RESEARCH ETHICS COMMITTEE GUIDANCE NOTES

On Completing the Application Form

Version No: 4.0
Effective Supersedes: 3.0
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1 INTRODUCTION

The function of the NUI Galway Research Ethics Committee is to safeguard the health, welfare and rights of human participants and researchers (in the case of hazardous materials) in research studies and to afford dignity to the handling and treatment of biological materials, taking into account the scientific procedures and concerns of the local community. For any research proposal to gain ethical approval it must be necessary and of a design that minimises predictable risk to both the research participant and the researcher.

The NUI Galway Research Ethics Committee aspires to provide timely, comprehensive and independent reviews of the ethics of proposed studies, acting in accordance with the Declaration of Helsinki, statements of appropriate ethical practice produced by relevant professional organisations, following International Good Practice Guidelines, relevant EU Directives, National Guidelines and National legislation pertaining to the ethical conduct of research, and acting in good faith with respect to both applicants and the community. Through its operation, the NUI Galway Research Ethics Committee would hope to provide NUI Galway researchers (staff and students) with the resources for understanding and addressing ethically significant problems which might arise in their research and to promote responsible research and practice.

2 COMPLETING THE APPLICATION FORM

Research involving human subjects requires prior approval by the NUI Galway Research Ethics Committee (REC). Applications to the NUI Galway Research Ethics Committee (REC) must at all times be submitted on the designated Application Form. The application form and guidance notes can be downloaded from the Research Ethics Committee website or may obtained in hardcopy from:

NUI Galway Research Ethics Committee
Office of the Vice President for Research
NUI Galway
Web: http://www.nuigalway.ie/research-office/documentationpolicies/researchethicscommittee/
Email: ethics@nuigalway.ie;

It is essential that you complete the checklist on the front of the application form and enclose the relevant documents. Forms must be typewritten. Incomplete forms cannot be considered by the REC.

If you are in any doubt about the application, then a letter to the Chairperson, NUI Galway Research Ethics Committee (c/o Office of the Vice President for Research) should resolve the matter. All enquiries should be processed through the Secretary, NUI Galway Research Ethics Committee (c/o Office of the Vice President for Research, NUI Galway).

2.1 Submitting the application

Applicants are requested to submit one electronic copy (single PDF document) and one hard copy (typed and containing original signatures) of the complete application.

In addition to the completed Application Form, the applicant should include: Protocol (3 to 4 sides of A4) and the Principal Investigator’s CV (on a maximum of two A4 sheets). Supplemental material should also include, where relevant, Questionnaires, Participant Information Sheets, Consent Forms, Advertising Materials and any other material relevant to the application. This supplemental material should be combined with the application form in the single PDF document to be submitted electronically and in hard copy. Please note that all materials relating to the application should carry the NUI Galway logo.

Only one copy of a drug company complete protocol is required and will be retained by the NUI Galway Research Ethics Committee.
On receipt of the Application form the application will be allocated an REC Reference number as quickly as possible, which will be sent to the Principal Investigator with the acknowledgement of receipt. Investigators should quote this number in all further correspondence relating to the application.

In cases where there are other institutions/organisations involved in the study, apart from NUI Galway, details of each institution/organisation involved, the nature of their involvement and the signature of a representative of each institution/organisation must be appended to the application form.

2.2 Annexes to the application form

ANNEX 1 Must be completed if the study involves the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence.

ANNEX 2 Must be completed if the study involves the use of ionising or non-ionising radiation, radioactive substances or X-rays.

ANNEX 3 Must be completed for each procedure that involves risk to the participants other than trivial risk.

2.3 Additional Guidance Notes

APPENDIX 1 Writing a Participant Information sheet.

APPENDIX 2 Sample consent form.

APPENDIX 3 Consent to participate in medical research.

APPENDIX 4 Consent checklist for investigators.

