UNIVERSITY OF ULSTER

RESEARCH GOVERNANCE

Guidance Notes on Completion of Form RG1a and associated documentation

SECTION A

Form RG1a is the University's own research ethics and governance application form. It is for use by staff and students who are conducting research studies on human subjects and which fall into research categories A, B and D (non-NHS/HPSS). It should not be used for research being conducted in collaboration with the NHS/HPSS; the national NHS application form (also known as the NRES/ORECNI form) must be used in such cases.

Chief Investigator

The Chief Investigator (CI) should normally be an appropriately experienced academic or academically trained member of staff of the University and should have experience relevant to the proposed study. The University has decided that CIs should be staff because of issues related to experience, accountability, continuity and indemnity. For student projects, the CI will normally be the first-named supervisor.

Title

The project title must be given in full. This is the title under which the project will be recorded. It must remain unchanged in all correspondence and in use. The project will also be given a reference number by the Research Governance section. If you do not have a reference number, then it is likely that your project has not been fully reviewed and recorded and does not, therefore, have the University's permission to proceed.

Other Investigators

All staff, students and any other investigators involved in the study should be named. For student projects, all supervisors (other than the first-named supervisor – see CI above) should be recorded.

Declaration

The CI should assess and indicate the category of the research (A B or D – see *Policy and Procedures*) and confirm that the research will be conducted appropriately by signing the declaration. (For definitions of research categories please see http://www.ulster.ac.uk/research/rg/governance_policy.html)

Peer Review

The application should be submitted for peer review. This should be carried out by one or more members of academic staff or equivalent who are independent of the research team involved in the study but are sufficiently knowledgeable to be able to make an informed judgement on the scientific quality and viability of the research and the suitability of the CI to conduct it. Advice on accessing a suitable reviewer is available from the chairperson or administrator of your filter committee (please see below). For student projects, peer review may be arranged by the course director or module co-ordinator.

Filter Committee

All applications must go through a filter committee. The role of filter committees is to scrutinize applications to ensure that they are complete, properly presented, ethically sound and generally viable. A filter committee will either need evidence that peer review has been conducted (a complete RG2 form) or will conduct the peer review as part of its scrutiny. For category A research, an opinion from a filter committee is sufficient for research to proceed. For category B and D research, further ethical consideration will be required by the University Research Ethics Committee.

SECTION B

Please remember that the **form RG1a** is only part of the information required. Where relevant, you must also provide a **project description/protocol complete with pertinent references**, a **statistical model**, a **subject information sheet** and a **consent form**.

1. Where will the research be undertaken?

   Please indicate precisely where the research will be undertaken, including an address (for example name of laboratory or other facility, room number, town, district, school etc).

2. Prior approval and /or funding

   Please confirm whether or not the research has already received any approval from, for example, an ethics committee in another jurisdiction such as the Republic of Ireland, or funding from, for example, a charity or funding body.

   You must also disclose any commercial interest in or sponsorship of the study and bear in mind that conflicts of interest can arise.

3. Duration

   Please provide the start and end dates and duration – this information will be used to remind you to provide progress and final reports. The start date – beginning of data collection; the end date – completion of the study.

4. Background to and reason(s) for the project

   Please provide a brief summary description of the background to the study and the reason for conducting it. This should reflect the complete information contained in the project description/protocol and be written in language that is comprehensible to a non-expert or lay person.

5. Aims of the project

   Please provide a brief summary of the aims of the project. These should be clear and unambiguous and should demonstrate that the potential outcomes and the uses of the information being sought have been thought through and are compatible with the reasons given for undertaking the study in the first place. This should reflect the complete information contained in the project description/protocol and be written in language that is comprehensible to a non-expert or lay person.

6. Procedures

   a. Methods

Please provide a brief summary the methods to be used. You should include all relevant procedures in detail but not extensive laboratory methods. Again, this should reflect the complete information contained in the project description/protocol and be written in language that is comprehensible to a non-expert or lay person.

