



RESEARCH ETHICS PRINCIPLES AND PROCEDURES

Updated December 2013, January/February 2014/April 2015

FOREWORD

All research involving human participants and including human tissue conducted by staff and students of the University are subject to ethical scrutiny and approval. This requirement is derived from the University's *Code of Good Practice in Research* and the *Concordat to Support Research Integrity*. It applies to all levels of study, to funded and unfunded research, the use of simple questionnaires as well as to more complex research carried out in educational, health, social care or prison settings. This is in addition to compliance with any conditions of grant specified by a research funder.

The majority of the work involved in ethical scrutiny and approval will be carried out by the School/GCU Lead Ethics Committees (researchers located outwith Schools/GCU Lead will seek approval through the appropriate subject area School Ethics Committee). The University Research Ethics Committee deals with research involving major invasive methods or procedures and has an overall monitoring and audit function.

Schools/GCU Lead are advised to model their ethical application forms on the guidance contained within this document but may make adaptations in line with codes of conduct published by professional, statutory or regulatory bodies. Schools/GCU Lead 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** details the operation of the University Research Ethics Subcommittee and the process for making an application to it or to School Ethics Committees.

Section **3** provides detail on research carried out in National Health Service (NHS) and/or Community Care settings under the Scottish Executive's *Research Governance Framework for Health and Community Care in Scotland* (RGF) Second Edition, 2006.¹

This document should be read in conjunction with the University's *Code of Good Practice in Research*, UKRIO *Code of Good Practice in Research* and the RCUK *Policy and Code of Conduct on the Governance of Good Research Conduct*. The University supports the principles of the *Concordat to Support Research Integrity*.

¹ Under the requirements laid down in the for Health and Community Care in Scotland, 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 Integrated Research Application System (IRAS) website and to their School Ethics Committee chair for guidance.

CONTENTS

Page

Foreword

Section 1

Ethical Principles to guide research involving human participants

1.1	Introduction	1
1.2	The main ethical principles	1
1.3	The two rules of veracity and confidentiality	3

Section 2

Procedures for ethical approval and monitoring of research involving human participants

2.1	The University Scrutiny Process	4
2.2	The University's Research Ethics Subcommittee Composition and Terms of Reference	4
2.3	University procedures - non-invasive, minor invasive and major invasive research methods and procedures	5
2.4	Procedures for seeking ethical approval	6
2.5	Disclosure Procedures and the Protecting Vulnerable Groups Scheme	6
2.6	Application to a School Ethics Committee	7
2.7	Scrutiny of research involving non-invasive or minor invasive research methods	7
2.8	Research submitted for external scrutiny	7
2.9	Consideration of undergraduate and taught postgraduate empirical project work	8
2.10	Reporting mechanism	9
2.11	Submissions to the University Research Ethics Subcommittee for approval	9
2.12	Clinical Trials	10
2.13	Additional Information	10

Section 3

Research Governance Framework for Health and Community Care, NHS Research and the IRAS process

3.1	Research Governance Framework	10
3.2	NHS setting	10
3.3	NHS Committee and IRAS	10
3.4	NHS Passport	10
3.5	Clinical Trials and MHRA	10
3.6	Treaty of Helsinki	11
3.7	Sponsorship signatory	11

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 requires careful consideration in certain 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. Guidance on consent procedures is available at: http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf

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. 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. 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.

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.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a participant's identity.

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.

Nursing Research. Methods, Critical Appraisal and Utilization, Geri LoBiondo-Wood, Judith Haber, 1990

MRC Guidelines for Good Clinical Practice in Clinical Trials, MRC 1998

SECTION 2

Procedures for ethical approval and monitoring of research involving human participants²

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/GCU Lead' Committees in relation to approval of research ethics are outlined in this section. The relevant form and suggested templates are attached as Appendices.

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/GCU Lead 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 Subcommittee³ Composition and Terms of Reference

2.2.1 Composition

- Two members from each School: Associate Deans Research and the School Ethics Committee Chair
- GCU Lead Ethics Committee Chair
- Head of Information Compliance
- Director of Academic Research Development
- 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 University Research Committee and must not concurrently chair a School Ethics Committee.

2.2.2 Terms of Reference

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

² Research undertaken by undergraduate, taught postgraduate, postgraduate research students and research staff involving NHS patients, staff, premises, or equipment, is covered in section 3.

³ The Research Ethics Subcommittee is a subcommittee of the University Research Committee (URC) and the minutes of its meetings will be submitted to URC.

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.

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/GCU Lead, 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:

(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 and GCU Lead.

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/GCU Lead 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/GCU Lead 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/GCU Lead 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/GCU Lead 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 is responsible for overseeing policy and procedures with regard to the Protecting Vulnerable Groups Scheme, under the Protection of Vulnerable Groups (PVG) (Scotland) 2007 Act and an information sheet on the procedure is available on the GCU Portal.

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.

Should a PVG application be required then the applicant needs to complete Part B and sign the declaration at Part C of the relevant form, i.e.

- 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 costs to join the scheme are detailed on the Disclosure Scotland website at <http://www.disclosurescotland.co.uk/>. Applicants to the PVG scheme are advised to allow 6 weeks for completion of the process.

If a PVG membership is not relevant then it may be possible to request a Basic or standard disclosure.