2.4 Risk Assessment Form – Procedures for involving Human Subjects

An important part of the application for ethical approval is the completion of the Risk Assessment Form (Annex 3) by the assessor, who is the Principal Investigator and thus should have competence in the research area under investigation. The Risk Assessment Form should be completed with particular reference to the study to be competed.

The form requires the assessor to identify all of the risks to human subjects associated with the study. It is the assessor’s responsibility, as the person most familiar with the study, to identify all reasonable risks associated with the investigation. Where the research project involves a number of risks to participants, a separate Risk Assessment Form should be completed for each risk.

The assessor should then identify, in some detail, what measures have been taken to reduce those risks or minimise their effects to an acceptable level. This might include identification of the equipment to be used and confirming its compliance with the relevant standards, or might indicate the number of persons to be present during the investigation to ensure subject safety.

In some cases Risk Assessment Forms may already exist for some procedures associated with the study but in any event a full risk assessment of the overall study needs to be carried out.

Any risks identified in the Risk Assessment Form need also to be highlighted in the Subject Information Sheet to ensure that subjects are aware of the risks that are involved.

Copies of the Risk Assessment Form are available (either electronically or in hard copy) from the Secretary, NUI Galway Research Ethics Committee, c/o Office of the Vice President for Research.
3 NOTES ON COMPLETING THE APPLICATION FORM

The application form should describe the study in plain English, so that members of the REC not specialising in scientific study will be able to assess the significance of the research and the associated ethical issues.

Most of the application form is considered as straightforward to complete; notes are therefore not provided for every question. The REC welcomes advice from users about improvements of its guidance notes or application forms.

Section 1 – Applicant(s) Details

1. The Project title should be descriptive of the research work to be carried out, and should, where the project is being funded, be identical to the title used in the application for funding.

2. The Principal Investigator is deemed responsible for the accuracy of the information contained in this application. Where the Principal Investigator is not a permanent academic member of the university, the responsibility for accuracy of information and submission of Report Forms will lie with the relevant Head of Department.
   Please give a contact telephone number in case the REC assessor wishes to discuss aspects of the application to assist processing.
   Please provide a CV (max. 2 A4 pages) for the Principal Investigator.

3. Other Investigators are collaborators who have a significant input into the design and conduct of the study outlined in this application.

4. Other workers include technical staff, students, and medical/paramedical personnel etc. who will carry out some part of the study described here under the supervision of the Principal and/or Other Investigator(s).

5. Please give a start date and end date for the research work (there will normally be the start and end date of a funded project).

6. The main applicant should sign, together with the relevant head of department or supervisor (in the case of a post-graduate student).

Section 2 – Study Details

Members of the REC should be able to review the project from the details given on the application form. It is not sufficient to enter “refer to protocol”. However, one version of the complete protocol should be sent in as indicated on the Checklist in order that members can refer to this in cases of uncertainty.

7. Please state clearly the hypothesis that this research is intended to test, or the question it is expected to answer.

8. A brief synopsis of the relevant research in this area should be given. A limited number of key references should be cited.

9. Describe briefly how you intend to conduct the study. This should comprise a summary of the detailed study plan appended to the application. The REC members should be able to understand in broad terms what you intend to do, from this description.

10. Where a risk analysis of the proposed research project has identified some risks to participants, please list these here and complete a Risk Assessment Form (Annex 3) for each risk.

12. Details should be given as to how the size of the study was determined; this should usually include a formal
Section 3 – Recruitment of participants

This section should outline for the REC the methodologies that you plan to use in the recruitment and selection of participants. From the information you provide in Section 3, the REC should:

- clearly understand how you intend to recruit volunteers
- clearly understand what criteria will be applied to the selection of participants and to the exclusion of participants for the study
- be assured that participants will not be pressurised in any way to participate in the study.

Copies of recruitment materials should be appended to the Application Form (advertisements, participant information sheets, posters etc).

