

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

PROCEDURES FOR UNIVERSITY FACULTIES

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 Faculties 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 Faculty. In exceptional instances the UEC will also consider and give guidance upon specific cases, or other matters referred to it by Faculty Ethics Committees, including appeals from decisions of Faculty Ethics Committees.

1.2 This paper:

(a) sets out the nature of some of the ethical issues which might face University Faculties in research and raises questions for faculties 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 Faculties and the University Ethics Committee.

1.3 Within this paper the term "Faculty" is used as shorthand for University units and should be taken to include academic Faculties, institutes and inter-Faculty centres of the University. Centres and Institutes are expected to ensure applications for ethical review of research are dealt with through the procedures of the Faculty to which they are cognate or linked.

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" 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 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 in Scotland 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 Faculties have the responsibility for ensuring that:

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

3. Faculties

3.1 Faculties vary widely in the scope and significance of the ethical issues affecting their work. Some Faculties regularly engage in research that requires the approval of an NHS ethics committee. Some Faculties have significant numbers of research students whose studies involve human

subjects. Some Faculties house research projects involving the recruitment of people as subjects of research. Other Faculties may not engage in any of these activities.

3.2 Each Faculty 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 Faculty 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 Faculty is expected or required to observe?
- (g) Does research within the Faculty 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 Faculty 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 Senate has decided that all Faculties 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 Faculty. It is the responsibility of the UEC to approve all Faculty procedures or written explanations.

4.2 The scale of a Faculty's procedures will be determined by the extent to which ethical issues are raised and their frequency. Where a Faculty's work rarely (if at all) raises ethical issues, a complex procedure would clearly be inappropriate and the Faculty 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 Faculty 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 Faculty.

4.3 Taking into account the matters described in 3.2, each Faculty 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. Guidelines for Faculty procedures are attached as

Appendix I. A template that can be adapted by Faculties for their own use is set out in the document “Template for Faculties”.

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 Faculty 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 Faculty teaching committees and the Senate Education Committee

4.5 Each Faculty must appoint an officer with specific responsibility for the management of ethical issues raised by the research work of the Faculty. 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 Faculty Ethics Committee to the attention of staff and students for whom the Faculty is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;
- (b) keeping Faculty 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 Dean of Faculty as appropriate;
- (f) reporting to the Faculty through an appropriate forum;
- (g) reporting on an annual basis (using the format provided in Appendix IV) on behalf of the Faculty to the University Ethics Committee.
- (h) conducting a three yearly review of Faculty ethical procedures and reporting on behalf of the Faculty to the University Ethics Committee.
- (i) 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 Faculty 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.

Recent surveys of current practice in the University have indicated that some Faculties already have procedures or bodies to consider ethical issues in non-clinical research. It is expected that these Faculties should be able to implement this guidance with little difficulty. Other Faculties may not have formal procedures in place and the University Ethics Committee will be happy to provide any additional assistance necessary to them in implementing the University's policy and guidelines.

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

4.7 It is expected that Faculties will normally have a single ethics committee to deal with ethical review of research. Any Faculty wishing to establish or continue Ethics Committees at School or Department level must make the case for doing so to the University Ethics Committee and have this approved.

If there are exceptional reasons for establishing Ethics Committees at School or Department level, these Ethics Committees are expected to have the same responsibilities as Ethics Committees at Faculty level, save that instead of reporting directly to the University Ethics Committee they will report to Faculty. So, for example, the School or Department will appoint an Ethics officer and an Ethics Committee with the general constitution and responsibilities outlined in this document for Faculties.

It should be noted that Faculties who chose to adopt this structure will still be required to appoint an Ethics officer with responsibilities for the Faculty who will report to the University Ethics Committee and co-ordinate the ethical review of research for the Faculty. Since ordinarily the Faculty Ethics Committee would be a sub-committee of the University Ethics Committee, it may be appropriate for a Faculty level committee to be established in addition to the School Committees, including the School Ethics officers, since Faculty retains overall responsibility for ensuring the appropriate ethical review of its research.

4.8 Faculties 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. (See Appendix I).

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. Faculties must either incorporate responsibility for ethical issues into the terms of reference of an existing Faculty ethics committee or set up a separate Faculty Ethics Committee with explicit membership, terms of reference and operating procedures. Guidelines on these matters are attached as Appendix II. A Faculty Ethics Committee should vet and approve or otherwise give feedback on all student and staff research proposals.