2.6 Application to a School/GCU Lead Committee

- 2.6.1 In making an application to the School/GCU Lead Committee, the applicant should complete form EC1⁴. A copy of the completed form should be kept on file in the School with the project proposal. 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, 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/GCU Lead may want to amend these in light of the codes of practice published by professional bodies and associations.
- 2.6.2 Form EC1 should be submitted to the School/GCU Lead Committee 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/GCU Lead 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

⁴ The EC1 form is intended as an exemplar that can be adapted by School's to suit subject area requirements.
Research Ethics Principles and Procedures: Revised 2014-2015

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 (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/GCU Lead. 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 template for use in Schools/GCU Lead. 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 Schools/GCU Lead are required to prepare an annual report on the activity of its Ethics Committees each year. This report should be completed using the pro forma in Appendix x 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/GCU Lead 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 Exceptionally, where an applicant requires an urgent decision, a request should be lodged with the Secretary to the Committee who may initiate the fast track approval procedures. The item of business will be circulated to Committee members by the Secretary who will coordinate responses. These comments will then be used to assist the Chair in taking Chair's Action. The decision 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/GCU Lead 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/GCU Lead 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 GCU portal)
 - The University's *Data Protection Guidelines* (<http://www.gcu.ac.uk/dataprotection/>)
 - Procedures for Project and Dissertation Supervision (available on the Governance and Quality Enhancement website under Assessment Regulations and associated policies)
 - Information on *Freedom of Information* (<http://www.gcu.ac.uk/foi/>)
- 2.13.2 *The following papers may also be useful to Schools/GCU Lead. They are included in the Appendix document.*

Appendix 12

Retention Periods for Research Activities

Appendix 13
Appendix 14

Risk Assessment (Psychology Pro Forma) PDF
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.show.scot.nhs.uk/cso/>
- 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 the *National Institute for Health Research* website: <http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>
- 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). www.mhra.gov.uk
- Procedures for conducting a clinical trial are governed by the EU Clinical Trials Directive. The European Union Directive 2001/20/EC, 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'. The directive will be replaced by regulation (EU) No 536/2014 for applications after 28 May 2016. More information can be found at: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm
- 3.6** *The World Medical Association Declaration of Helsinki (2008 amendments), relating to the ethical principles for Medical Research involving Human Subjects is available from* <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

Appendices		Page
Appendix 1	Application for ethical approval for research involving human participants - Form EC1 and Guidelines for completion	2
Appendix 2	Procedures for ethical approval - Flow Chart	11
Appendix 3	Submission of a research proposal for external scrutiny: suggested template for School use	13
Appendix 4	Scrutiny of undergraduate and postgraduate projects involving human participants - suggested template for School use	14
Appendix 5	Undergraduate/Taught Postgraduate research project – ethical consideration -suggested template for School use	15
Appendix 6	Standard Pro forma for sponsor	
	6a – for student	18
	6b – for staff	19
	6c – important insurance information for sponsors	20
Appendix 7	Sample Consent Forms	32
Appendix 8	Retention Periods for Research Activities	36
Appendix 9	Risk Assessment (Psychology Pro Forma) PDF	38
Appendix 10	Guidelines on using Survey Monkey	41

RESEARCH ETHICS PRINCIPLES AND PROCEDURES

APPENDICES		Page
Appendix 1	Application for ethical approval for research involving human participants – Template form EC1 and guidelines for completion	2
Appendix 2	Procedures for ethical approval - Flow Chart	8
Appendix 3	Template: submission of a research proposal for external scrutiny:	9
Appendix 4	Template: scrutiny of undergraduate and postgraduate projects involving human participants	10
Appendix 5	Template: Ethical consideration of Undergraduate/Taught Postgraduate research project	11
Appendix 6	Standard Pro forma for sponsor 6a – for student 6b – for staff 6c –insurance contact details for sponsors	13 14 15
Appendix 7	School Annual Report Pro Forma	16
Appendix 8	Sample Consent Forms	19
Appendix 9	Retention Periods for Research Activities	22
Appendix 10	Risk Assessment Pro Forma	24
Appendix 11	Ethical guidelines for using Survey Monkey	27

GLASGOW CALEDONIAN UNIVERSITY

Form EC1 - Applications for Ethical Approval for Research Involving Human Participants

1. Reason for Submission to Committee (tick as many as appropriate)	
a) minor method or procedure	<input type="checkbox"/>
b) minor extended method or procedure	<input type="checkbox"/>
c) major invasive research method or procedure involved	<input type="checkbox"/>
d) submission to School Committee	<input type="checkbox"/>
e) to place an appeal before the University Committee subsequent to School refusal	<input type="checkbox"/>
f) failure to reach agreement at School level	<input type="checkbox"/>
g) School seeks advice and/or guidance	<input type="checkbox"/>

2. School:

3. Category of Researcher			
Staff	<input type="checkbox"/>	Temporary	<input type="checkbox"/>
Postgraduate	<input type="checkbox"/>		Permanent
Post-Doctoral	<input type="checkbox"/>		<input type="checkbox"/>
Contract	<input type="checkbox"/>		
Other	<input type="checkbox"/>		

4. If contract staff please give date of termination of contract:

5. Researcher's Name:
Dean/Associate Dean for Research:
Director of Studies:

6. Title of Study:

7. Outline the aims and objectives of the study:
--

8. Research Participants:
i) Approximate numbers:
ii) Inclusion criteria:

iii) Recruitment method:

9 (a). Methods/Procedures to be Used – non-invasive procedures

(for definition see guidelines paragraph 2.3.2(a))

i) Non-invasive Procedure:

ii) Non-invasive Procedure:

iii) Non-invasive Procedure:

iv) Non-invasive Procedure:

9 (b). **Name of Approved Supervisor (if the researcher is a student)**

10 (a). Methods/Procedures to be Used – Minor invasive research method

(for definition see notes overleaf and guidelines paragraph 2.3.2 (b))

i) Minor Invasive Method:

ii) Minor Invasive Method:

10 (b). **Name of Approved Supervisor (if the researcher is a student)**

11. Implications of any of the above non-invasive/ minor invasive procedure(s):

(Outline any stress or discomfort to research participants which may be involved in any of the above minor/extended minor procedures which have not been approved)

12. Major Invasive research methods and procedure(s): (for definition see notes overleaf and guidelines paragraph 2.3.2(c))

(Please describe each procedure and state number of times it is to be performed on each subject and over what time period)

13. Potential hazards of major invasive research methods and procedures, and precautions taken to meet them:

14. Please state the name of a qualified and suitably experienced person who will be available during the conduct of the major invasive research methods and procedures.

15. Will the participants be paid? Yes No
(for research involving major invasive procedures only)

If yes, please state amount:

£

16. Start Date:

Estimated Completion Date:

17. Location(s) in which study/project will be undertaken:

18. Ethical principles incorporated into the study:

(i) Explanation of the aims and benefits of the study for research participants:

- | | | |
|--|------------------------------|-----------------------------|
| (i) Written explanation (please enclose copy for major procedures) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (ii) Oral explanation | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (iii) If the procedure involves justifiable deception will explanation be offered following participation? (see note overleaf) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (iv) Consent form (please enclose a copy for major procedures) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (v) Oral consent | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

(ii) Safeguarding the rights of subject in respect of participation:

- | | | |
|--|------------------------------|-----------------------------|
| (i) Subject offered opportunity to decline to take part | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (ii) Subject offered opportunity to withdraw at any stage | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (iii) Expert advice available if required | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| (iv) Participants informed there may be no benefit to them | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

(iii) Safeguarding the rights of subject in respect of participation:

- | | | |
|--|------------------------------|-----------------------------|
| (i) Subject guaranteed confidentiality | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
|--|------------------------------|-----------------------------|

(ii) Subject guaranteed anonymity Yes No

(iii) Provisions of the Data Protection Act met. Yes No

a. Will the processing be fair and lawful? Will the participant been given enough information to ensure that they understand the research and their role in it? Will the participant fully understand how their information will be used? Will you tell participants that their participation is voluntary and enable them to freely give their consent without coercion? Will you obtain written consent? Will participants be able to withdraw their consent at any time? Within questionnaires, will you give participants the option of omitting questions that they do not want to answer?

b. will the data being collected be adequate, relevant and not excessive for the purposes of the research?

c. will procedures be in place to ensure that the data is accurate and, where necessary, kept up to date?

d. will the data be held securely so that it is protected from unauthorised access or accidental loss, damage or destruction? Has the guidance in the University's Information Classification & Handling Policy been followed?

e. will the data be held in a country within the EEA? If not, what measures will be taken to maintain its security.

(iv) Safe data storage secured Yes No

19. Has this application been considered by a School Ethics Committee?

Yes No

20. Protection for the researcher:

Will the researcher be at any risk of sustaining either physical or psychological harm as a result of the research?

Yes No

If yes, please specify and give details of precautions which will be taken to protect the researcher:

21. Academic scrutiny of the research proposal:

Will the research proposal be submitted to the Higher Degrees Committee? Yes No

If no, will the research proposal be subject to peer review within the School? Yes No

22. Declaration:

I declare that the proposed investigation described in this application will be carried out as detailed and that if any changes to the procedures are planned, written permission will be sought from the School Ethics Committee/GCU Research Ethics Subcommittee. (*Delete as appropriate*).

Approved Supervisor: _____

Date: _____

23. School Approval:

This study was considered by the School Ethics Committee on (date):

Signed: _____

Position: _____

24. University Research Ethics Subcommittee Approval:

This study was approved by the University Research Ethics Subcommittee on (date):

Signed: _____

Position: _____

Notes of Guidance for completion of EC1

- 1 Question 8(i) - When noting details of the research participants, it is acceptable to indicate approximate numbers. The information can be given as a number where they are all from one group. Where they are from 2 or more groups the information can be given very concisely e.g. "10 children, 10 sets of parents, 2 teachers".
- 2 Question 8(ii) - The inclusion criteria refer to the particular group of research participants being invited to participate e.g. 'school children aged 9 and 10 years' or 'school children of 14 - 18 years who are smokers'.
- 3 Question 8(iii) - The recruitment method should be expressed as simply as possible e.g. 'Canvassing shoppers in Argyle Street', or 'invitation extended to all third year GCU students studying Engineering'. If confidential records are being used in order to recruit subjects then this should be stated.
- 4 Questions 9 & 10 - A definition of approved non-invasive, minor invasive and major invasive research methods and procedures can be found under paragraph 2.3.2 of *the Research Ethics - Principals and Procedures Booklet* and are quoted below. Lists of approved research methods and procedures for each School will be available from the Secretary to the Research Ethics Subcommittee. Please indicate which of these are being used in the research and whether the researcher or supervisor (in the case of students) has been approved to use them.