Section 4 – Consent

Elements of informed consent

Informed consent must include the following elements:

a) A statement that the protocol involves research; an explanation of the purposes of the research; the expected duration of the participant’s participation; a description of the procedures to be followed; and identification of any procedures, drugs or devices which are experimental.

b) Description of any reasonably foreseeable risks or discomforts to the participant.

c) Description of any benefits to the participant or to others that may reasonably be expected from the research, including payment or free treatment.

d) A disclosure of appropriate alternative procedures or courses of treatment, if applicable, that might be advantageous to the participant.

e) A statement confirming confidentiality of participant records and limits of that confidentiality.

f) A statement as to whom to contact (an individual) for answers to pertinent questions involving the research and research participant’s rights to contact in the event of a research-related injury to the participant.

g) A statement similar to “participation is voluntary” or “you may choose not to participate” and a statement that refusal to participate, or discontinuing participation at any time, will involve no penalty, loss of benefits or denial of treatment or services.

26. Written consent must be obtained for all human studies. A copy of the consent form to be used must be enclosed. If written consent is not to be obtained, a full explanation must be given.

28. If a significant proportion of participants do not speak or read English, special arrangements should be made to inform and include them.

29. Participants (or their carer) should receive a written information sheet. This should be separate from the Consent Form. The Participant Information Sheet should be written clearly, in plain English. Appendix 1 of these Guidance Notes contains information on writing a Participant Information Sheet.

30. Involvement of children and participants with a mental disorder or understanding difficulty requires special consideration. With regard to children, consent must usually be obtained from both the child and the child’s legal guardian (which is obligatory). Children have a right to withdraw their consent at any time, regardless of the fact that their legal guardian has given consent. Ensure that GPs and other doctors, where relevant, are fully informed about their patients’ participation. If there are problems with consent because the study groups falls into the above listed categories, the relevant details must be provided.
Particular care should also be taken for participants who are in a position of dependency for other reasons. This includes those who could feel under obligation to participate (e.g. students, patients of the investigator, junior staff, prisoners).

31. Guidelines for research on women of childbearing potential. The REC recognises the importance of undertaking research in diverse population groups including women of childbearing potential. However, there is a need for special care with invasive or other intervention studies in this group because of possible hazards to the potential fetus. In order to minimise any risk, the REC requires that the following 8 questions be considered before it will give permission to perform invasive or other intervention studies involving women of childbearing potential.

A. Does the nature of the study justify involving women of childbearing potential?
B. Has toxicological and pharmacological testing in animals or humans, performed to date, failed to produce any evidence that the study drug or other intervention may be teratogenic?
C. Is there a clear warning in the participant information sheet that the effects of the study drug or other intervention on a fetus are unknown but that they may be damaging?
D. Is a pregnancy test to be performed immediately before the study begins?
E. Are forms of contraception allowed (and those forms which are unacceptable) specifically stated in the research protocol?
F. Is there a clear indication in the participant information sheet that effective contraception must be practised during and for a time (corresponding to drug elimination kinetics or other relevant intervention timeframe) after the trial?
G. Does the study exclude any woman whom the investigators feel is unlikely or unable to follow contraceptive advice?
H. Is there a statement that if the participant becomes pregnant, or thinks she may be pregnant, she should contact the study doctor immediately?

Section 5 – Details of interventions

An Information Sheet should be given to the participant’s general practitioner if a drug is given or an invasive procedure is undertaken. Justification must be given if this is not to be done.

32. If the study involves the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence, ANNEX I of the application form must be completed and returned with the application form. Please note that many medical devices are subject to similar regulations to those of new drugs. All medical devices must meet the appropriate safety regulations.

33. If blood and/or tissue samples are taken, consideration must be given to whether they will be destroyed when the study is complete. If they are to be retained, participants must be informed. Additional ethical approval will be needed for any further studies using these samples.

34. If the study involves the use of ionising or non-ionising radiation, radioactive substances or X-rays, ANNEX 2 of the application form must be completed and returned with the application form.

