# RESEARCH ETHICS PRINCIPLES AND PROCEDURES

## APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix 1</td>
<td>Application for ethical approval for research involving human participants – Template form EC1 and guidelines for completion</td>
<td>2</td>
</tr>
<tr>
<td>Appendix 2</td>
<td>Procedures for ethical approval - Flow Chart</td>
<td>8</td>
</tr>
<tr>
<td>Appendix 3</td>
<td>Template: submission of a research proposal for external scrutiny:</td>
<td>9</td>
</tr>
<tr>
<td>Appendix 4</td>
<td>Template: scrutiny of undergraduate and postgraduate projects involving human participants</td>
<td>10</td>
</tr>
<tr>
<td>Appendix 5</td>
<td>Template: Ethical consideration of Undergraduate/Taught Postgraduate research project</td>
<td>11</td>
</tr>
<tr>
<td>Appendix 6</td>
<td>Standard Pro forma for sponsor 6a – for student 6b – for staff 6c –insurance contact details for sponsors</td>
<td>13 14 15</td>
</tr>
<tr>
<td>Appendix 7</td>
<td>School Annual Report Pro Forma</td>
<td>16</td>
</tr>
<tr>
<td>Appendix 8</td>
<td>Sample Consent Forms</td>
<td>19</td>
</tr>
<tr>
<td>Appendix 9</td>
<td>Retention Periods for Research Activities</td>
<td>22</td>
</tr>
<tr>
<td>Appendix 10</td>
<td>Risk Assessment Pro Forma</td>
<td>24</td>
</tr>
<tr>
<td>Appendix 11</td>
<td>Ethical guidelines for using Survey Monkey</td>
<td>27</td>
</tr>
</tbody>
</table>
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
   b) minor extended method or procedure
   c) major invasive research method or procedure involved
   d) submission to School Committee
   e) to place an appeal before the University Committee subsequent to School refusal
   f) failure to reach agreement at School level
   g) School seeks advice and/or guidance

2. School:

3. Category of Researcher
   Staff
   Postgraduate
   Post-Doctoral
   Contract
   Temporary
   Permanent
   Other

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?  
(for research involving major invasive procedures only)  
Yes ☐ No ☐  
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 ☐ No ☐  
       (ii) Oral explanation Yes ☐ No ☐  
       (iii) If the procedure involves justifiable deception will explanation be offered following participation? (see note overleaf) Yes ☐ No ☐  
       (iv) Consent form (please enclose a copy for major procedures) Yes ☐ No ☐  
       (v) Oral consent Yes ☐ No ☐  

   (ii) Safeguarding the rights of subject in respect of participation:  
       (i) Subject offered opportunity to decline to take part Yes ☐ No ☐  
       (ii) Subject offered opportunity to withdraw at any stage Yes ☐ No ☐  
       (iii) Expert advice available if required Yes ☐ No ☐  
       (iv) Participants informed there may be no benefit to them Yes ☐ No ☐  

   (iii) Safeguarding the rights of subject in respect of participation:  
       (i) Subject guaranteed confidentiality Yes ☐ No ☐
(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.
PROCEDURES FOR ETHICAL APPROVAL

Approved Supervisor considers proposal.

Does it involve the NHS or require other external scrutiny?

Is the proposal undergraduate/taught postgraduate?

Yes

No

School Committee considers proposals (using Appendix 5 template).

School incorporates information in annual report for the University Research Ethics Subcommittee.

No

Yes

Consideration by University Research Ethics Subcommittee and feedback to School.

Completed Form EC1 forwarded to University Research Ethics Subcommittee for consideration and feedback to School

Completed EC1 held on file and reported in annual report to the University Research Ethics Subcommittee.

IRAS online form completed.

Application forwarded to external body.

Consideration by School Ethics Committee.

Once response is received from External Body, School keeps on record and notes in annual report to University Research Ethics Subcommittee.

Does the research involve major invasive research methods and procedures?

Yes

No

School scrutiny of EC1 before forwarding to University Research Ethics Subcommittee.

Consideration of EC1 by School Ethics Committee. Any problems?

Yes

No

Consideration by University Research Ethics Subcommittee and feedback to School.

Completed Form EC1 forwarded to University Research Ethics Subcommittee for consideration and feedback to School

Completed EC1 held on file and reported in annual report to the University Research Ethics Subcommittee.

No

Yes
## Submission of a Research Proposal for External Ethical Scrutiny

<table>
<thead>
<tr>
<th><strong>School:</strong></th>
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The enclosed research proposal entitled:  

was submitted by the following researchers:  

<table>
<thead>
<tr>
<th><strong>to the following external body (bodies) for ethical approval</strong></th>
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On: 

(Date)  

**Supervisor’s name, if researcher is a Student:**  

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**Anticipated Start Date for Study:**  

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**Completion Date:**  

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<tr>
<th><strong>Note:</strong> Please attach the full proposal to this form</th>
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<tr>
<th><strong>To be completed following return from the external body</strong></th>
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**Ethical Approval Was Granted/Not Granted**  

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* Delete as appropriate  

<table>
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<tr>
<th>Date Approval Granted</th>
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</table>

updated 2003/August 2000/updated Nov 2004
## School Scrutiny of Undergraduate/Taught postgraduate Projects Involving Human Participants

<table>
<thead>
<tr>
<th>School:</th>
<th></th>
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<tbody>
<tr>
<td>Programme:</td>
<td></td>
</tr>
<tr>
<td>Date of School Scrutiny Approval:</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Student’s Name</th>
<th>Title of Study</th>
<th>Supervisor Name and signature</th>
</tr>
</thead>
</table>