4.10 Research work should not proceed without explicit, written approval. Copies of the formal written approval must also be retained by Faculty. Reference to a project having received "Ethics

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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 Faculties. In such cases it would be necessary for the Faculty to ensure that treatment was comprehensive (i.e. all relevant proposals were taken to the appropriate committee) and that the Faculty, through its designated officer, played an active role in reviewing procedures and managing the link between the Faculty 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.

The following types of research must be referred to a NHS research ethics committee: research involving

a. patients and users of the NHS. This is intended to mean 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. fetal 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

g. NHS staff recruited as research participants by virtue of their professional role.

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. In cases of doubt, applicants should contact the secretary to the University Ethics Committee for further guidance.

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 University Ethics Committee will look at such proposals, usually delegating the matter to the relevant Faculty Ethics Committee to consider the application, 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 UEC. However, if Glasgow University is the only University involved it also requires approval from the UEC 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 Faculty Ethics Committee. If Glasgow University is the only University concerned, the research also requires approval from the Faculty 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 Faculty 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 Faculty in the University, the research should undergo ethical review by only one Faculty. The decision on which is the most appropriate faculty should take into account the Faculty to which 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, Faculty Ethics Officers in the relevant Faculties must be asked for their opinion and reach agreement. A copy of any ethical approval obtained from one Faculty must be sent to the Faculty Ethics Officers in the other Faculties where researchers are based and research may not proceed until this is done.

4.17 Cases which cannot be satisfactorily resolved by the Faculty Ethics Committee must be referred to the University Ethics Committee which will provide advice and guidance to the Faculty Ethics Committee. The Faculty 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 Faculty Ethics Committees until Faculty level remedies have been exhausted. Faculties 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 Faculty 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 Faculties 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 Faculties 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 Faculties, 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 Faculty'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 the Research Planning and Strategy Committee. The University Ethics Committee will also report to the Research Planning and Strategy Committee on any outstanding or anticipated difficulties.

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

6.3 Detailed audit of the operation of Faculty ethics procedures will be part of the three yearly review process for all Faculties (Appendix V). Advice will be given on documentation and potential audit trails. The University Ethics Committee may request to see the minutes and

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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 Faculty 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 Vice Principal (Research Office) for further investigation.

APPENDIX I

GUIDANCE FOR FACULTY 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 Faculties

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 Faculty.

2 The University requires all Faculties

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 Faculty and to keep the situation under continuous review

3. The University requires all Faculties 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 Faculty Ethics Committee to the attention of staff and students for whom the Faculty is responsible. These mechanisms must make it clear that it is a University requirement that these policies, guidelines and procedures are followed;
- (b) keeping Faculty 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 Dean of Faculty as appropriate;
- (f) reporting to the Faculty 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 Faculty to the University Ethics Committee.
- (h) conducting a three yearly review of Faculty ethical procedures and reporting on behalf of the Faculty to the University Ethics Committee.
- (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 Faculties 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 Faculties 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 Faculties 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 Faculty'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 Faculty are aware of the need to refer research to these committees, for liaison with these committees as appropriate, and for reporting back to the Faculty and the University Ethics Committee as necessary.

In some cases Faculties with an extensive or varied research profile may wish to appoint more than one designated officer to manage and monitor procedures.

6.2 Where research is subject to approval by external bodies as described above, it shall not be necessary to obtain approval from the Faculty Ethics Committee or University Ethics Committee in addition. However, the fact that ethical approval has been obtained must be notified to the Faculty

Ethics Officer who will ensure a record is kept of this approval. Researchers must ensure that they 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 Faculty Ethics Committee.**

8.2 **The Dean of Faculty 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 Faculty 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.**

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 providing 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 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 Faculty 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 Vice Principal (Research Office) for further investigation.

APPENDIX II

GUIDANCE FOR THE ESTABLISHMENT AND OPERATION OF FACULTY ETHICS COMMITTEES

1 It is recommended that, where consideration of ethical issues is not within the remit of an existing Faculty Ethics Committee, a Faculty Ethics Committee 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 Faculty Ethics Committees have an established membership and terms of reference, and operate in strict accordance with approved written procedures. All Faculty Ethics 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 Faculty 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 Faculty ethics committee should have no fewer than six members, one of whom shall be the Faculty 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 Faculty, preferably from outside the University. To be quorate Faculty 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 Faculties 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 Faculty Ethics Committee shall be approved by a Faculty Meeting (or equivalent).

4 Terms of Reference

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

- (a) to consider non-clinical research proposals (from both the Faculty'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.

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

5 Procedures

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

5.2 The Faculty 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 Faculty 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 Faculty. 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 Faculty 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.