Section 6 – Risks and ethical problems

36. Careful and realistic consideration must be given to any potential risks or hazards to participants, the likelihood of these occurring and the steps taken to deal with these issues. This will include side effects and adverse effects resulting from treatment or study evaluation.
37. Consideration must be given as to the potential discomfort or distress, psychological or physical, caused to participants.

Where a risk or risks are identified, an important part of the application for ethical approval is the completion of the Risk Assessment Form (Annex 3) by an assessor who is the research supervisor or principle investigator and thus should have competence in the research area under investigation. The Risk Assessment Form should be completed with particular reference to the Study to be completed. Approval, by signature, of this completed Risk Assessment for by the Head of Department/Institute/Centre where the work is to be carried out, is required.

The form requires the assessor to identify all of the reasonable risks to human subjects associated with the study. The assessor should then identify, in some detail, what measures have been taken to reduce those risks or minimize their effects to an acceptable level. This might include identification of the equipment to be used and confirming its compliance with the relevant standards, or might indicate the number of persons to be present during the investigation to ensure subject safety.

The form must be signed by the assessor and the relevant Head(s) of Department/Institute/Centre. Signature by the relevant Head(s) is important as the Head(s) is/are the line manager(s) with responsibility for the activities of the Department(s)/Institute/Centre and must thus be satisfied that the risks associated with the investigation are low or have been reduced to an acceptable level.

In some cases Risk Assessment Forms may already exist for some procedures associated with the study but in any event a FULL assessment of the overall study needs to be carried out.

Any risk identified in the Risk Assessment Form must also be highlighted in the Participant Information Sheet, to ensure that participants are aware of the risks that are involved.

Separate copies of the Risk Assessment Form are available to download from the Ethics Committee website [http://www.nuigalway.ie/research/vp_research/ethics.htm](http://www.nuigalway.ie/research/vp_research/ethics.htm) or may be obtained from the Secretary.

Section 7 – Indemnity

Suitable indemnity cover is a requirement for every study submitted to the NUI Galway REC for consideration. While the NUI Galway Professional Indemnity Cover will cover the majority of studies, the policy may not cover all studies, or elements of studies. Investigators should carefully view the University Indemnity Policy to ascertain if their study is covered in full or in part. (Please contact Sinead.OConnor@nuigalway.ie for further information). In cases where the study, or parts of the study, is not covered by the University Indemnity Policy, investigators are required to provide evidence of indemnity in writing. Possible sources are the individual, Health Service Executive Regions or commercial companies (if appropriate). It is the responsibility of the Principal Investigator(s) to ensure that indemnity arrangements are in place before the study begins.

Where more than one institution/organization is involved in a study, each institution/organization is responsible for providing its own indemnity, and written confirmation of such cover must be appended to the Application Form.

In the case of drug studies commercially sponsored, confirmation of acceptance of ABPI guidelines by the company must be provided before the NUI Galway REC will consider the Application.

Section 8 – Confidentiality

Please give details of any additional steps to be taken over and above the requirements of the Data Protection Act.
42. Special precautions are needed in the case of the use of audio or video recording to ensure confidentiality and anonymity.

43. If medical records are to be examined, participants should be reassured that only information directly relevant to the study will be extracted.

44. It is the responsibility of the main investigator to ensure that research workers outside the employment of NUI Galway are fully aware of the need for confidentiality of information about and from participants.
APPENDIX 1: Writing a Participant Information Sheet

All research involving human participants should be described in a Participant Information Sheet. This sheet is given to participants when they are invited to participate and should be retained by them. Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. The Participant Information Sheet should form part of the application to the NUI Galway Research Ethics Committee. The Information Sheet should be separate from the Consent Form (see Appendix 2).

The scope and depth of the Participant Information Sheet will vary depending upon the scale and type of research activity. However, regardless of the complexity of the research proposal or the degree of involvement of participants, there are a number of common guidelines that should be applied.

Use headed paper of the institution where the research is being carried out. Always include the contact details of the Principal Investigator.

