

Guidance for completing the YNiC Research Ethics and Governance Form

1. INTRODUCTION

- 1.1 Neuroimaging differs from much other research with human participants in three ways: (1) It may be uncomfortable and stressful for participants. (2) It is expensive. (3) It may be hazardous unless procedures that protect the safety of participants and experimenters are followed.
- 1.2 The primary responsibility of the YNiC Research Ethics Committee (YNiC REC) is to protect participants from harm. Secondary responsibilities include contributing advice that helps YNiC to achieve high standards of research governance, health and safety, and value for money. To achieve those goals, the YNiC REC expects studies to have been planned carefully. Preparing an application for research ethics approval is an essential part of planning research at YNiC. Where members of the public are involved in research, the image of YNiC, the University of York, and scientific research in general are also at stake.
- 1.3 Applications to the YNiC REC take one of two forms:
 - 1.3.1 Type 1: An application for research that **does** involve patients or employees of the National Health Service. Research of this sort must have received prior approval from NRES. This type of application consists of five parts:
 - (1) the *NRES Application*,
 - (2) the *Information Sheet* for Participants approved by NRES,
 - (3) the *Study-specific Consent Form* approved by NRES,
 - (4) a *YNiC Advice of External Approval Form*,
 - (5) the *NRES Approval Letter*.
 - 1.3.2 Type 2: An application for research that **does not** involve patients or employees of the National Health Service. This type of application consists of three parts:
 - (1) a *YNiC Research Ethics & Governance Application Form*,
 - (2) an *Information Sheet* for Participants,
 - (3) a *Study-specific Consent Form*.
- 1.4 For an application of Type 2, the *YNiC Research Ethics & Governance Application Form* should be completed with sufficient detail for members of the Research Ethics & Governance Committee to understand the impact on participants of participating. Further guidance is given in Section 2 of this document.
- 1.5 The *Information Sheet* should provide information which a participant needs to know in order to give informed consent to participate. It differs from a set of instructions that may be given to a participant after consent has been received. Information sheets should be written in lay language, avoiding technical terms and abbreviations. Information sheets usually run to 2 or 3 pages. Detailed guidance is given in Section 3 of this document.

- 1.6 Participants must read and sign those YNiC consent forms that are relevant to the study in which they are consenting to participate. In addition, applicants should prepare a *Study-specific Consent Form*. Among other issues, a study-specific consent form should establish that potential participants have read the information sheet, have had the opportunity to discuss the study and ask questions, have received satisfactory answers to those questions, understand that they are free to withdraw from the study, and that they agree to participate. Detailed guidance on writing a study-specific consent form is given in Section 4 of this document.

Quentin Summerfield, Chair: YNiC Research Ethics Committee

4th October 2006

2nd March 2007 (revised)

14th March 2007 (revised)

Antony Morland, Deputy Director, YNiC

27th June 2007

31st July 2007

2. INSTRUCTIONS FOR WRITING AND SUBMITTING AN APPLICATION FOR YNIC RESEARCH ETHICS & GOVERNANCE APPROVAL

2.1 The process of submission

2.1.1 Information must be provided in lay language that is free from jargon, undefined technical terms, and abbreviations.

2.1.2 All of the required documents must be submitted together (Research Ethics & Governance Application, Information Sheet(s), Study-specific Consent Form(s)).

2.1.3 Documents **must** be submitted in **portable document format (.pdf)** to ethics.submission@ynic.york.ac.uk.

2.1.4 The submission should be accompanied by an e-mail message which confirms that all individuals named on the application have read and approved the application.

2.1.5 When the application has been approved, possibly after revision, applicants and PIs/supervisors will be asked to sign a paper copy of the application and lodge it at YNiC.

2.2 Check Boxes on front cover of the Research Ethics and Governance Application

Please ensure that all the check boxes on the front cover are checked. Failure to do so will mean the application will be returned without being assessed. **ALSO NOTE THAT THIS FORM MUST ONLY BE SUBMITTED AFTER YOU HAVE COMPLETED A PROJECT PROPOSAL FORM AND RECEIVED A LETTER RECOMMENDING HOW TO APPLY FOR A RESEARCH PROJECT AT YNIC.**

2.3 Section 1: The applicant

2.3.1 The *Applicant* is the person taking primary responsibility for writing and submitting the application, for answering questions about the application, and for revising the application, if necessary.