APPENDIX III

UNIVERSITY ETHICS COMMITTEE: REFERRALS BY FACULTIES

1 The primary purpose of the University Ethics Committee is to issue general advice and guidance to Faculties on ethical issues arising from non-clinical research. The Committee has a responsibility to approve Faculty procedures and to consider annual and three yearly reports from Faculties on the management of ethical issues in research. Decisions in respect of research with ethical implications will normally be made by the Faculty 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 Faculty 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 Faculty 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 Faculty 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 Faculty. 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 Faculty Ethics Committee.

2.3 The University Ethics Committee will give guidance to the Faculty Ethics Committee but it remains the responsibility of the Faculty 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 Faculty Ethics Committee on the following matters:

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- (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 Faculty Ethics Committees, but only once the local procedure for resolving difficulties has been exhausted.

APPENDIX IV

ANNUAL REPORTS BY FACULTIES TO THE UNIVERSITY ETHICS COMMITTEE

1 Each Faculty, through its designated officer, 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 Faculty 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 Annexe 1)

5 Faculties with nothing to report will be required to submit a signed statement to that effect on the pro forma.

APPENDIX V

THREE YEARLY REVIEW OF FACULTY ETHICS PROCEDURES

1 The three year review of Faculties ethics procedures has the following objectives:-

- (a) To review the operation of their ethics procedures over the past three years;
- (b) To make changes and amendments to procedures in the light of cases that have arisen during that time that may have impact on the operation of the procedures;
- (c) To make changes to the procedures in line with changes in legislation, University policy or changes in guidelines of relevant professional bodies or associations;
- (d) To consider the question of ethics as it relates to all of the activities of the Faculty.

2 The review will consider:

- (a) either the Faculty's detailed procedures for the consideration of ethical issues as they arise in teaching and research or its written explanation as to why such procedures are considered unnecessary;
- (b) a description of the role and remit of the Faculty's designated officer;
- (c) where relevant, the terms of reference, procedures and membership of the Faculties ethics committee;
- (d) where relevant, reports from the Faculties ethics committee to its appropriate management committee include a brief summary of the types of cases considered;
- (e) where relevant, evidence that decisions by the ethics committee are acted upon.

3 The process will be as follows:

- (a) The review will be based on a self-evaluation to be completed to a template by the Faculty's designated Ethics Officer. Faculties will be invited to undertake the activity on a three yearly basis at the request of the University Ethics Committee.
- (b) The completed self-evaluation form should be submitted to the Clerk to University Ethics Committee.
- (c) This form will be considered by the Committee and a representative from the Faculty will be invited to meet with the Committee (at one of its regular meetings) to talk through responses made in the self evaluation document
- (d) Broad issues will be minuted and written feedback will be provided to the Faculty (via the Faculty Ethics Officer and the Dean of Faculty)

4 Further information can be obtained from the Clerk to the University Ethics Committee.

APPENDIX VI

THE CONSTITUTION AND OPERATION OF THE UNIVERSITY ETHICS COMMITTEE

1 The Glasgow University Ethics Committee (UEC) has been established by Senate as a Senate Committee 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 University Faculties 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 also considers and gives guidance on research referred to it from Faculties and hears appeals on decisions made by Faculties. In exceptional cases the University Ethics Committee may itself make decisions on research referred to it from Faculties.

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

- (a) to develop policy and guidelines for and with Faculties;
- (b) to approve Faculty procedures or statements;
- (c) to assist with the provision of appropriate training for Faculty 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 Faculty decisions. In exceptional cases the University Ethics Committee may itself make decisions on research referred to it from Faculties;

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

(f) to make an annual report to the Research Planning and Strategy Committee 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 the former members of the Glasgow University Ethics Committee for Non-Clinical Research involving Human Subjects who are:

- 2 people not employed by the University, one of whom is medically qualified;
- a member of the former Faculty of Law and Financial Studies;
- a member of the Faculty of Divinity;
- a member of the Department of Philosophy;
- a member of the Faculty of Science;
- 2 members of the former Faculty of Social Sciences, one of whom is a psychologist.

The University Ethics Committee shall also include all Faculty Ethics Officers.

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 Membership of the Faculty Ethics Committee shall be approved by Senate.

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 Convenor

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may act after consultation with no less than two other members of the UEC who are not members of the Faculty or Faculties 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.

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. Faculty may also nominate a substitute from the Faculty Ethics Committee to attend a meeting which the Faculty 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 Faculty 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 Faculty 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 Faculty 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 Faculty. 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.

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- (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 Faculty Ethics Committee.

5.3 The University Ethics Committee will give guidance to the Faculty Ethics Committee but it remains the responsibility of the Faculty 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 Faculty 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 Faculty 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.