General

Anything to be read by a participant in a research project should be written in simple, non-technical terms and be easily understood by a layperson. Use short words, sentences and paragraphs. Technical terms and jargon should be avoided. Any necessary simplification should not have the effect of understating any risks or of glossing over inconvenience or discomfort. The provision of a Participant Information Sheet is not a substitute for talking to the participant.

Different study groups may require separate information sheets. For example children and 'compromised' adults will require suitably worded information sheets.

The Participant Information Sheet should always contain statements on the following:

a) The purpose of the investigation, the nature of the procedures, the risks (including psychological distress) and the possible benefit to the individual or to society.

b) A statement that the participant may decline to participate without giving reasons or incurring displeasure or penalty.

c) A statement that the participant will be free to withdraw at any time without giving a reason and without incurring displeasure or penalty.

d) Where the Research Ethics Committee considers that the risks of any intervention warrant it, a statement about the availability or non-availability of compensation for injury.

e) An invitation to ask for more information.

Part 1: Introduction

1 The information sheet must include the title of the study and state that it is a Participant Information Sheet. Is the title self-explanatory to a layperson? If not, a simplified title should be included.

2 The objective of the study should be clearly stated.

Part 2: Invitation to take part in the study

This should explain that the participant is being asked to take part in a research study. The following is a suitable example:
You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This Participant Information Sheet will tell you about the purpose, risks and benefits of this research study. If you agree to take part, we will ask you to sign a Consent Form. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision.

Thank you for reading this.

[Note: The fact that approval has been granted by a Research Ethics Committee or by the Irish Medicines Board should not be referred to in any way that may cause potential volunteers to think that the project is specially recommended or is safe.]

Part 3: Purpose of the Study

The background and aim of the study should be given here. Also mention the duration of the study. Avoid being technical or using unexplained abbreviations. It should ideally have one sentence each covering:

1. the general subject of the research
2. what question the study is designed to answer
3. why this person has been asked to participate
   (You should explain how the participant was chosen and how many other participants will be studied)
4. how this person has been identified or contacted for the study

Example:
Our study is looking at the effect that participating in competitive sport has on breathing and lung function. In particular, we are interested in people between the ages of 30 and 45 years old. You have been asked to take part because you have been participating in competitive sport for a significant period of time. We wish to measure your lung function so that we can compare it with people who do not participate in competitive sport.

Part 4: Taking part – what it involves

The section should clearly state what taking part in the study will involve for the participant. Potential risks should not be understated or misrepresented as less serious than they are. The following questions are some of the things that should be covered in this section:

Do I have to take part?

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:

*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 and be asked to sign a consent form. If you 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 in any way.*

What will happen to me if I take part?

You should explain what exactly will happen e.g. interviews, blood tests, x-rays etc? Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit (if appropriate).

What are the participant’s responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use e.g. survey, questionnaire, randomised trial etc, providing a simple definition of the methodology may help.
How long will my part in the study last?

You should say how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to visit your office or laboratory (if this is appropriate) and how long these visits will be.

What do I have to do?

Are there any lifestyle restrictions? You should tell the participant if there are any dietary restrictions. Can the participant drive, drink, take part in sport? Can the participant continue to take their regular medication? Should the participant refrain from giving blood? What happens if the participant becomes pregnant?

What is the procedure being tested?

Where appropriate, you should include a short description of the device or procedure and give the stage of development.

What are the possible benefits in taking part?

Point out benefits the participant can get from participating. For example, if the study includes an assessment of cardiovascular fitness, the participant will be able to learn more about their own fitness level.

What are the possible disadvantages and risks of taking part?

If there are no foreseeable risks attached to taking part, say so here. If there are, it is very important that you state what they are and how you plan to a) safeguard the participant and b) deal with anything that might happen. Note that your study protocol must include a description of how you will deal with problems that could arise.

Example:

Study includes a questionnaire that measures depression and anxiety

The study includes a questionnaire that measures your well-being in the recent past. You might find, while you are answering it, that you would like to talk to someone about some of the issues it raises. We will be happy to recommend someone to you.