2.3.2 Non-invasive, minor invasive and major invasive methods and procedures are defined in the following ways (updated in 2006):

- (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:

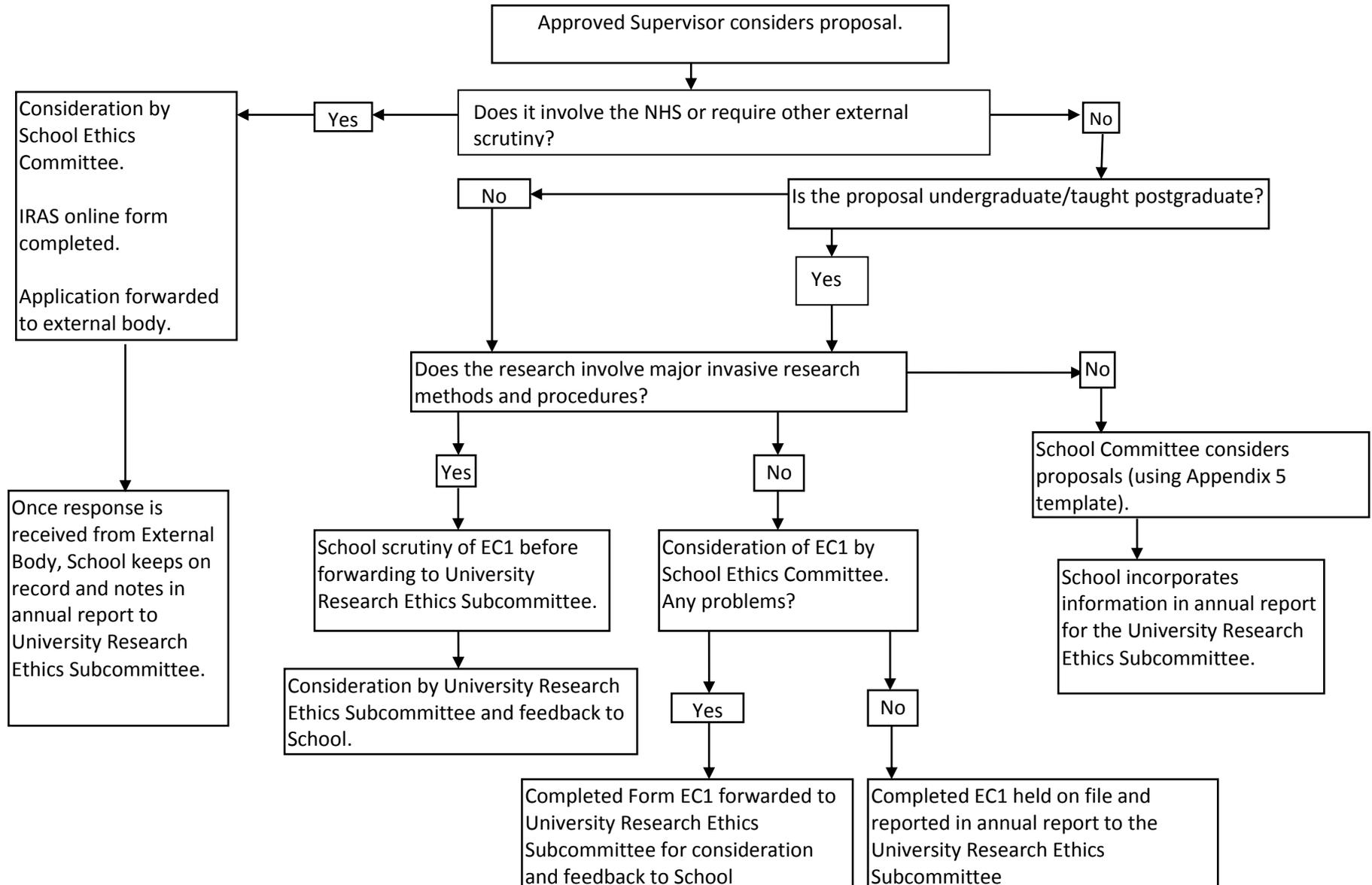
“More complex methods involving invasive techniques or pain or discomfort either physical or emotional for the research subject”

Where a member of staff or a student wishes to use a non-invasive or minor invasive research method that is not listed, they should provide the Dean (or his/her nominee) with a description of the method and a statement of the effect that it might have on a research participant in terms of degree of discomfort. The Dean (or nominee) will then discuss this with the School Ethics Committee to determine its view. The Dean (or nominee) will then collaborate with the University Research Ethics Subcommittee in obtaining formal approval of the new research method.

- 5 Question 11 - It is important to note that an entry only need be made if there is any anticipated stress or discomfort which has not already been detailed. An example might be where a particularly sensitive topic is to be broached in an interview, or where research is planned with participants whose understanding is impaired.
- 6 Question 13 - For entering details of potential hazards, it is acknowledged that more space might be required for a full explanation. Please feel free to append an additional page for this purpose.
- 7 Question 14 - It is important to reassure the Committee that where the researcher plans to use a major invasive research method and/or procedure as part of their research, that they have the necessary technical competence to undertake the research competently and safely.
- 8 Question 16 – refers to the start date of the whole project.
- 9 Question 18 - The purpose of question 18 is to ensure that key ethical principles have been incorporated into the study as outlined in Section 1 of *the Research Ethics: Principles and Procedures – Ethical Principles to guide research on human participants*. There should always be one form of explanation for research participants and researchers should be confident that the research participants have consented freely to their participation. Where participants have not been offered the opportunity to decline to take part or to withdraw at any stage, the University Research Ethics Subcommittee will ask for an explanation, if this is not evident within the proposal itself.
- 10 Question 18(i) - Please note that a research participant information sheet and a copy of the consent form must accompany the application where research involving major invasive methods or procedures are concerned.
- 11 Question 18(iii) - Justifiable deception may form part of a research study. Examples would include making research participants aware of the purpose of the study in such general terms that they are not aware of the precise topic of interest. It may also involve the offering of a placebo instead of a therapeutic drug. Where a researcher plans to use justifiable deception, this must be explained and justified in the appropriate section on the application form.
- 12 The applicant must sign and date the form.
- 13 Question 23 - A summary of the School consideration should be attached.

Academic Governance\researchethicssubcommittee\ethics documents\appendices
August 2000/revised Aug 2004&Oct 2006 for Dec 2006, minor changes February 2013; revised April 2015

PROCEDURES FOR ETHICAL APPROVAL



Submission of a Research Proposal for External Ethical Scrutiny

School:

The enclosed research proposal entitled:

was submitted by the following researchers:

to the following external body (bodies) for ethical approval

On: (Date)

Supervisor's name, if researcher is a Student:

Anticipated Start Date for Study:

Completion Date:

Note: Please attach the full proposal to this form

To be completed following return from the external body

Ethical Approval Was Granted/Not Granted *

** Delete as appropriate*

Date Approval Granted

APPENDIX 4
(Template Form)

School Scrutiny of Undergraduate/Taught postgraduate Projects Involving Human Participants

School:		
Programme:		
Date of School Scrutiny Approval:		<input type="text"/>
Student's Name	Title of Study	Supervisor Name and signature

**Undergraduate/Taught Postgraduate Research Project –
Ethical Considerations**

Name:	
School:	Date:
Programme:	Level:

Title of project:

Main aim of study:

Number of research participants:

Who are the research participants?

How will you recruit them for your study?

Research Procedures:	Questionnaires	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	Interviews	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Other: (please specify)	1.				
	2.				
	3.				
	4.				

Will any of these procedures cause discomfort, anxiety, stress or embarrassment?

Yes No

Is this unavoidable?

Yes No

If yes, please give details and explain how you will seek to minimize the impact of this.

(An extra page may be appended to this form)

Please indicate your response to the following questions and discuss your response with your supervisor.

Will you provide a written/oral explanation of the project to the subject?

Yes No

Will you ask the research participants to fill in a consent form?

Yes No

Will you explain to the participants that you are a student and undertaking degree studies?

Yes No

Will you explain to the research participants that they may not benefit from your study?

Yes No

Will you offer your research participants the opportunity to decline to take part?

Yes No

Will you offer your research participants the opportunity to withdraw at any stage?

Yes No

Will you offer a guarantee of confidentiality?

Yes No

Will you offer anonymity?

Yes No

Will you adhere to the provisions of the Data Protection Act 1998?

Yes No

a. Will the processing be fair and lawful? Will the participant been given enough information to ensure that they understand the research and their role in it? Will the participant fully understand how their information will be used Will you tell participants that their participation is voluntary and enable them to freely give their consent without coercion? Will you obtain written consent? Will participants be able to withdraw their consent at any time? Within questionnaires, will you give participants the option of omitting questions that they do not want to answer?

b. will the data being collected be adequate, relevant and not excessive for the purposes of the research?

c. will procedures be in place to ensure that the data is accurate and, where necessary, kept up to date?

d. will the data be held securely so that it is protected from unauthorised access or accidental loss, damage or destruction? Has the guidance in the University's Information Classification & Handling Policy been followed?

e. will the data be held in a country within the EEA? If not, what measures will be taken to maintain its security.

Signed:
(Student)

Date

Signed:
(Supervisor)

Date



Dear Sir or Madam

Title of Research Study:

Name of Researcher:

Location of Research:

I am writing to confirm that Glasgow Caledonian University is aware of the above student research proposal and has agreed to undertake the role of Sponsor as outlined in the Scottish Executive's Research Governance Framework for Health and Community Care. I am the student's supervisor for the study. I understand that the University may delegate the responsibilities of the sponsor to me and I agree to undertake them accordingly. I confirm that Glasgow Caledonian University has appropriate insurance cover under the terms of its Professional Negligence Insurance Policy.

Under the Framework the Sponsor must ensure:

- The research has appropriate ethical and R&D management approval
- The researchers have the necessary expertise and access to the resources required to conduct the proposed research
- The proposed work is consistent with the Research Governance Framework
- The research is appropriately managed and monitored
- That any Intellectual Property (IP) arising from the research is identified. If deemed necessary, arrangements should also be put in place to ensure any IP is protected.
- Other stakeholder organisations are alerted of any significant developments that occur as the study progresses, whether in relation to safety of individuals or to scientific direction
- There is a clear statement provided concerning the arrangements for compensation in the event of non-negligent harm
- Arrangements are proposed for disseminating the research findings

I understand that we must have approval letters from an appropriate Ethics Committee and NHS **NAME OF HEALTH BOARD** Research & Development Office before we can commence the proposed research.

Yours faithfully

To be signed by an NHS passport holder or supervisor.

Counter signatory – Associate Dean for Research



Dear Sir or Madam

Title of Research Study:

Name of Researcher:

Location of Research:

I am writing to confirm that Glasgow Caledonian University is aware of the above research proposal and has agreed to undertake the role of Sponsor as outlined in the Scottish Executive's Research Governance Framework for Health and Community Care. I am the Dean of the School of and am responsible for the conduct of the study. I understand that the University may delegate the responsibilities of the sponsor to me and agree to undertake them accordingly. I, in turn may delegate sponsorship duties to the Principal Investigator of the study. I confirm that Glasgow Caledonian University has appropriate insurance cover under the terms of its Professional Negligence Insurance Policy.