Separate guidance on writing and presenting a **project description/protocol** is provided in Appendix 1.

b. Statistical techniques

Most studies will rely on an appropriate statistical model to underpin their viability and effectiveness. This is likely to include a calculation to determine the appropriate number of subjects and also techniques to analyse and present the data once it has been obtained. Advice on relevant statistical models should be sought from your research group or course director/supervisor. It is accepted that there will be some exceptions (for example, some single-case studies and certain qualitative studies). A description of the statistical model should be presented on a separate page. Guidance on preparing an appropriate **statistical model** is provided in Appendix 2.

7. Subjects

a. Numbers of subjects

Please clearly state the numbers of subjects to be recruited by group where appropriate. You might have a treatment group, a placebo group and controls, for example. The rationale for the number must be clearly stated in your statistical model and protocol.

b. Vulnerable groups

Please clearly state whether any of the subjects are from a vulnerable population (refer to *Policy and Procedures*). Vulnerability will have implications for the viability of the study, access to subjects, insurance and other matters.

c. Inclusion and exclusion criteria

Please clearly describe the criteria used to determine who is eligible/ineligible to take part. This might take into account existing medical or other conditions, age, gender, socio-economic circumstances etc.

d. Inducements or rewards for participation

Please indicate whether or not subjects will be offered any financial or equivalent inducements or rewards. If these are to be offered, you must ensure that they are commensurate with the commitment from or inconvenience to those taking part. They should not be sufficiently large that they are likely to cause potential subjects to be attracted to take part in the study for financial gain.

e. Recruitment

How and where subjects are to be recruited are important. Are they to be recruited in the workplace, at school/university or on the street/at home? Who will recruit them? How will they be identified and how will their contact details be accessed? How will you make contact (please also refer to section 12 – consent form and information sheet).

8. Ethical implications

This is your opportunity to describe the ethical implications of the research. There is a great deal of information available about research ethics (see the full text policy and procedures and Ethical Consideration Guidelines). The usual concerns are about the risk to subjects (and researchers) of discomfort, pain and emotional upset. Vulnerability, information and consent, follow-up contact and treatment are also issues raised by ethics committees.

Please think carefully about your project and discuss it with others to try to identify the ethical issues and, where possible, find ways to deal with them. A change of approach or even, in some cases, a change of wording might be sufficient.

You should note that where there are serious and/or insurmountable ethical issues or objections, it is likely that the study will be denied permission to proceed.

9. Informing subjects' GPs

Please consider whether subjects' GPs should be informed of their involvement and also of any outcomes (with the subject's permission, of course). Your study might show an undiscovered underlying condition and there could be implications for treatment. You might also find that a subject has a pre-existing condition that is not compatible with the study.

10. Risk Assessment

Most studies will carry some risk. This might be relatively minor or it might be serious and substantial. The research proposal should demonstrate that the benefit expected outweighs the risk-exposure. The benefit may be partly or wholly educational. An ethics committee might not approve a study that is perceived to be high risk if the risk is not controlled. Please assess your proposed study for risk – this might be to do with potential harm to the subject, the investigator or the institution. You should try to remove as much risk as possible. Likewise, you should try to maximize the possible benefit, through dissemination of findings and consideration of implementation of systematic improvement.

11. Precautions

Where an element of risk remains, you should take measures to address it. This might include having qualified first aid or paramedical staff in attendance, the provision of a helpline number, access to a counselor or even a hospital, the provision of mobile phones for researchers working alone in the community etc.

Risk and the associated precautions are closely linked to the ethical implications of the study and should be thought through in the same way.

12. Consent

As this is a study on human subjects, you will probably need to seek and obtain subjects' consent before proceeding. You must provide complete information on the study, using language that the subjects will readily understand. You should not use jargon and technical terminology. Remember that the average reading age of the population is approximately that of a nine year old child and 25% are functionally illiterate so you should be prepared to give an oral description of the study and the consent process.