[Note: if you are carrying out research, you must avoid getting involved yourself with the participant’s problems but you should be able to refer them for appropriate help. These sources of help or onward referral must be planned in advance of commencing the study.]

For studies where there could be harm to an unborn child if the participant were pregnant or became pregnant during the study, the following (or similar) should be said:

It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if a treatment used in the study could damage sperm, which might therefore lead to a risk of a damaged fetus.
If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part, this should be stated (if e.g. high blood pressure is detected.)

You should state what happens if you find a condition of which the participant was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

**What are the side effects of any treatment received when taking part?**

Where appropriate, you should explain to the participants any possible side effects. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

**What if something goes wrong?**

Where there are potential side-effects or adverse events attached to the study, or where a risk has been identified, the information sheet should describe what measures are in place to deal with these, should they arise.

**What happens at the end of the study?**

You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which part of the study they were in? You might add that they will not be identified in any report/publication.

If a treatment has been administered, will the participant have access to this treatment after the study finishes?

**What happens if I change my mind during the study?**

You should make it clear to participants that they are entitled to change their mind about participation at any time during the course of the study without disadvantage or penalty to themselves.

**What if I have a complaint during my participation in the study?**

You should inform participants how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from participants as to their treatment by members of the research team and something serious happening during or following their participation in the research i.e. a reportable serious adverse event.

**Whom do I contact for more information or if I have further concerns?**

You should give the participant a contact point for further information. This can be your name or that of another researcher involved in the study.

The following standard paragraph should also be included:

*If you have any concerns about this study and wish to contact someone independent and in confidence, you may contact the Chairperson of the NUI Galway Research Ethics Committee, c/o Office of the Vice President for Research, NUI Galway, ethics@nuigalway.ie.*
Part 5: Confidentiality

You will need to obtain the participant’s permission to allow restricted access to any information collected about them in the course of the study. The information sheet should describe what happens to the information collected in the study and contain a statement assuring the participant that any information pertaining to them will be treated in the strictest confidence.

Example:
All information that is collected about you during the course of the research will be kept strictly confidential and will not be shared with anyone else. The information collected in this research study will be stored in a way that protects your identity. [If you are collecting sound or video recordings:] The recordings will be transcribed for analysis. We will store the original recordings securely for [length of time] after which they will be destroyed. Results from the study will be reported as group data and will not identify you in any way.

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in Ireland or in any other participating country, in the case of a multi-centre study. This is not the responsibility of the REC.

Part 6: Summary

This section should reiterate that participants should contact the researcher to clarify any points on which they remain unclear. Therefore, it should contain the name, address and telephone number of the person who should be contacted (the Principal Investigator or a designated individual).

It should emphasise again that the participant is free to refuse to take part in the study without any disadvantage and that should they agree to take part, that they can change their mind at any point during the study and decide not to continue in the study without any disadvantage.

Remember to thank your participant for taking part in this study!

The participant information sheet should be dated and given a version number.

The Participant Information Sheet should state that the participant will be given a copy of the information sheet and a signed consent form to keep.
APPENDIX 2: Sample Consent Form (Non-medical research)

(Form to be on headed paper)

Centre Number:
Study Number:
Participant Identification Number:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated .........................
   (version .............) for the above study and have had the opportunity to ask questions.

2. I am satisfied that I understand the information provided and have had enough time
   to consider the information.

3. I understand that my participation is voluntary and that I am free to withdraw at any
   time, without giving any reason, without my legal rights being affected.

