RESEARCH ETHICS BOOKLET
PRINCIPLES AND PROCEDURES

Updated December 2013, January/February 2014

FOREWORD

All research involving human participants and including human tissue conducted by staff and students of the University must be subject to ethical scrutiny and approval. This requirement is derived from the University's *Code of Good Practice in Research* which has Senate approval. It applies to all levels of study and to funded and unfunded studies. It embraces the use of simple questionnaires distributed to healthy volunteers as well as to more complex research carried out in educational, health, social care or prison settings.

The majority of the work involved in ethical scrutiny and approval will be carried out by the School Ethics Committees which have been set up in all Schools. The University Committee deals with a much smaller proportion of work including research involving major invasive methods or procedures and has a monitoring and audit function. Schools are advised to model their ethical application forms on the guidance contained within this document but are free to make adaptations in line with codes of conduct published by professional or academic associations and societies. Schools must also ensure that the requirement to seek ethical approval for research involving human participants is noted clearly in dissertation guidelines for students and that sufficient time for ethical approval is allowed when applying for research grant.

The principles and guidelines contained within this document have been developed by the University Research Ethics Subcommittee to clarify the responsibilities of staff and to support them in achieving ethically sound research practice in their own and their students' work. Section **1** provides an outline of ethical principles to guide decision making. Section **2** includes details of the operation of the University Research Ethics Subcommittee and the process for making an application to it or to School Ethics Committees. Sections **3** mentions the Scottish Executive's Research Governance Framework (RGF) Second Edition, 2006. This Framework applies currently to research carried out in National Health Service (NHS) and/or Community Care settings but it sets out a vision for excellence that embraces all research. Excellence in research practice is taken to involve good science, probity in financial management and a research culture that supports knowledge and understanding of, and adherence to, all relevant legislation and codes of good conduct. From March 2004, the requirements laid down in the Research Governance Framework state that **all research conducted in the NHS and Community Care settings** whether it involves staff, patients, buildings or equipment, will require approval by an NHS Committee. This applies also to research carried out by undergraduates and postgraduates. Researchers are asked to refer to the **IRAS website** and to their University Research Ethics Subcommittee member for up-to-date guidance.

This document contains details of procedures and requirements that may be amended over time. Staff are therefore urged to check any updated versions each year in case further refinements to the procedures have been made. It should be read in conjunction with the University's *Code of Good Practice in Research (available from the HR website see 2.12.1) .*

This document may be produced in electronic and booklet form. The booklet form containing all the relevant paperwork is a limited edition and will have restricted circulation. The electronic version will be available on the Department of Governance and Quality website[1].

Paul Woods, Secretary to the University Research Ethics Subcommittee
February 2014

[1] http://www.gcu.ac.uk/gaq/senateandacademicgovernance/researchcommittee/researchethicssubcommiittee/

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SECTION 1

Ethical Principles to guide research involving human participants

1.1 Introduction

This section provides an outline of the main principles that are the foundation for sound ethical practice in research. It is essential for researchers to gain an understanding of these principles because there are few 'absolute rules' to guide the ethical conduct of empirical work. Rather researchers use these principles to guide their decisions about how to treat their research participants and the data that they gather about them. For most research within the University, researchers will find that these decisions are straightforward. However in some cases deciding on an acceptable ethical approach within a study may be more challenging. In such cases, discussion with members of the School or University Research Ethics Subcommittee should provide a resolution to any difficulty.

1.2 The Main Ethical Principles

According to one of the most widely quoted ethics texts there are four 'clusters' of moral principles which provide a framework for making decisions about the ethical aspects of a study [Beauchamp and Childress 2001]. These are:

* **Respect for autonomy**
* **Non-maleficence**
* **Beneficence**
* **Justice**

1.2.1 *Respect for autonomy*.

Respect for autonomy refers to the requirement to ensure that **research participants are entirely free to make a choice about their participation in a research study.** In order to be in a position to make such a choice they must be given sufficient information about the research and what participation involves, they have to be sufficiently competent to understand this information and to understand it to their own satisfaction. They must also be free from influence or coercion. In ethical terms this means that researchers have to obtain 'informed consent' and provide assurance that non-participation or withdrawal from participation can occur with no adverse consequences for the participants. A template form for routine use can be found in Appendix 10.

Informed consent is the subject of a large literature and requires careful consideration in some circumstances. Researchers who are working with vulnerable people such as children, prisoners, those with some form of mental illness or incapacity or the very sick or old will need to pay particular attention to the way in which they gain informed consent. The process of gaining informed consent from young people and children is complex and must be informed by current legislation (BMA 2000). Guidance on consent procedures is available on the following website.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

While the guidance focuses on clinical practice it is essential to note that legally the principles that apply to clinical practice also apply to research.

1.2.2 *Non-maleficence*

The principle of non-maleficence means that researchers have an obligation not to inflict harm on their study participants. Of course 'harm' is a contested concept. It could be argued that the use of some research methods may cause minor discomfort or 'harm'. For example taking a blood sample may cause temporary discomfort, pain or bruising. Asking certain questions may cause psychological 'harm' such as embarrassment, distress or unwelcome emotions. It is the researcher's duty to weigh up the potential for harm against the benefits of the study and to come to a justifiable conclusion. It is also his/her duty to ensure that research, which carries a risk of harm, should only be conducted by properly qualified investigators. Therefore, particular care should be exercised in decisions about what types of research can be conducted by undergraduates.

In order to address the issue of 'risk of harm', researchers must demonstrate that they have exercised a standard of due care. This would involve identifying the likely risks, assessing the probability that they will occur, evaluating the risk to determine its acceptability in relation to the objectives of the research and finally managing the risks which involves the steps that can be taken to minimise them [Beauchamp and Childress 2001:199]. Examples of managing risk are as follows -

* the provision of counselling if the research subject is likely to become distressed;
* advice about services or help as a result of discussing needs which are not being met;
* offering the benefits of an intervention after completion of an intervention programme;
* an explanation of why deception has been used.

1.2.3 *Beneficence*

The principle of beneficence has two elements – positive beneficence and utility beneficence. Positive beneficence means doing positive good in the sense that the research has some value scientifically, practically or educationally i.e. it must address an important question. Utility beneficence refers to the requirement that the researcher 'balances benefits and drawbacks' to produce the best overall results [Beauchamp and Childress 2001:165]. In other words, an assessment has to be made about whether the benefits of the research justify the level of effort, resources, costs or risk of harm to the research participants and the community.

1.2.4 *Justice*

The principle of justice means treating people equally and fairly and ensuring that they are accorded their full rights. More details can be found in Chapter 6 of Beauchamp and Childress 2001.

1.3 The two rules of veracity and confidentiality

In addition to the four clusters of principles, Beauchamp and Childress [2001:283] argue that there are four rules to guide ethical practice. These are veracity, privacy, confidentiality and fidelity. The two that most concern researchers are veracity and confidentiality. Veracity refers to the need for researchers to tell the truth and to impart information in a comprehensive and objective way. There may be a methodological reason for limited disclosure but this must be carefully justified. Confidentiality is also the subject of a considerable literature and legislation in the form of the Data Protection Act 1998. The term is sometimes used inter-changeably with anonymity. The definitions used by the Committee are given below:

Anonymity is the protection of the participant in a study so that even the researchers cannot link the subject with the information provided.
(*Nursing Research. Methods, Critical Appraisal and Utilization,* Geri LoBiondo-Wood, Judith Haber, 1990)

Confidentiality
Prevention of disclosure, to other than authorized individuals, of a participant's identity.
(MRC Guidelines for Good Clinical Practice in Clinical Trials, MRC 1998)

Reference

Beauchamp T L and Childress J F (2001) *Principles of Biomedical Ethics*. 5th Edition. Oxford University Press.
British Medical Association (2000) *Consent. Rights and Choices in Health Care for Children and Young People.* BMA Medical Ethics Department.

SECTION 2

Procedures for ethical approval and monitoring of research involving human participants

2.1 The University's Scrutiny process

The University Research Ethics Subcommittee's composition and Terms of Reference are given below. Details of the role of the University Committee and the Schools' Committees in relation to approval of research ethics are outlined in this section. The relevant form and suggested templates are attached as Appendices.

For any research undertaken by undergraduate, postgraduate and research students and staff involving the NHS (including NHS patients, staff, premises, equipment) application is made to an NHS Research Ethics Committee using the IRAS process. Please refer to Section 3 of this booklet. For grant applications, funders, including the Finance Office, often required to see a copy of the ethical approval as a condition of grant.

Each School has processes for dealing with the majority of research proposals that involve non-invasive and minor-invasive research methods. It will only refer to the University Research Ethics Subcommittee when in doubt about such proposals. In the case of research involving major invasive research methods and procedures, Schools will make an application to the University Research Ethics Subcommittee after initial discussion at School level for those applications which are not subject to further external scrutiny.

2.2 University Research Ethics Subcommittee Composition and Terms of Reference

2.2.1 Composition

- Two members from each School: Associate Deans Research plus one nominee of Executive Dean)
- Head of Information Compliance (for data protection issues)
- Director of Academic Research
- Up to two members of staff from any academic area of the University deemed to have particular expertise
- One lay member
- Chair*

The Chair is nominated by the Research Committee and s/he must not concurrently chair a School Ethics Committee.

A list of current members is given in Appendix 11.

2.2.2 **Terms of Reference**

1. To consider applications from School Ethics Committees for proposed staff, postgraduate and undergraduate research involving human participants that is deemed to be non-routine, intrusive or likely to be ethically contentious.

2. To consider an annual report from each School, and other approved grouping, detailing the numbers of proposals considered by School Ethics Committees and those submitted externally, in addition to a commentary on any specific ethical issues facing the School

3. To report and act on recent legislation/developments which may have ethical implications for research undertaken in the University.

4. To prepare an annual report on the Committee's operation for the Research Committee.

The Research Ethics Subcommittee is a subcommittee of the University Research Committee and the minutes of its meetings will be submitted to that Committee.

The following procedures apply <u>only</u> to research involving human participants that is not located in NHS or Community Care settings. For research related to the NHS, see Section 3

2.3 University Procedures - non-invasive, minor invasive and major invasive research methods and procedures

2.3.1 The University Research Ethics Subcommittee has a monitoring function and needs to have an understanding of the different types of research methods and procedures being used in the course of research work involving human participants and including human tissue throughout the University. The Committee is charged with responsibility for drawing up a list of **non-invasive, minor invasive** and **major invasive** research methods and procedures being used. In collaboration with Schools, a system for identifying and describing these methods has been established.

2.3.2 Non-invasive, minor invasive and major invasive methods and procedures are defined in the following ways:

Section 2.3.2 (a)

(a) **Non-invasive research methods** are defined as:

"The use of research methods that cause little or no discomfort to the research participants" Examples of non-invasive methods include some questionnaires, some interviews, taking blood pressure, pinprick blood sampling, psychological testing and procedures that form part of routine clinical and professional practice in line with the guidance of the relevant professional bodies"

(b) **Minor invasive research methods** are defined as:

"the use of research methods that cause little or no discomfort to the research participant but which will require repeated or interval measurement over a period of time in excess of 4 weeks."

(c) **Major invasive research methods and procedures** are defined as:

"More complex methods involving invasive techniques or pain or discomfort either physical or emotional for the research subject"

2.3.3 The Committee will maintain an overview of the methods being undertaken in each School.

2.3.4 The Committee will consider an annual report (see 2.9.1 below) from each School which will include specialist methods and procedures.

2.3.5 The Committee will receive confirmation from the School that all staff who undertake methods and procedures are approved to do so.

2.3.6 Schools will not normally apply to the University Research Ethics Subcommittee for approval for research involving non-invasive or minor invasive research methods. They will instead notify the Committee of their decisions as part of the annual report. However, Schools may seek approval for proposals for which they require additional advice or where the School Ethics Committee/Group has been unable to reach agreement.

2.3.7 After initial discussion at School level, Schools will make an application to the University Research Ethics Subcommittee in the case of research involving major invasive research methods and procedures which is not already subject to scrutiny by an external committee.

2.4 Procedures for Seeking Ethical Approval

2.4.1 It is anticipated that in the majority of cases ethical scrutiny of research proposed by students or staff will be unproblematic. Glasgow Caledonian University Research Ethics Subcommittee seeks to promote and operate a consistent and appropriate system where Schools assume a major part of the responsibility for considering the ethical implications of their research.

2.5 Disclosure Procedures and the Protecting Vulnerable Groups Scheme

The Directorate of People are responsible for overseeing policy and procedures with regard to the Protecting Vulnerable Groups Scheme, introduced by the Protection of Vulnerable Groups (PVG) (Scotland) 2007 Act.

Regulated Work
The PVG Scheme is concerned with those individuals who are undertaking 'regulated work' with children or protected adults. If an individual is refused membership of the PVG Scheme it is an offence for them to undertake regulated work.

There are five steps to assessing whether an individual is doing regulated work:

1. Is it work?
2. Who are they working with?
3. What do they do?
4. Is it their normal duties?
5. Are there any exceptions which apply?

A regulated work self-assessment tool is available on the Disclosure Scotland web site here: http://www.disclosurescotland.co.uk/pvg_training/self-assessment/. This tool takes you through the five steps set out in the PVG Scheme Guidance to find out if the individual is undertaking regulated work, and therefore requires a PVG application.

Application to Join PVG form

Applicants to the PVG scheme should allow 6 weeks for completion of the process

Should a PVG application be required then the individual needs to complete Part B, and sign the declaration at Part C, of the relevant form:

- Application to Join PVG scheme form – If they are not already a member of the scheme
- Existing PVG Scheme member Application form – If they are already a member of the scheme.

The form should then be passed to the Directorate of People counter signatory along with 3 forms of suitable identification. The counter signatory will ensure that the form has been completed correctly, complete Part E and sign the declaration in Part F.
The cost to join the PVG is £59. If the individual is already a member of the PVG Scheme then only an update fee of £18 would be payable.
If a PVG membership is not relevant then it may be possible to request a Basic or standard disclosure.

Further information can be found on the Disclosure Scotland website at:
https://www.disclosurescotland.co.uk/

2.6 Application to a School Committee

2.6.1 In making an application to the School Committee/Group, the applicant should complete form EC1[1]. Questions relating to several key ethical principles have been incorporated into Form EC1 in order to demonstrate that they have been taken into account. In the interests of offering a consistent approach across the University, it is hoped that the School scrutiny will adhere to the guidelines published by the University Research Ethics Subcommittee and embodied within Form EC1. However, it is acknowledged that Schools may want to amend these in light of the codes of practice published by professional bodies and associations. A copy of the completed form should be kept on file in the School with the project proposal.

[1] The EC1 form is intended as an exemplar that can be adapted by School's to suit subject area requirements.

2.6.2 Form EC1 should be submitted to the School Committee/Group at least two weeks in advance of the next scheduled meeting. At least one scheduled meeting is expected to take place every semester. Where an application is also being submitted to the Higher Degrees Subcommittee, the School Ethics Committee should normally deal with the ethical approval in advance of the meeting of the Higher Degrees Subcommittee.

2.6.3 Following its deliberations, the School Committee/Group will notify the applicant of its decision. Where ethical approval has been refused, a full explanation will be offered in writing. The applicant is then free to make a further application, modified in line with the School Committee/Group's comments.

2.6.4 If, in re-submitting, the applicant has not been able to respond to the School Committee/Group's points, then a written explanation will again be sent. Ethical approval will be refused unless the School Committee/Group's points are fully addressed. In other words, the research work cannot proceed until the School Committee/Group has granted ethical approval.

2.6.6 Schools may wish to apply to the University Research Ethics Subcommittee in cases where internal agreement cannot be reached, or where the non-invasive research methods are new and/or considered to be contentious. Where internal agreement has not been reached, all paperwork pertaining to the proposal should be submitted with Form EC1.

2.6.7 In addition to situations where agreement has not been reached, there may be other circumstances in which one member of a School is in dispute over ethical decisions made within a School. In such cases of dispute, the University Research Ethics Subcommittee will act in arbitration if requested to do so.

2.6.8 When an application is referred to the University Research Ethics Subcommittee, following its deliberations the University Research Ethics Subcommittee will notify the applicant and the School of its decision. Where ethical approval is not granted, a full explanation will be offered in writing. The applicant is then free to make a further application, modified in line with the Committee's comments.

2.7 Scrutiny of research involving non-invasive or minor invasive research methods

2.7.1 Each School will have processes for dealing with the majority of research proposals that involve agreed non-invasive and minor-invasive research methods. It will only refer to the University Research Ethics Subcommittee when in doubt about such proposals and then complete Form EC1. The School will notify the University Research Ethics Subcommittee of its own ethical scrutiny as part of the annual report submitted in January (see 2.9.1 below).

2.8 Research submitted for external scrutiny

2.8.2 Where a research proposal has to be sent to an external Ethics Committee for scrutiny, it should first be considered by the School Committee. Appendix 3 contains a suggested template for use within Schools. A copy of the proposal should be held in the School.

2.9 Consideration of undergraduate and taught postgraduate empirical project work

2.9.1 All undergraduate project work that involves human participants must be considered by the School Ethics Committee. Appendices 4 and 5 contain a suggested templates for use in Schools. Alternatively, Schools can design their own forms for scrutiny and recording. Module Co-ordinators responsible for project or dissertation modules are requested to feed information into the School Ethics Committee. The School Ethics Committee must notify the University Research Ethics Subcommittee of their consideration of projects undertaken by undergraduates and postgraduates on taught programmes as part of the annual report.

2.10 Reporting mechanism

2.10.1 Each School is required to prepare an annual report on the activity of its Ethics Committee/Groups each year. This report should be completed using the pro forma in Appendix 9 (and available from the Secretary to the Ethics Committee) and should contain:

(1) Details of membership of the School/other Committee including its administration

(2) Overview of procedures operated by School/other Committee

(3) Summary of applications covering undergraduate, taught postgraduate, research postgraduate and staff applications and the number which required amendment or resubmission and the number which required to be submitted externally

(4) Details of specialist procedures where approved/registered members of staff are required. The School also confirms that all staff who undertake methods and procedures are approved to do so

(5) Details of the secure storage of associated paperwork

(6) Any comments or issues which the School/other Committee wishes to make the University Committee aware of.

2.11 Submissions to the University Research Ethics Subcommittee for Approval

2.11.1 Where research involves major invasive research methods and/or procedures which is not already subject to external scrutiny, an application must be made to the University Research Ethics Subcommittee on Form EC1 (See Appendix 1).

2.11.2 Schools wishing to make an application to the University Research Ethics Subcommittee for approval for research involving non-invasive or minor invasive research methods, in line with 2.6 above, should also use Form EC1

2.11.3 The University Research Ethics Subcommittee usually meets twice a year. Applications should be forwarded to its Secretary who will place them on the agenda of the next appropriate meeting.

2.11.4 Where an applicant requires an urgent decision, a special request to this effect should be lodged with the Secretary to the Committee who may initiate the fast track approval procedures. It should be noted that application via the fast track system should be made only in exceptional circumstances. Where urgent consideration is required an item of business will be circulated round members by the Secretary who will co-ordinate responses. These comments will then be used to assist the Chair in taking Chair's Action. The decision of the Chair with regard to the application will be communicated to the applicant, as soon as possible, by the Secretary.

2.11.5 The University Research Ethics Subcommittee will not normally scrutinize applications for their scientific merit. It is expected that Schools will assume responsibility for this. If the Committee is not happy with an aspect of the proposal with regard to its scientific merit, then it will take this into account when considering its approval.

2.12 Clinical Trials

The University does have insurance cover for clinical trials but it is the responsibility of the individual researcher and/or the School to ascertain from the Depute Court Secretary that the trial in question falls within the University policy. Schools are asked to confirm to the University lawyers, via the Depute Court Secretary, on a sixth monthly basis, which investigations are running to ensure adequate insurance cover is in place.

2.13 Additional Information

2.13.1 The following related sources of information are available within the University:

- The University's *Code of Good Practice in Research* – available on Directorate of People Website under Policies, second entry from the top)

  http://www.gcu.ac.uk/hr/policies/general.html

- The University's *Data Protection Guidelines*

  http://www.gcu.ac.uk/dataprotection/

- Assessment and Graduation Processes (part of the University Assessment Regulations document) - Section 13 Procedures for Project and Dissertation Supervision - available on the Governance and Quality Enhancement website

  http://www.gcu.ac.uk/gaq/regulationsandpolicies/

Information on *Freedom of Information*

http://www.gcu.ac.uk/foi/

2.13.2 The following papers have been considered by the Ethics Committee and may be useful to Schools. They are included in the Appendix document.

Appendix 12 Retention Periods for Research Activities

Appendix 13 Risk Assessment (Psychology Pro Forma) PDF
Appendix 14 Guidelines on using Survey Monkey

SECTION 3

The Research Governance Framework for Health and Community Care.

3.1 The Research Governance Framework (RGF) is a Scottish Executive Health Department document that embodies the Government's commitment to achieving high standards of conduct in research. The Framework applies to all research that involves human participants who are recruited by virtue of their connection with services, or locations, that fall within the remit of the Minister for Health and Community Care. In essence the Framework sets national standards for the conduct of research, defines mechanisms to deliver those standards and describes monitoring and assessment arrangements. The Framework can be found by clicking on Research Governance via the Chief Scientist's Office at:

http://www.cso.scot.nhs.uk/nrs/research-governance/

3.2 Research that falls within the provisions of the Research Governance Framework includes human participants who are healthy or sick, who are recruited to a study by virtue of their connection to the NHS in any of its settings, or by virtue of a condition for which they require NHS care. The term 'human participants' therefore includes patients, service users, carers of users, care professionals or volunteers, or their organs, tissue or data.

3.3 All research in this field must be submitted for approval to an NHS Ethics Committee. These Committees use the Integrated Research Application System (IRAS). IRAS is a single system for applying for permissions and approvals for health and social care/community care research in the UK.

Full details and the application process can be found on:

https://www.myresearchproject.org.uk/Signin.aspx

3.4 Staff undertaking research in NHS settings may have to obtain an honorary NHS passport Information can be found on:

http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

3.5 All clinical trials involving the use of devices or medicinal products with people must be notified to the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA was formed in April 2003 from a merger between the Medicines Control Agency and the Medical Devices Agency.

Details of its work can be found on the following website

www.mhra.gov.uk

and information on clinical trials specifically can be found on

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=101

Procedures for conducting a clinical trial are complex and governed by the EU Clinical Trials Directive. The European Union Directive 2001/20/EC, dated 4 April 2001, is concerned with the legal, regulatory and administrative aspects necessary for implementing good clinical practice in the conduct of clinical trials on medicinal products for human use'. Information on the definitions in the Directive is available on the following website:

http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

3.6 The most up to date version of the World Medical Association Declaration of Helsinki (2008 amendments), relating to the ethical principles for Medical Research involving Human Subjects is attached as Appendix 7. It may also be viewed or downloaded from the following link

http://www.wma.net/en/30publications/10policies/b3/index.html

3.7 Where a sponsor letter is required, whether for a student or a member of staff, this must be countersigned on behalf of the University by an appropriate senior member of School staff (i.e. the Associate Dean for Research). See Appendix 6