Guides on plain English are available to help you. You must ensure that a potential subject understands what is expected of them before inviting them to sign the consent form. If they decline, you must not persist.

Separate guidance on preparing a **subject information sheet** and **consent form** is provided in Appendices 3 and 4.

13. Personal information

Please remember that personal information is protected by the Data Protection Act. However, access to information (other than personal data) can be requested under the Freedom of Information Act. You will be expected to store raw and processed data securely but also to make it accessible to those with a legitimate requirement to view it (for example, the Data Protection Officer or the funding body).

You must provide details of how long data will be retained for and how it will be disposed of at the end of the study.

14. Copyright

If permission has not been granted to use all copyright materials the reason should be clearly stated.

If copyright materials have been modified in any way please state in the text box whether or not permission has been granted by the copyright holder.

15. Checklist

Please complete the checklist to confirm that you have submitted all the necessary items with your application. If you do not complete the checklist or if any items are missing, the application will be returned to you without any review having been carried out.

Appendix 1

Writing and presenting a project description/protocol

Research project descriptions/protocols will vary between disciplines, but will generally contain similar categories of information. These are likely to be:

- Background
  This section should provide basic information such as what the study is about and why it is being undertaken. 200 - 300 words should be enough to convey the information required although there might be exceptions to this for particularly complex or novel research. The background might include a short review of relevant key literature

- Aims/hypotheses
  This information can be presented as a series of short numbered or bullet points, and should list clearly the aims of the research. Again, 100 – 200 words should be sufficient.

- Methods/procedures
  A description of how the research will be carried out must be provided. This might be written as a series of chronological stages (e.g., step 1, step 2 etc) or as a narrative. This section must contain sufficient information, presented in a logical way, for those reviewing the research to be able to understand what you are proposing to do and how and when you will do it. If there are separate stages in the study, you should divide them up clearly, but also describe the relationship between them. It is expected that this section will contain information on technical aspects of the study, but it should be written in such a way that non-experts can understand it. For studies with a quantitative element your proposed statistical model will also be relevant to this section. It is expected that this section will be up to 1000 words long.

- Data analysis
  This section should be used to describe how the data you have obtained will be analysed. It should relate to the methods/procedures and to the aims. It is expected that the aims of the study will be realized fully only if the methods/procedures are carried out properly and the data analysed correctly. Again, the proposed statistical model will be relevant.

- Resources
  It is helpful to consider, identify and justify the reasonable human, physical and financial resources that will be required to initiate, recruit, analyse, report and reach a satisfactory conclusion to the study.

- References where appropriate
  Most research is not entirely novel and it is likely that some previous work will have been conducted in related areas. This means that there will be some existing relevant literature that provides additional background or supports your methodology. A short list of references will help reviewers to determine the validity and viability of your proposal and the approach you have chosen.

Overall, the document must be clearly and logically presented and, crucially, must contain sufficient information for a meaningful review to be conducted. It should be an absolute maximum of six sides of A4 and should be single spaced with an 11-point font or larger.

Please remember that this description is also the protocol for your study. This means that it illustrates an agreed version of how you will conduct the study and, once reviewed, revised, approved and recorded, it must not be changed without seeking advice and permission

If you are a student researcher, your supervisor will be able to provide you with advice and possibly even sample documentation.

Appendix 2

Preparing a statistical model

The following is an aid to researchers completing the University's ethics application form and associated documentation.

1. **Outcome measures**

What is/are the primary outcome measure(s) for the study; i.e. what is being tested, why and how?
What, if any, is/are the secondary outcome measures(s)?
Are the measures Nominal, Ordinal, Interval or Ratio?

2. **Sample size**

Has a formal power calculation been done to determine sample size? Yes or no?

If ***yes***, please give details of how this was done, e.g.

- The numerical difference the study is powered to detect
- The justification for choosing this difference and whether it has any clinical, as opposed to statistical, significance
- Details of any assumptions made in the power calculations, e.g. baseline rates, effect size in previous studies and standard deviations
- The power of the study to detect this difference e.g. 80%, 90% etc
- The statistical level being tested, e.g. 5%, 1%
- Allowance made for non-response, dropouts, incomplete records

The actual calculations of the sample size MUST be included in the application.

If ***no*** or ***n/a,*** please explain how the size of the study was determined and why a formal sample size calculation is not required or not possible.

If tabular analysis is to be the main method of analysis, please give the calculations of how the number of the smallest cell was estimated.

3. **Method of analysis**

Describe the statistical methods and/or other relevant methodological approaches to be used in the analysis of the results taking into account the level of measurement. If quantitative, are descriptive and/or inferential procedures/tests to be used and, in the case of inferential statistics, will they be parametric or nonparametric tests. Please justify the choice and the level of significance being used to test null hypothesis. Similarly, in the case of qualitative analysis, what procedures will be used and why?

4. **Data collection**

Copies of the proposed data collection forms, record sheets, questionnaires, etc must be attached to the application.

Appendix 3

Preparing a Subject Information Sheet

The subject information sheet is a vital component of the study. It forms the basis of the consent process and represents the best opportunity to explain the study to the potential subjects/ participants (and also to non-expert members of an ethics committee).

The subject information sheet must be presented logically and in plain English (translated where appropriate for use with other language groups). Jargon and technical terminology should be avoided unless it is explained carefully. Remember that the average "reading age" of the general population is around 9 years (year 5 of primary school). Your study might involve professional people or students who will have the ability to comprehend more complex presentation, but you should always aim for the simplest way of expressing your message.

The information provided should be structured as follows:

1. Study title
   Is the title self-explanatory to a lay person? If not, a simplified sub-title should also be provided.

2. Invitation paragraph
   Remember that you cannot expect or require people to participate; they must be asked or invited. For example:

   You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information and do not hesitate to ask any questions about anything that might not be clear to you. Make sure that you are happy before you decide what to do. Thank you for taking the time to consider this invitation.

   If the study is part of an academic qualification this should be stated.

3. What is the purpose of the study?
   The background to and aims of the study should be set out here in clear language. You should include a description of the product, procedure, hypothesis or idea that is being researched.

4. Why have I been chosen?
   You should explain how the potential subject was chosen and also how many others will be involved in the study.

5. Do I have to take part?
   It should be made clear that participation is entirely voluntary. For example:

   It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep. You will also be asked to sign a consent form. If you choose to take part, you can change your mind at any time and withdraw from the study without giving a reason.

6. What will happen to me if I take part?
   This is probably the most important section to the potential subject. They will want to know where they will have to go, when, how often and what will happen when they are there. They will also want to know who will be carrying out the research and whether anyone else will be there. You should consider using a step-by-step guide or simple flow chart. If subjects are expected to maintain any documentation (e.g. food diaries or other self-assessments) you must make this absolutely clear. All interventions must also be

clearly described, including those of a physical nature (exercise, blood or other sampling, x-rays) and others (interviews, questionnaires, focus groups etc). Do not underestimate the commitment required by subjects, as this will probably lead to disaffection and drop out.

You might also wish to set out the methods to be used. The approach will depend upon the particular discipline (life sciences, social sciences, etc) and further appropriate advice should be sought from researchers in your own academic area.

7. What do I have to do?
You should explain any dietary or lifestyle restrictions and also any potential risks associated with deviating from the restrictions.

8. Are there any alternative interventions?
If the study is a therapeutic intervention (e.g., in Health Sciences, Psychology, Biomedical Sciences) you should make clear what, if any, alternatives are available.

9. What about side effects?
Possible side effects should be explained. These might be physiological or psychological/emotional depending upon the type of study. Contact names, addresses and telephone numbers for use in case of queries and/or emergencies must be provided if there is any possibility that they will be needed.

10. Risks and/or disadvantages?
These should be made clear. They should be considered alongside the exclusion criteria for the study and might include both psychological and physiological factors. Particular attention should be paid to a potential subject's medical or other relevant history and to any existing conditions or status (for example, medication, other treatment, physiological, psychological/psychiatric or other conditions and, of course, pregnancy). Sensitivity must be used in your approach to this information. At this point, particularly in certain physiological studies, you might also wish to ask a potential subject for permission to contact their GP either prior to the study or with information on outcomes, where appropriate. Implications for future life insurance and existing private medical cover should also be explored where appropriate.

11. Are there any possible benefits in taking part?
Potential benefits, both to the subjects and to others in the future, should be stated but not over-emphasised. Where no benefits will be experienced by the subjects, this should be made clear.

12. What if new information becomes available?
You should inform potential subjects that if new information becomes available during the course of the study, they will be kept informed and any options or requests/requirements fully explained. You should let them know that new information could result in termination of the study, withdrawal of certain participants or modification/amendment.

13. What happens when the study ends?
You should describe what will happen at the end of the study, particularly if some form of treatment or therapeutic intervention is being provided or if the study is long-term or includes significant contact between the researcher(s) and the subject(s). If follow-up support or treatment is required/available, this should be made clear.

14. What if something goes wrong?
It should be made clear to subjects that it is very unlikely that anything will go wrong, but any risks should be quantified for them as far as possible. It should also be made clear that the University has procedures in place for reporting, investigating, recording and handling adverse events. Subjects should be informed that any complaints will be taken seriously and should be made to the appropriate authority. This might be the Chief Investigator, the University or other organization, depending upon who is involved in the research.

The University or other organization will provide an indemnity statement for research that has been approved through the appropriate governance and ethical review processes.

15. Will my taking part in this study be kept confidential?
You should explain that data will be held securely and in confidence and that any identifiers will be removed prior to publication as required under Data Protection legislation. However, you should also make it clear that Freedom of Information legislation will allow access to certain non-personal or generalized data. You must also indicate that, depending upon the type of study, disclosure of personal information might be either desirable or required. For example, it might be in a subject's best interests to have certain test results passed, with their consent, to their GP. It should also be borne in mind that where criminal behaviour likely to harm others is disclosed, the researcher has a duty to report this to the police.

16. What will happen to the results of the study?
You should describe to the subjects what will happen to the results. Will they be published and, if so, when and where? Will they lead to further research or directly to improvements/changes in procedures, treatment, established practice?

17. Who is organising and funding the research?
You should include details of the organisations directly involved and, for those who are interested, provide some general details on the funding arrangements.

18. Who has reviewed this study?
You should indicate that study has been reviewed by other people who are knowledgeable in the subject area and/or by a review committee/ethics committee in accordance with the University or other procedures. You should inform subjects that they can contact the University Research Governance section for further details if they require them.

19. Contact details
You should provide contact details for people who are likely to be available and who will be able to provide information associated with the study.

Appendix 4

Preparing a Consent Form

A sample consent form is provided below. It is simple and straightforward and must, of course, be used in conjunction with the subject information sheet.

Consent Form

_____

Title of Project

_____

Sub Title where appropriate

_____

Name of Chief Investigator

	Please initial
• I confirm that I have been given and have read and understood the information sheet for the above study and have asked and received answers to any questions raised	[ ]
• I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my rights being affected in any way	[ ]
• I understand that the researchers will hold all information and data collected securely and in confidence and that all efforts will be made to ensure that I cannot be identified as a participant in the study (except as might be required by law) and I give permission for the researchers to hold relevant personal data	[ ]
• I agree to take part in the above study	[ ]

_____ _____ _____

Name of Subject ***Signature*** ***Date***

_____ _____ _____

Name of person taking consent ***Signature*** ***Date***

_____ _____ _____

Name of researcher ***Signature*** ***Date***

One copy for the subject; one copy for the researcher.