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

Name of Participant               Date               Signature

Name of Person taking consent      Date               Signature
(if different from researcher)

Researcher                        Date               Signature

1 for participant; 1 for researcher; 1 to be kept with research notes
APPENDIX 3: Consent to participation in medical research

(Form to be on headed paper)

Centre Number:
Study Number:
Participant Identification Number:

CONSENT FORM

Form of consent by a participant volunteering to take part in medical research not associated with clinical treatment

I __________________________________________________________ (Full name)
of ______________________________________________________ (Address)
hereby fully and freely consent to participate in a study entitled:

I agree that my general practitioner may be notified of my participation in the study and that he/she may release information on my past medical history. I have informed the investigator of any drugs that I am presently taking.

I understand that I may withdraw my consent at any stage in the study. I acknowledge the purpose of the study and any risks involved in the study procedures. The nature and purpose of such procedures has been described to me in the Information Sheet and has been explained to me by:

(name of researcher)
and I have discussed these matters with him/her to my satisfaction.

Signed: ___________________________________________________
(Children between 8 and 16 years should, where capable, sign the consent form in addition to a parent)

Witness:

Date:

DECLARATION BY THE INVESTIGATOR

I confirm that I have provided an Information Sheet and explained the nature and effect of the procedures to the participant and that his/her consent has been given freely and voluntarily.

Signed: ___________________________________________________

Status: ___________________________________ Date:
APPENDIX 4: Consent checklist for investigators

In order to document consent, investigators might wish to complete the following checklist for each participant who agrees to take part in the research study.

*Questions marked with an asterisk (*) are relevant to medical research only.*

Research project name: __________________________________________ Date: ____________________
No.: __________________________ Participant name: ____________________________________________ Sex: M/F
DOB:

Name of investigator obtaining consent:

1. Have you given the participant an oral explanation of the proposed research project? Yes / No
2. Did your oral explanation to the participant include:
   1.2. Have you given the information sheet to the participant? Yes / No
   1.3. Have you told the participant that he/she will be kept informed of all relevant information that becomes available during the course of the study? Yes / No

2.1. that this is a research project? Yes / No
2.2. that participation is voluntary? Yes / No
2.3. the aims of the project? Yes / No
2.4. the likely duration of the participant’s involvement? Yes / No
2.5. the expected benefits to the participant and/or others? Yes / No
2.6. the expected nature of the drug, device or intervention being tested? Yes / No
2.7. the procedures which will be involved in participation? Yes / No
2.8. that the participant may instead receive a reference treatment or placebo?* Yes / No
2.9. what alternative standard medical therapy is available?* Yes / No
2.10. what risks, inconvenience, discomfort or distress may reasonably be anticipated for this participant: the level and the likelihood? Yes / No
2.11. that there may be some unforeseen risks? Yes / No
2.12. that a refusal to participate may be given without reasons and will not affect the participant’s rights or their right to care? Yes / No
2.13. that the participant may be withdrawn from the study if the study investigator considers this is necessary in the best interests of the participant? Yes / No
2.14. that personal information may be scrutinised during audit by competent authorities and properly authorised people, but all personal information will be treated as strictly confidential and will not be made publicly available? Yes / No
2.15. that information generated by the study may be published but that no details will be divulged from which the participant could be identified? Yes / No
2.16. that some such information will be retained for a period after the end of the trial? Yes / No
2.17. what compensation arrangements are available? Yes / No
2.18. whom to contact in an emergency and how? Yes / No
2.19. what activities, if any, must be avoided during participation (e.g. driving, operating machinery, drinking alcohol, sport, pregnancy, breast feeding), after participation (e.g. blood donation, participation in another trial) and for what period? Yes / No

3. 3.1. Has the participant given authorisation to you to inform his/her GP of the participants involvement in this study? Yes / No
3.2. Has the participant given permission for their GP to disclose medical information?* Yes / No

4. 4.1. Has the participant recently been involved in any other research studies relevant to the present one? Yes / No
5. 5.1. Is or has the participant been involved in any other research studies relevant to the present one? Yes / No
6. 6.1. Have you allowed the participant sufficient time to consider the matter on his/her own, to discuss with others if wished, or ask you questions? Yes / No
7. 7.1. In your opinion, has the participant understood and consented to take part in this research? Yes / No