2.3.2 Be clear about the other investigators who are involved in the study. Give all of the details that are requested.

2.3.3 Please provide details of your relevant publications. Publications on research in areas other than neuroimaging may be included.

2.4 Section 2: Context

2.4.1 Date of Project Presentation & Project Proposal Outcome: usually investigators will have been asked to give a Project Presentation after completing the Project Proposal Form. Enter the date of the Presentation and indicate the outcome of the Proposal, which will have been communicated to you in a letter, whether or not a presentation was made.

2.4.2 Please provide details of the educational course that the study may be attached to. It is essential that all student investigators are included in the Section on The Applicant (Section 1).

2.5 Section 2: The Study

2.5.1 The YNiC REC needs to understand what will be done to participants and why. It is important therefore to provide a rationale for the study in Section 3.1. It is also essential that the hypotheses that the study will address a clearly set out in this section.

2.5.2 Insofar as neuroimaging is expensive and can be uncomfortable for participants, the YNiC REC is required to ensure that studies have been planned carefully. We want studies to produce clear-cut results while recruiting the minimum number of participants. Thus, the study is required to have an appropriate design, which must be described in Section 3.2. Also provide a careful justification for the planned number of participants and for the duration of

experiments. The YNiC REC will ask for revision of applications which have not justified the required number of participants. It is also important that investigators are clear about how they intend to assess the data they acquire and analyze them. Details of the statistical treatment of the data must be included. It will also be of great assistance to YNiC to indicate the software and tools that will be used to perform data analysis and the level of experience that applicants have in using these tools.

2.5.3 Timetable and Milestones (Section 3.3). It is essential that research projects are appropriately supported and to this end the duration of the study needs to be estimated and any deadlines associated with the study need to be declared.

2.5.4 Study resource requirements (Section 3.4). It is essential that each study provides details of how much scan time is required. This is the maximum amount of time that will be allocated to the project and no more can be used by investigators unless subsequent approval is obtained. It should be noted that many projects may receive preliminary approval that grants only a fraction of the requested time, so that the feasibility of the study can be determined. The figures provided must match those in the protocol submitted with the application. The remaining boxes in the section concern other resources that are required for the study and are important because they will determine whether the project is feasible or not.

2.6 Section 4: Participants

The methods to be used to recruit participants should be described. Note that third parties may be in breach of the Data Protection Act if they give the names and addresses of potential participants to a researcher. It is best for the third party to make contact with the potential participant to invite them to contact the researcher if they wish to learn about a study in which they might participate. Enter details concerning the inclusion and exclusion criteria, financial reimbursement, and whether or not you are testing participants recruited through the NHS.

2.7 Section 5: Funding

2.7.1 Sources of funding must be declared.

2.7.2 Any conflict of interest, or apparent conflict of interest, must be declared and discussed.

2.8 Section 6: Interventions, Hazards, and Risks

2.8.1 If your study involves any of the four procedures which are listed in the application form, you will need to explain the procedures and also the steps that you will take to ensure the safety and welfare of participants.

2.8.2 Studies should not put participants at risk of harm.

2.8.3 Applicants must explain what professional indemnity insurance is provided by their employer against claims for negligent harm. Section 3 of this document provides more information.

2.9 Section 7: Security of Data

Participants are entitled to confidentiality, and to know who will use their data and for what purpose.

- The steps that will be taken to ensure the security and confidentiality of data must be described.
- The people who will have access to the data must be named.

2.10 Section 8: Security of Biological Samples

Participants are entitled to confidentiality, and to know who will use any biological samples which they provide and for what purpose.

- The steps that will be taken to ensure the security and confidentiality of biological samples must be described.
- The people who will have access to the biological samples must be named.

2.11 Section 9: Consent and Debriefing

2.11.1 Consent: Competent healthy adult volunteers must give written consent to participation. Applicants should follow the advice in Section 3 for obtaining consent from the other groups of participants listed in the Application Form.