Updated /August 2004/February 2003/August 2000/.Nov 2004
**Undergraduate/Taught Postgraduate Research Project – Ethical Considerations**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>School:</td>
<td></td>
</tr>
<tr>
<td>Programme:</td>
<td>Level:</td>
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</tbody>
</table>

**Title of project:**

**Main aim of study:**

**Number of research participants:**

**Who are the research participants?**

**How will you recruit them for your study?**

<table>
<thead>
<tr>
<th>Research Procedures:</th>
<th>Questionnaires</th>
<th>Yes □ No □</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interviews</td>
<td>Yes □ No □</td>
</tr>
</tbody>
</table>

**Other: (please specify)**

1. 
2. 
3. 
4.
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Will any of these procedures cause discomfort, anxiety, stress or embarrassment?</td>
<td></td>
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<tr>
<td>Is this unavoidable?</td>
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<td>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)</td>
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<tr>
<td>Please indicate your response to the following questions and discuss your response with your supervisor.</td>
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<tr>
<td>Will you provide a written/oral explanation of the project to the subject?</td>
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<tr>
<td>Will you ask the research participants to fill in a consent form?</td>
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<tr>
<td>Will you explain to the participants that you are a student and undertaking degree studies?</td>
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<td>Will you explain to the research participants that they may not benefit from your study?</td>
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<tr>
<td>Will you offer your research participants the opportunity to decline to take part?</td>
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<td></td>
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<tr>
<td>Will you offer your research participants the opportunity to withdraw at any stage?</td>
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<tr>
<td>Will you offer a guarantee of confidentiality?</td>
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<tr>
<td>Will you offer anonymity?</td>
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<tr>
<td>Will you adhere to the provisions of the Data Protection Act 1998?</td>
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</tr>
<tr>
<td>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?</td>
<td></td>
<td></td>
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<tr>
<td>b. Will the data being collected be adequate, relevant and not excessive for the purposes of the research?</td>
<td></td>
<td></td>
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<tr>
<td>c. Will procedures be in place to ensure that the data is accurate and, where necessary, kept up to date?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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 &amp; Handling Policy been followed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Will the data be held in a country within the EEA? If not, what measures will be taken to maintain its security?</td>
<td></td>
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</tbody>
</table>
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**

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
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<tbody>
<tr>
<td>Number of Undergraduate Applications</td>
<td></td>
</tr>
<tr>
<td>e.g. Honours project dissertations</td>
<td></td>
</tr>
<tr>
<td>Number of Taught Postgraduate Applications</td>
<td></td>
</tr>
<tr>
<td>e.g. Taught Masters dissertations</td>
<td></td>
</tr>
<tr>
<td>Number of Research Postgraduate Applications</td>
<td></td>
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<tr>
<td>e.g. MPhil or Doctorate students</td>
<td></td>
</tr>
<tr>
<td>Number of Staff Applications</td>
<td></td>
</tr>
<tr>
<td>[Excluding those of students counted above]</td>
<td></td>
</tr>
<tr>
<td><strong>Total Number of Applications</strong></td>
<td></td>
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</table>

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**

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Application requiring revision prior to approval</td>
<td></td>
</tr>
<tr>
<td>Number of Applications rejected</td>
<td></td>
</tr>
<tr>
<td>Number of Applications forwarded to UEC</td>
<td></td>
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</tbody>
</table>

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

**Table 3**

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Applications sent to External Ethics Committees</td>
<td></td>
</tr>
<tr>
<td>Number of these returned for significant amendment</td>
<td></td>
</tr>
<tr>
<td>Number Approved by External Committees</td>
<td></td>
</tr>
<tr>
<td>[either initially or after amendments]</td>
<td></td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Method/Procedure or Project Title</th>
<th>Approved Researcher</th>
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<tbody>
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</table>

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]
APPENDIX 8

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:...............................
CONSENT FORM

Please initial box

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, and without my treatment or any help that I receive being affected

3. I agree to take part in the above study.

----------------------------------
Name Date Signature

----------------------------------
Researcher’s name Date Signature

Please return the signed form to:
Name of researcher
School location
Glasgow Caledonian University
Cowcaddens Road
Glasgow
G4 0BA
Tel:

Keep one copy of this form for yourself

Date
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 xxxx 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 cannot 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

<table>
<thead>
<tr>
<th>Name of Interviewer/Researcher</th>
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<tbody>
<tr>
<td>Name of Supervisor/Principal Investigator</td>
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<tr>
<td>Name of Study</td>
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<td>Number of respondents</td>
<td></td>
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<td>Date study start</td>
<td></td>
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<td>Date (approx) study ends</td>
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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

<table>
<thead>
<tr>
<th>Likelihood of Occurrence</th>
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<tbody>
<tr>
<td>High</td>
<td>4 Tolerate/Treat</td>
<td>7 Treat/Transfer</td>
<td>9 Treat/Transfer/Terminate</td>
</tr>
<tr>
<td>Medium</td>
<td>2 Tolerate/Treat</td>
<td>5 Treat/Transfer</td>
<td>8 Treat/Transfer/Terminate</td>
</tr>
<tr>
<td>Low</td>
<td>1 Tolerate</td>
<td>3 Tolerate/Treat</td>
<td>6 Treat/Transfer</td>
</tr>
<tr>
<td>Impact of Risk ⇒</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Severity</th>
<th>Likelihood</th>
<th>Treatment of Risk</th>
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Devising and implementing safe working practice
Describe below what measures will be taken to minimise the risks identified above and promote safe working practice:-
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

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’

![Survey Monkey Collect Responses](image)

2. Click on ‘Web Link’

3. Then choose ‘show advanced options’
4. Click on ‘Make Anonymous’

5. Choose ‘Yes, make respondent data anonymous’.
6. A dialogue box will appear on the top right hand corner stating: