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GLASGOW CALEDONIAN UNIVERSITY

Applications for Ethical Approval for Research Involving Human Participants

**APPENDIX 1 EC1**

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

<table>
<thead>
<tr>
<th>2. School:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>3. Category of Researcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
</tr>
<tr>
<td>Postgraduate</td>
</tr>
<tr>
<td>Post-Doctoral</td>
</tr>
<tr>
<td>Contract</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>4. If contract staff please give date of termination of contract:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5. Researcher's Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dean of School:</td>
</tr>
<tr>
<td>Director of Studies:</td>
</tr>
</tbody>
</table>
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 □

(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/Glasgow Caledonian University 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. The first seven questions are straightforward.

2. 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”.

3. 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’.

4. 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.

5. 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 will then discuss this with the School Ethics Committee/Group to determine its view. The Dean will then collaborate with the University Research Ethics Subcommittee in obtaining formal approval of the new research method.
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.

Question 12 is self explanatory.

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.

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.

Question 15 is self explanatory.

Question 16 - refers to the start date of the whole project.

Question 17 is self explanatory.

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 Booklet - 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.

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.

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.

Questions 19 - 21 are self explanatory.

The applicant must sign and date the form.

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?**

- **No**
  - Is proposal undergraduate/taught postgraduate?
    - **No**
      - IRAS online form required to be completed for all NHS work.
      - Application then forwarded to external body.
      - Once response is received from External Body, School keeps on record and notes in annual report to University Ethics Committee using template in Appendix 3 as a basis.

  - **Yes**
    - Completed EC1 for School scrutiny before forwarding to University Ethics Committee.
    - Consideration by University Ethics Committee and feedback to School.

  - **No**
    - School incorporates information in annual report for the University Ethics Committee using template 4 as a basis

**Does the research involve major invasive research methods and procedures?**

- **No**
  - Completed Form EC1 forwarded to University Ethics Committee for consideration and feedback to School

  - **Yes**
    - Consideration by School Ethics Committee. using EC1 as a basis
      - Any problems?
        - **Yes**
          - Completed EC1 held on file and reported in annual report to the University Ethics Committee

        - **No**
          - School Committee considers proposals using template in Appendix 5 as a basis.

- **Yes**
  - School Committee considers proposals using template in Appendix 5 as a basis.
APPENDIX 3
Suggested Template

GLASGOW CALEDONIAN UNIVERSITY
Submission of a Research Proposal for External Scrutiny

<table>
<thead>
<tr>
<th>School:</th>
</tr>
</thead>
</table>

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

updated 2003/August 2000/updated Nov 2004
APPENDIX 4
Suggested Template

GLASGOW CALEDONIAN UNIVERSITY
School Scrutiny of Undergraduate/Taught postgraduate Projects
Involving Human Participants

<table>
<thead>
<tr>
<th>School:</th>
</tr>
</thead>
</table>

| Programme:                  |

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

<table>
<thead>
<tr>
<th>Student’s Name</th>
<th>Title of Study</th>
<th>Undergraduate/taught Postgraduate form completed with Supervisor named below</th>
</tr>
</thead>
</table>

Updated /August 2004/February 2003/August 2000/.Nov 2004
## GLASGOW CALEDONIAN UNIVERSITY

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

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>School:</td>
<td>Level:</td>
</tr>
<tr>
<td>Programme:</td>
<td></td>
</tr>
</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</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interviews</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Other: <em>(please specify)</em></td>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will you offer a guarantee of confidentiality?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will you offer anonymity?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Will you adhere to the provisions of the Data Protection Act 1998?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Will you adhere to the provision of the Freedom of Information Scotland Act 2002</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Signed: 
(Student) Date

Signed: 
(Supervisor) Date

Updated Feb 2003/August 2000/Nov 2004
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 Executive Dean of School

Counter signatory – Associate Dean for Research
APPENDIX 6 (c)

Insurance Details which Sponsorship signatories must be aware of:

2011 version included. Contact Janice Bruce, Depute Court Secretary if further information is required.
To Whom It May Concern

Our ref: AB/IND 8 September, 2010

Zurich Municipal Customer: Glasgow Caledonian University

This is to confirm that Glasgow Caledonian University have in force with this Company until the policy expiry on 31 July 2011 Professional Negligence Insurance incorporating the following essential features:

Policy Number: NHE-06CA01-0023

Services covered: Clinical Trials

Limit of Indemnity: £10,000,000 any one claim and in the aggregate for all claims first made against the Insured and notified to Zurich Municipal during the period of insurance

Excess: £500 any one claim

Retroactive Date: 01 August 2004

Exclusions

Standard insurance market exclusions apply, notably exclusion of Pollution other than sudden and accidental; punitive or exemplary damages; express warranties or guarantees; claims the cause of which occurred prior to the Retroactive Date.

This is a brief summary and the full policy should always be referred to for exact details of cover.

Yours faithfully

Nicola Pilbury
Underwriting Services
Zurich Municipal
Farnborough
To Whom It May Concern

Our ref: AB/IND 8 September, 2010

Zurich Municipal Customer: Glasgow Caledonian University

This is to confirm that Glasgow Caledonian University have in force with this Company until the policy expiry on 31 July 2011 Professional Negligence Insurance incorporating the following essential features:

Policy Number: NHE-06CA01-0023

Services covered: Training, research and consultancy

Limit of Indemnity: £5,000,000 any one claim and in the aggregate for all claims first made against the Insured and notified to Zurich Municipal during the period of insurance

Excess: £5,000 any one claim

Retroactive Date: 01 August 1997

Exclusions
Standard insurance market exclusions apply, notably exclusion of Pollution other than sudden and accidental; punitive or exemplary damages; express warranties or guarantees; claims the cause of which occurred prior to the Retroactive Date.

This is a brief summary and the full policy should always be referred to for exact details of cover.

Yours faithfully

Nicola Pilbury
Underwriting Services
Zurich Municipal
Farnborough
APPENDIX 7

DECLARATION OF HELSINKI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
And the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002
Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical
principles to provide guidance to physicians and other participants in medical research involving human
subjects. Medical research involving human subjects includes research on identifiable human material or
identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician's
knowledge and conscience are dedicated to the fulfillment of this duty.

3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The
health of my patient will be my first consideration," and the International Code of Medical Ethics declares
that, "A physician shall act only in the patient's interest when providing medical care which might have
the effect of weakening the physical and mental condition of the patient."

4. Medical progress is based on research which ultimately must rest in part on experimentation involving
human subjects.

5. In medical research on human subjects, considerations related to the well-being of the human subject
should take precedence over the interests of science and society.

6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic
and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even
the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged
through research for their effectiveness, efficiency, accessibility and quality.

7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic
procedures involve risks and burdens.

8. Medical research is subject to ethical standards that promote respect for all human beings and protect
their health and rights. Some research populations are vulnerable and need special protection. The
particular needs of the economically and medically disadvantaged must be recognized. Special attention
is also required for those who cannot give or refuse consent for themselves, for those who may be
subject to giving consent under duress, for those who will not benefit personally from the research and
for those for whom the research is combined with care.

9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on
human subjects in their own countries as well as applicable international requirements. No national
ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections
for human subjects set forth in this Declaration.
B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists. See footnote

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study. See footnote

31. The physician should fully inform the patient which aspects of the care are related to the research. The
refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

**Note: Note of clarification on paragraph 29 of the WMA Declaration of Helsinki**

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

**Note: Note of clarification on paragraph 30 of the WMA Declaration of Helsinki**

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

9.10.2004
RESEARCH GOVERNANCE FRAMEWORK

http://www.show.scot.nhs.uk/cso

For the most up-to-date version, online users should click on the above link and go into publications under NHS (.pdf version)
School/Unit Ethics Annual Report
To
University Research Ethics Subcommittee (for use from 2010)

From:  [please enter name of School or Unit]

Calendar Year:  [enter calendar year to which report applies – not academic year]

Signed:  [signed off by Chair of School/ Unit Committee – electronic signature acceptable]

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:

   Administrative support:

2. **Overview of Procedures:**
   [Please 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 |  
   | *e.g. Honours project dissertations* |  
   | Number of Taught Postgraduate Applications |  
   | *e.g. Taught Masters dissertations* |  
   | Number of Research Postgraduate Applications |  
   | *e.g. MPhil or Doctorate students* |  
   | Number of Staff Applications |  
   | *[Excluding those of students counted above]* |  
   | Total Number of Applications |  

   N.B. Table 1 can, if appropriate, be broken down by Division.
Please 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>Number of Application requiring revision prior to approval</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Number of Applications rejected</td>
<td></td>
</tr>
<tr>
<td>Number of Applications forwarded to UEC</td>
<td></td>
</tr>
</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>Number of Applications sent to External Ethics Committees</th>
<th></th>
</tr>
</thead>
<tbody>
<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>
</tr>
</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/Unit 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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</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 UEC:** [use this space to detail any issue or good practice which has emerged that you feel should be discussed by UEC]
APPENDIX 10

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 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 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.
APPENDIX 11

UNIVERSITY RESEARCH ETHICS SUBCOMMITTEE MEMBERSHIP

GLASGOW CALEDONIAN UNIVERSITY

ETHICS COMMITTEE

Membership as at March 2012

GLASGOW CALEDONIAN UNIVERSITY

Research Ethics Subcommittee

Membership for Academic year 2012-13 (updated May 2013)*

<table>
<thead>
<tr>
<th>Name</th>
<th>School/Constituency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Alex de Ruyter</td>
<td>Associate Dean Research, Glasgow School for Business and Society</td>
</tr>
<tr>
<td>Professor Hugh O’Donnell</td>
<td>Glasgow School for Business and Society representative,</td>
</tr>
<tr>
<td>Professor Scott McMeekin</td>
<td>Associate Dean for Research, School of Engineering and Built Environment</td>
</tr>
<tr>
<td>Ms Morag Ferguson</td>
<td>School of Engineering and Built Environment Representative</td>
</tr>
<tr>
<td>Professor Bill Hughes</td>
<td>Appointed by Research Committee</td>
</tr>
<tr>
<td>Professor Paul Flowers</td>
<td>Associate Dean for Research, School of Health and Life Sciences</td>
</tr>
<tr>
<td>Dr David Watson</td>
<td>School of Health and Life Sciences Representative</td>
</tr>
<tr>
<td>Mr John Ferguson</td>
<td>Scottish Council for Voluntary Organisations - Lay member</td>
</tr>
<tr>
<td>Professor Hugh McLachlan</td>
<td>Ethics specialist</td>
</tr>
<tr>
<td>Dr Christina Knussen</td>
<td>Ethics specialist</td>
</tr>
<tr>
<td>Professor John Marshall</td>
<td>Director of Academic Research Development</td>
</tr>
<tr>
<td>Ms Hazel Lauder</td>
<td>Assistant Head Governance and Quality Enhancement (Information Compliance)</td>
</tr>
<tr>
<td>Mr Paul Woods</td>
<td>Secretary Academic Registry</td>
</tr>
</tbody>
</table>
APPENDIX 12

Retention Periods for Research Activities

The JISC\(^1\) produced a Records Retention Schedule specifically for higher education activities. They then commissioned Scottish lawyers to adapt it to take into account any relevant Scottish legislation. The following information has therefore 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 publica tions 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

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\(^1\) Joint Information Systems Committee
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 from Psychology and is commended for use in Schools. It ties in with their application form (PDF document).

Division of Psychology,
Glasgow Caledonian University:
Research-related Risk Assessment (Form C).

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

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. Please refer to research related risk assessment guidelines (Forms A & B).

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>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<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/Transfer</td>
<td>6 Treat/Transfer</td>
</tr>
</tbody>
</table>

Impact of Risk $\Rightarrow$ 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

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Severity</th>
<th>Likelihood</th>
<th>Treatment of Risk</th>
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</table>
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’, and then select ‘Change Settings’. The option to ‘Save IP Address in Results?’ should be set to ‘No’. 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

SurveyMonkey instructions
When Creating the link to send out for your SurveyMonkey questionnaire you MUST enter the Change Settings option on left menu and then you MUST alter the default at the foot of the page to NO i.e. you will not store the respondents IP address. See diagram below.