Under the Framework the Sponsor must ensure:

- The research has appropriate ethical and R&D management approval
- The researchers have the necessary expertise and access to the resources required to conduct the proposed research
- The proposed work is consistent with the Research Governance Framework
- The research is appropriately managed and monitored
- That any Intellectual Property (IP) arising from the research is identified. If deemed necessary, arrangements should also be put in place to ensure any IP is protected.
- Other stakeholder organisations are alerted of any significant developments that occur as the study progresses, whether in relation to safety of individuals or to scientific direction
- There is a clear statement provided concerning the arrangements for compensation in the event of non-negligent harm
- Arrangements are proposed for disseminating the research findings

I understand that we must have approval letters from an appropriate Ethics Committee and NHS (Name of Health Board) Research and Development Office before we can commence the proposed research.

Yours faithfully

To be signed by Dean of School

Counter signatory – Associate Dean for Research

Insurance Details

Sponsorship signatories should contact the Department of Governance and Quality Enhancement for insurance details and for any further information regarding insurance cover.



**School/GCU Lead Ethics Annual Report
To
University Research Ethics Subcommittee**

School:

Year:

Signed: [signed off by Chair of School/GCU Lead Committee]

N.B. This Annual Report should, where appropriate, be placed on the School Board agenda for consideration, approval or for information, depending on School procedures.

1. Membership:

Chair:

Members:

Administrator:

2. Overview of Procedures:

[Summarise in one paragraph or by attaching a flow chart detailing how internal procedures work]

3. Summary of Applications:

Table 1

Number of Undergraduate Applications <i>e.g. Honours project dissertations</i>	
Number of Taught Postgraduate Applications <i>e.g. Taught Masters dissertations</i>	
Number of Research Postgraduate Applications <i>e.g. MPhil or Doctorate students</i>	
Number of Staff Applications <i>[Excluding those of students counted above]</i>	
Total Number of Applications	

N.B. Table 1 can, if appropriate, be broken down by Division.

Use Table 2, below, to summarise how many of the Total Number of Applications detailed above required amendment/resubmission prior to Approval, how many were rejected and how many require submission to the University Research Ethics Subcommittee (UREC).

Table 2

Number of Application requiring revision prior to approval	
Number of Applications rejected	
Number of Applications forwarded to UEC	

Please use Table 3, below, to summarise details of applications submitted to external ethics committees e.g. NHS NRES

Table 3

Number of Applications sent to External Ethics Committees	
Number of these returned for significant amendment	
Number Approved by External Committees <i>[either initially or after amendments]</i>	

4. Specialist submissions:

Please use Table 4 to detail individual specialist procedures where a named approved/registered member of staff was required. By completion of Table 4 the School is confirming that all staff who undertake said specialist procedures are qualified to do so.

N.B. This table will usually only apply to some clinical/medical submissions.

Table 4

Method/Procedure or Project Title	Approved Researcher

The School confirms that all other staff who undertake methods and procedures are qualified to do so.

5. Secure storage

Please provide details of the storage of documentation and applications for the Ethics Committee

5. Comments/Issues to University Research Ethics Subcommittee: [use this space to detail any issue or good practice which has emerged that you feel should be discussed by the Subcommittee]

SAMPLE CONSENT FORMS

NAME OF RESEARCH PARTICIPANT

CODE NO.

TITLE OF THE RESEARCH STUDY

CONSENT TO TAKE PART IN THE STUDY

I,.....(put your name in here)

agree to take part in the research study being carried out by the School of XXX at Glasgow Caledonian University. I have read the information sheet and have had chance to discuss it.

I understand that:

- I do not have to take part in the research if I don't want to.
- If I change my mind and decide to withdraw from the research at any stage after signing this form, I can. I do not have to give a reason or sign anything to do so.
- If I decide to withdraw from the research study, this will not influence any help or treatment I get in any way.
- The information kept on me will be treated as strictly confidential and will be stored securely.
- Any information I give will be used for research only and will not be used for any other purpose.

SIGNATURE

DATE:.....

WITNESSED

DATE:.....

Organisation name

Study title

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is this study being carried out?

Simple explanation of reason for doing study.

Why have you been chosen?

Altogether x people have been approached to take part in this study. You have been approached because xxx and you have been sent this request through the offices of xxx..

Do you have to take part?

You can decide whether or not you want to take part. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights/ treatment/ relationships.

What will happen if you take part?

A researcher, (name if available) who works in the School of XXX at Glasgow Caledonian University will arrange XXX (detail data gathering procedures).

How long will it take?

It may take XXX of your time.

What will happen to the information that you give?

Explain data analysis, storage and destruction.

Will you benefit directly from this research study?

We hope that this evaluation will help XX. However, this can not be guaranteed. The information we get from this study may help in XXXX in future.

What to do now

If you would like more information before you decide about taking part, please contact XXX.

If you would like to take part, a consent form is enclosed.

Who to contact for more information

Thank you for taking time to read this information.

Retention Periods for Research Activities

The following information has been extracted from the Scottish version of the JISC Records Retention Schedule for HE.

For externally funded research the researcher must always check with the Sponsor for any specified retention periods. E.g. Medical Research Council requires specified documents to be kept for 10, 20 or 30 years after project completion. Where the Sponsor has no specified retention period the following should be followed.

1. The activities involved in conducting research

e.g. developing and establishing research protocols and procedures; obtaining approval for subsequent amendments to, or deviations from, protocols and procedures; carrying out research in accordance with project protocols and procedures, and with all legal and ethical requirements; identifying and reviewing issues and risks which arise in the course of research work, and taking appropriate action; obtaining approval for modifications to the design of research; managing research data.

Depending on the discipline and on the nature of research, specific activities might also include: obtaining informed consent from participants in health-related studies; reporting adverse reactions or adverse events in clinical studies; consulting beneficiaries/consumers (e.g. in applied research); conducting surveys.

i.e. Records documenting the conduct of all funded research.