2.11.2 Debriefing: Applicants should state that they will answer participant's questions at the end of the study. If other steps are planned for disseminating the results of the study to participants (e.g. newsletters, summaries of results, talks at participants' schools or clubs), these intentions should be described. If a study has involved any degree of deception, the nature and purpose of the deception must be explained to participants no later than the conclusion of the data-gathering phase of the study.

2.12 Section 19: Secrecy

Any constraints on the conduct of the research or the way it is reported must be declared.

2.13 Section 11: Special considerations

This section provides an opportunity for an applicant to raise any issues that have not been addressed elsewhere in the form.

2.14 Section 12: Declarations

By submitting an application in electronic form, applicants and PIs/supervisors, confirm their agreement with the declarations in Section 12. When an application has been approved, possibly following revision, applicants and PIs/supervisors will be required to sign a paper copy of the approved version of the application and submit it to YNiC before starting the study.

3. GUIDANCE ON WRITING AN INFORMATION SHEET FOR A STUDY AT YNIC

The purpose of an Information Sheet is to explain to potential participants what will happen if they consent to take part in a study. An information sheet must have been read and understood before a participant gives consent. Before writing their information sheet(s), applicants should consult the documentation produced by NRES which can be found at <http://www.nres.npsa.nhs.uk/>

Information Sheets should state the brief title of the study. The footer of each page should carry the version number of the information sheet, should be labelled with the date when the version was created, and should include the page number (e.g. 'Page 2 of 3').

The YNiC REC will accept Information Sheets in two parts, as advocated by NRES, or in one part. Applicants should follow the relevant sections of the NRES guidance. For example, the YNiC REC would expect to see the sections that are discussed below in an information sheet intended for competent healthy adult volunteers. Applicants intending to write information sheets for other groups (e.g. children, parents/guardians) should study the NRES guidance.

Part 1

1. Study Title

It is recommended that the document be headed 'Participant Information Sheet'. One consistent title for the study should appear on all the documents and should be self-explanatory to a layperson. If acronyms are used in the title they must be spelled out in full the first time they appear. The title should not consist of an acronym alone.

2. Invitation paragraph

This should explain that the participant is being asked to take part in a research study. The following is an 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. Please take time to read the following information carefully. Talk to others about the study if you wish.'

- *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives you more detailed information about the conduct of the study. 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.*

3. What is the purpose of the study?

The background and aim of the study should be given here. The purpose should be brief but informative and should not mislead. It should be made clear if the study is a student research project. It is legitimate to express the hope that the results of the study will contribute to greater understanding of a problem that affects some other people, but applicants should avoid statements that imply that patients will benefit directly or that participants themselves will benefit from taking part.

4. Why have I been chosen?

You should explain briefly why the participant was chosen and how many other participants will be studied. It will generally be helpful to include a list of the main inclusion/exclusion criteria. For example:

We are seeking to recruit 16 adults with these characteristics

- *They are 18-30 years old.*
- *They are right handed.*
- *They have no problems with their hearing.*

More details are given in Part 2.

5. Do I have to take part?

You should explain that taking part in the research is entirely voluntary. The following is an example:

'No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason.'

6. (a) What will happen to me if I take part?

This paragraph should explain:

- How many times the participant will have to visit YNiC and any other location(s) at which the research will be carried out.
- How long these visits will be.
- What will happen during the visits. In this section it is vital to provide information about what it is like to be scanned. There are information leaflets (<https://www.ynic.york.ac.uk/information/participant-leaflets/participant-information>) that provide these details and they can be used as a separate document (that is, one of two elements of the information sheets). Alternatively the information from the leaflets can be inserted into your single information sheet.

6. (b) Payments to participants

If it is proposed to pay participants, the amounts should be described. Payment is not mandatory. Where payment is proposed, the YNiC REC considers it appropriate to reimburse participants (or their parents/guardians) for expenses incurred in visiting YNiC, and to pay participants (or their parents/guardians) at a rate similar to the minimum wage (e.g. about £5 per hour). Children should not be offered inducements to participate in research.

6. (c) Benefits of taking part in the research

Describe the benefits that will arise from taking part in the study. Benefits could include gaining fundamental new knowledge, developing new methods for research or treatment, and (where participants are healthy and competent) obtaining data with which to compare data obtained from patients.

