exceptionally, small tokens of appreciation for taking part in research or small prizes may be given, provided they are not deemed to amount to an inappropriate inducement to take part.

### **What happens if I want to publish the research?**

There are ethical issues involved in respect of publishing research.

You must tell the proposed research subject in advance if you have any intention of publishing the results of the project. You must also explain the extent to which, if at all, any identifying information about the research subject will appear in the publication. If identifying information about the research subject is intended to be published, you must obtain and keep specific written agreement to this from the research subject. Preferably these issues should be addressed in the information sheet and consent form that are given out before the research starts. This will prevent any disappointment if the individual, when asked later, chooses not to agree and therefore reduces the value of the information that can be published.

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In most cases you will not be the only person with an interest in publishing the results. Research is a collaborative activity and, in the case of student work, supervisors may expect to claim some contribution.

### **Informing Research Subjects of Results of Research**

You are encouraged to consider the issue of informing research subjects of the results of the research or where they may be able to get access to this information, although research subjects may not be able to be given their individual results. Taking part in non-clinical research is a voluntary matter requiring good will on the part of the community and it is appropriate for research subjects to be able to receive feedback on research they have been involved in where this is possible.

### **Making an application to the College Ethics Committee**

There are five stages in preparing an application to the Ethics Committee. These are:

1. Discuss any ethical issues you have about the conduct of your research with your co-investigator(s) and/or supervisor(s).
2. Prepare your submission. Use the proforma provided by College for your submission
3. Append all ALL required documents.
4. Sign and date the form and ask any co-investigator / supervisor to sign. Unsigned submissions will not be considered. (This may not be applicable if there is an electronic submissions system)
5. Submit TWO copies of your application in time for the deadline for the next meeting of the Ethics Committee.

### **Late submissions**

Please note that submissions that are received late will NOT be considered until the next meeting of the Committee, save in the most exceptional circumstances. Delay in starting research will not normally be accepted as an exceptional circumstance.

It is the applicant's responsibility to submit applications timeously and in the proper format. It is the responsibility of a student's first named supervisor to draw the student's attention to these procedures.

### **The College Ethics Committee Meeting**

The Committee does not normally interview the researcher or request their attendance when the proposal is considered, although it may invite the researcher to attend if it is believed this would assist the Committee. Researchers may also request the opportunity to address the Committee. Members of the Committee must withdraw from consideration of any submission in which they are researchers or supervisors.

### **Powers of the College Ethics Committee**

The Committee may:

- authorise the research to proceed without requiring any amendment. Any such authorisation is granted on the basis of the project as stated on the research submission.

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Any changes must be notified to the Committee (see below) and normally approval obtained before proceeding.

- require clarification or modification of parts of the research submission. The Convenor will generally be granted the authority to approve the amendments without requiring to call a further meeting of the full Committee.
- defer consideration of a proposal to a subsequent meeting if substantial modifications are required or where significant additional information is required
- reject the research proposal in whole or in part
- revoke approval of the research if dissatisfied with the conduct of the research or of the researchers
- refer university students or staff through the University's disciplinary procedures if issues of concern arise from the research

As part of their assistance to researchers, the Committee will ordinarily give reasons for requiring modification to proposals, rejecting them or for revoking approval.

The Committee may call for reports on the conduct of the research during projects and on completion to help the Committee in formulating its guidance and so that the Committee can be assured that projects continue to conform to approved ethical standards. This will not in any way reduce the responsibility of the researcher to ensure such conformity.

The Committee will maintain a record of all proposed research projects, and may require a formal report on completion of the project in order to review the outcome of the research and its contribution to knowledge.

### **Appeals**

If you are dissatisfied with the decision made by the College Ethics Committee you should in the first instance discuss this with the Ethics Officer. If discussion is unable to resolve the issue satisfactorily an appeal from the decision of the College Ethics Committee may be made to the University Ethics Committee. However, it should be noted that the University Ethics Committee will not normally interfere with a College Ethics Committee decision to require revisions to the project, such to amend an information sheet or consent form. The University Ethics Committee is concerned with the general principles of natural justice, reasonableness and fairness of the decision made by the College Ethics Committee.

### **Consideration of the application by the University Ethics Committee**

The University Ethics Committee will provide general advice to the College Ethics Committee and will refer the matter back to them with that advice for them to make a decision. In such cases, to avoid additional delay to the applicant, the College Ethics Committee may consider the application between meetings if necessary.