Retention: Normally completion of project + 10 years.

2. The activities involved in disseminating research results

e.g. publishing research results; presenting research results at technical meetings.

i.e. *Working papers* for the preparation of publications, audio-visual presentations, etc. to disseminate research results (NOT interim or final research reports).

Retention: Normally publication/delivery + 1 year.

i.e. *Final versions* of publications and presentations made to disseminate research results (NOT interim or final research reports).

Retention: Normally publication/delivery + 3 years.

Interim or final reports of research studies are covered in *1. The activities involved in conducting research* (above)

3. The activities involved in managing the conduct of research projects from formal initiation (following receipt of funding) to formal completion.

e.g. monitoring and tracking the progress of research; preparing reports for project stakeholders; arranging appropriate insurance; managing project resources and complying with institutional policies and procedures to protect project staff, participants and the environment; facilitating and assisting with monitoring activities and audits conducted by the institution, by external project sponsors/funders or by regulatory bodies; selecting research partners and subcontractors, and managing relationships with them; managing the process of offering research data to, and

depositing it with, external research data archives, and ensuring future compliance with the terms and conditions of deposit.

i.e. Records documenting the management of *internally-funded* research projects

Retention: Normally publication/delivery + 3 years.

i.e. Records documenting the management of *externally-funded* research projects.

Retention: Normally publication/delivery + 6 years.

Retention Periods for Research STUDENT Activities (i.e. postgraduate research programmes)

4. The activities involved in managing the conduct of research projects from formal initiation (following receipt of funding) to formal completion.

i.e. Records documenting the conduct of formal assessments of work undertaken by research students.

Retention: Normally completion of student's programme + 5 years.

5. The activities involved in appointing research supervisors and in providing training for them.

i.e. Records documenting the appointment of supervisors for research students.

Retention: Normally termination of appointment + 1 year

6. The activities involved in monitoring, reviewing and supporting research student the academic progress of research students.

e.g. Activities include: providing support and guidance to research students on subject selection; providing feedback to students on their progress; conducting formal reviews of student progress; providing students with general academic advice and guidance; providing students with opportunities to develop their research and other skills; providing advice and guidance to students whose progress is unsatisfactory or who are considering suspending or terminating their studies.

i.e. Records documenting academic advice and guidance to individual students on the selection of research subjects and on the progress and standard of their work.

Retention: Normally completion of student's programme + 5 years

Pat McKay
Head of Information Strategy Unit
23rd September 2009

Risk Assessment

The following form is recommended for use in Schools.

Research-related Risk Assessment

Name of Interviewer/Researcher	
Name of Supervisor/Principal Investigator	
Name of Study	
Number of respondents	
Date study start	
Date (approx) study ends	

Give a brief description of the study:-

If you do not feel a risk assessment is necessary, please provide a rationale for this decision:

Identifications of hazards

Please indicate in the table below hazards identified as pertinent to your research project and rate them and indicate your rating of the likelihood of the identified hazard causing actual harm.
 Level of Risk = severity of harmful event x likelihood of event occurring

Risk Assessment and Response Matrix

Likelihood of Occurrence ↓			
High	4 Tolerate/ Treat	7 Treat/ Transfer	9 Treat/Transfer/ Terminate
Medium	2 Tolerate/ Treat	5 Treat/ Transfer	8 Treat/Transfer/ Terminate
Low	1 Tolerate	3 Tolerate/ Treat	6 Treat/Transfer
Impact of Risk ⇒	Low	Medium	High

e.g. Hazard 1 medium likelihood of occurrence x low impact = tolerable or treat
 Hazard 2 high likelihood of occurrence x high impact = treat, transfer or STOP

Hazard	Severity	Likelihood	Treatment of Risk

Devising and implementing safe working practice
--

Describe below what measures will be taken to minimise the risks identified above and promote safe working practice:-

ETHICAL ISSUES INVOLVED IN USING SURVEY MONKEY

Christina Knussen and Angus McFadyen, 1 November 2010,
Amended in October 2014

Online administration of surveys has many apparent advantages and is increasing in popularity. It is particularly attractive to those who wish to gain large numbers of respondents and to those who wish the respondents' responses to remain anonymous. It is more acceptable to use a survey software tool, such as Survey Monkey, than to attach a questionnaire to email (see below), but a number of ethical issues remain. Survey Monkey is not the only survey software tool, but it is probably the best known at GCU. The technical points raised here relate specifically to Survey Monkey, but the ethical issues are probably relevant to the use of other software tools.

Anonymity

Responses can only be anonymous if the option to collect computer IP addresses is switched to 'No'. The default is for this information to be collected. While designing the survey, the researcher has to go to 'Collect Responses', click on 'Weblink', which opens a list of options, then the researcher has to choose 'show advanced options' and click 'Make anonymous'. Here the setting should be 'Yes, make respondent data anonymous'. When this is chosen, a dialogue box appears in the top right corner stating that 'the changes have been saved'. If the researcher revises the design of the survey, this option may revert to the 'Yes' default, and the researcher should be alerted to the need to check the setting of this question immediately prior to finalising the survey. Unfortunately, it does not seem possible for anyone other than the researcher to verify that IP addresses have not, in fact, been collected.

Confidentiality

Everyone who has access to a single Survey Monkey account seems to have access to the data from all surveys. It does not appear to be possible to protect certain surveys within a shared account by password. This means that data stored within shared Survey Monkey accounts (such as the shared GCU account) cannot be held confidentially.