7. What are the other possible disadvantages and risks of taking part?

Research at YNiC must be planned and conducted in a way that minimises the risk of harm to participants. Procedures for ensuring the safety of participants during MRI in respect of the high magnetic field and the high sound levels must be understood by applicants and must be followed. This section should address the steps that the applicant will take to minimise any sources of stress or discomfort arising from, for example, claustrophobia and isolation, the high sound levels during MRI, the commitment to lie still for the duration of the experiment, dis-equilibrium and/or mild nausea on entering or leaving a strong magnetic field. This section should also explain two other requirements: first, that participants

must not carry ferromagnetic materials with them when being scanned; second, that it will not be possible to scan some groups of people (e.g. those with metal implants including dental braces, pacemakers, cochlear or brainstem implants, or those who have any other surgical implants containing metal; pregnant women).

8. What if there is a problem?

If the applicant is writing a 2-part information sheet, then a short statement could be given here, e.g.

'Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed'. The detailed information on this is given in Part 2.'

If the applicant is writing a 1-part information sheet, then the material set out in Section 13 below should be included.

9. Will my taking part in the study be kept confidential?

If the applicant is writing a 2-part information sheet, then a short statement could be given here, e.g.

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.'

If the applicant is writing a 1-part information sheet, then the material set out in Section 14 below should be included.

10. Contact details of the researchers.

You should give the name, telephone number, and e-mail address of the applicant and of any other investigator who will provide further information.

Part 2

11. (a) This paragraph is not relevant to research with competent healthy adult volunteers at YNiC.

11. (b) Additional considerations

It will be appropriate at this point to explain the inclusion and exclusion criteria for the study.

12. What will happen if I don't want to carry on with the study?

This section should explain that participants are free to withdraw from the study at any time and without giving an explanation. You should explain what you will do with data gathered from such a participant and you should explain what the implications are for any payment that you may be offering participants.

13. What if there is a problem?

You should inform participants how complaints will be handled and what redress may be available. You will need to distinguish between complaints from participants about their treatment by members of staff and something serious happening during or following their participation in the study. There should be a procedure for both.

Complaints

A suitable contact number should be given which can genuinely assist the participant. This may be the number of the applicant, who can try to solve the problem in the first instance. However, a participant may not wish to complain to

the applicant if he/she is the object of the complaint, and may wish to make a more formal complaint.

'If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. They may be reached by getting in touch with <<name of applicant, telephone number, and e-mail address>>. If you remain unhappy and wish to complain formally, you can do this through the complaints procedure of the University of York. Details can be obtained from the <<give address>>.'

Harm

The completion of this section depends on the form and extent of the professional indemnity insurance carried by the applicant's employer. The wording below is appropriate for applicants who are employees of the University of York.

'The York Neuroimaging Centre takes pride and care in ensuring that no harm, or risk of harm, occurs to participants in research. In the event that something does go wrong and you are harmed during the research study and this is due to someone's negligence, then you may have grounds for a legal action for compensation against The University of York.'

Applicants who are not employees of the University of York must establish the form and extent of professional indemnity insurance that is provided by their employer in respect of claims for negligent and non-negligent harm.

14. Will my taking part in this study be kept confidential?

The participant must be told in simple terms how their confidentiality is being safeguarded during and after the study. You may wish to tell the participants that your procedures for handling, processing, storage and destruction of their data are compliant with the Data Protection Act 1988.

The participant should be told in simple terms:

- that their data will be stored securely, giving the custodian and level of identifiability (e.g. coded, anonymous, etc).
- what their data will be used for. It must be clear if the data is to be retained for use in future studies and whether further REC approval will be sought.
- who will have access to view identifiable data, how long it will be retained, and that it will be disposed of securely.