Informed consent

It is not possible with Survey Monkey to provide an oral explanation of the study, or to take oral consent. This means that all of the relevant information must be given in the first 'page' of the survey or, indeed, on the email containing the link to the survey. This should follow the pattern of a paper-based information sheet, and cover the identity of the researcher(s), contact details, the reason for conducting the survey, the uses to be made of the data and so on. Warnings should be given if the survey covers potentially sensitive issues, and sources of further support and information should be given if warranted. Inclusion and exclusion criteria should be presented. The consent procedure also needs to be carefully considered. This can be addressed by presenting the items normally found on a paper-based consent form such that the items must be endorsed before the next page can be opened.

Right to withdrawal and omission of items

As a rule, no items (other than those relating to consent) should require a response. Respondents should be told that they can exit the survey at any point. However, they should also be told that they cannot withdraw any responses that have been made at the point of exit – if they wish to 'erase' their responses before exiting the survey, they need to backtrack through the survey.

Advantages and other issues

One of the key ethical advantages to using Survey Monkey or a similar software tool is that, if IP numbers are not collected, there is no way of tracing respondents. There is no need to use email addresses, and there is less likelihood of invading privacy (see BPS, 1997, p. 3). Further, it is likely that respondents will understand the uses that will be made of the data (including publication and other forms of dissemination), which is central to informed consent. However, it is not possible to verify identity in any way, and thus people who should be excluded from the survey (e.g., those under 16 years) may in fact complete the survey. Only minimal control by the researcher is available over access to and engagement with the material, and this must always be borne in mind. Finally, there is no guarantee that the responses will be equivalent to those that would have resulted from a paper-based survey.

Reference

British Psychological Society (2007). Report of the Working Party on conducting research on the internet: Guidelines for ethical practice in psychological research online. Available from http://www.bps.org.uk/sites/default/files/documents/conducting_research_on_the_internet-guidelines_for_ethical_practice_in_psychological_research_online.pdf

A Practical Guide to turning off the collection of IP Addresses on Survey Monkey

When Creating the link to send out for your SurveyMonkey questionnaire you **make sure that the settings do NOT collect IP addresses!** This is done as follows:

1. Click on 'Collect Responses'

The screenshot shows the SurveyMonkey interface. At the top, there's a navigation bar with 'Home', 'My Surveys', 'Examples', 'Survey Services', and 'Plans & Pricing'. A 'Create Survey' button is on the right. Below this is a yellow banner: 'Upgrade to a PLATINUM plan today. Upgrade →'. The main content area has tabs for 'Summary', 'Design Survey', 'Collect Responses', and 'Analyze Results'. The 'Collect Responses' tab is active. Below the tabs is a 'Survey Collectors' section with a '+ New Collector' button. A table shows 'COLLECTORS: 1 of 1' with columns: NICKNAME, STATUS, RESPONSES, and DATE MODIFIED. The table contains one row: 'Web Link' (CLOSED, 65, Tuesday, March 18, 2014 5:02 PM). Below the table is another 'ADD A NEW COLLECTOR' section with five options: Web Link, Email, Facebook, Website, and Manual Data Entry. A red arrow points to the 'Web Link' text in the table, and another red arrow points to the 'Web Link' option in the 'ADD A NEW COLLECTOR' section.

2. Click on 'Web Link'
3. Then choose 'show advanced options'

WEB LINK + Manual Data Entry

WEB LINK CLOSED ▾

<https://www.surveymonkey.com/s/FAIRCurrículumSurvey> Customize

- ▶ Responses Per Computer: One ?
- ▶ Edit Responses: Yes, respondents can edit their responses until the last page of the survey is completed ?
- ▶ Instant Results: Off ?
- ▶ Disqualification Page: Custom disqualification message ?

[Show advanced options](#) 

4. Click on 'Make Anonymous'

WEB LINK + Manual Data Entry

WEB LINK CLOSED ▾

<https://www.surveymonkey.com/s/FAIRCurrículumSurvey> Customize

- ▶ Responses Per Computer: One ?
- ▶ Edit Responses: Yes, respondents can edit their responses until the last page of the survey is completed ?
- ▶ Instant Results: Off ?
- ▶ Disqualification Page: Custom disqualification message ?
- ▶ **Make Anonymous: No, respondents' IP addresses are being stored.** ? 
- ▶ Thank You Page: Off ?
- ▶ SSL Encryption: On ?
- ▶ Cutoff Date and Time: None ?
- ▶ Maximum Response Count: No maximum ?
- ▶ IP Access: Off ?
- ▶ Password Protection: Off ?
- ▶ Survey Completion: Redirect respondents to www.surveymonkey.com ?

[Hide advanced options](#)

5. Choose 'Yes, make respondent data anonymous'.

WEB LINK + Manual Data Entry

WEB LINK CLOSED ▾

 Customize

- ▶ Responses Per Computer: One ?
- ▶ Edit Responses: Yes, respondents can edit their responses until the last page of the survey is completed ?
- ▶ Instant Results: Off ?
- ▶ Disqualification Page: Custom disqualification message ?
- ▼ Make Anonymous: ?
 - Yes, make respondent data anonymous ←
 - No, store respondent IP address in the survey results
- ▶ Thank You Page: Off ?
- ▶ SSL Encryption: On ?
- ▶ Cutoff Date and Time: None ?
- ▶ Maximum Response Count: No maximum ?
- ▶ IP Access: Off ?
- ▶ Password Protection: Off ?
- ▶ Survey Completion: Redirect respondents to www.surveymonkey.com ?

[Hide advanced options](#)

6. A dialogue box will appear on the top right hand corner stating:

 **Your changes have been saved** ✕