Applicants are advised to use these words:

'Any information which you give us, and all of the measurements that we collect from you, will be confidential. No names will be used when the research is written up. We shall keep your data for 10 years and will then destroy it securely. We shall comply with the terms of the Data Protection Act 1988. We shall store the information and the measurements in anonymous computer files and in locked filing cabinets. We shall store names and addresses separately from other data. We shall use your data in this study and we may combine your data with data that we gather in future studies. Only three people in our research team will know the contact details of the participants. They are Professor Alpha Beta, Dr Gamma Delta, and Dr Epsilon Zeta. In addition, staff of the York Neuro-imaging Centre have privileged access to the computer systems and can link the names of participants with their data. Those people are under a professional obligation not to abuse this privilege. With the approval of the Research Ethics Committee of the York Neuroimaging Centre, other researchers may be allowed access to the data

which you will provide for use in research and teaching. Those researchers will be allowed access to your data in anonymous form only.'

If a study involves MRI, then a paragraph should be included which explains that the participant's family doctor will be contacted in the event that a structural anomaly is suspected in a scan.

For example:

'We are not qualified to interpret brain images clinically. If we suspect that an image of your brain reveals a possible problem, we shall inform your GP (family doctor) who may then contact you and advise you. If you do not want us to do this, then you should not agree to take part in the study.'

15. (If relevant) What will happen to any samples that I give?

Applicants who are intending to obtain samples from participants should follow the NRES guidance.

16. Will any genetic tests be done.

Applicants who are intending to conduct genetic tests should follow the NRES guidance.

17. What will happen to the results of the research study?

You should be able to tell the patients what will happen to the results of the research, whether it is intended to publish the results, and how the results will be made available to participants.

18. Who is organising and funding the research?

Applicants should give the names and status of the main investigators and should explain who is funding the research (e.g. Medical Research Council, Wellcome Trust, Pharmaceutical Company, University of York, etc). For example:

'The study is being organised by Professor Alpha Beta, Dr Gamma Delta, and Dr Epsilon Zeta. They work in the Department of Psychology at the University of York. Alpha Beta is a professor of psychology. Gamma Delta is a reader in psychology. Epsilon Zeta is a research fellow in psychology.'

'The study is being funded by The University of York and a charity, the Pi Rho Sigma Foundation.'

19. Who has reviewed the study?

The Information Sheet should state:

'This study was given a favourable ethical opinion by the Research Ethics Committee of the York Neuroimaging Centre.'

4. GUIDANCE ON WRITING A CONSENT FORM FOR A STUDY AT YNIC

The example of the Consent Form on the next page is the minimum requirement for competent healthy adult volunteers. The participant is consenting to everything described in the text of the information sheet.

For some studies a fuller itemised consent form may be needed to cover other important issues, especially if additional elements are optional for the participant. These may include, for example, consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs.

Applicants who need to obtain consent from other groups (e.g. children, parents/guardians, visually-impaired participants) should follow the guidance provided by NRES.

CONSENT FORM FOR ADULT PARTICIPANTS

<<name of study>>

Participants should complete items 1 to 10 themselves

Please circle either
YES or NO

1. I have read the information sheet entitled '<<name of study>>, Information for Adult Participants'. YES / NO
2. I have had the chance to discuss the study and to ask questions. YES / NO
3. I have had satisfactory answers to all of my questions. YES / NO
4. Who has explained the study to you?
Prof/Dr/Mr/Mrs/Ms.....
5. I understand that I am free to withdraw from the study:
• At any time. YES / NO
• Without having to give a reason.
• Without prejudice to my academic standing at the University of York.
6. Do you agree to take part in the study? YES / NO
7. I understand that I can discuss the study with a researcher at any time, if I wish. YES / NO
8. I know that the research information which I will provide will be kept strictly confidential. When the results are published no individual person will be identified in any way without that person's written agreement. I agree that other researchers may access the data which I shall provide in this study for use in research and teaching. Those researchers will require the approval of the Research Ethics Committee of the York Neuroimaging Centre and will be allowed access to my data in anonymous form only. YES / NO
9. If I have any questions or concerns about the research, I know I can contact <<name of contact>> at <<place where the contact works>> on <<telephone number>>. YES / NO

10. PARTICIPANT

Signature of Participant..... Date.....

Name (BLOCK LETTERS)

11. INVESTIGATOR

I have explained the study to the above participant and he/she has indicated his/her willingness to take part.

Signature of Investigator..... Date.....

Name (BLOCK LETTERS)
