**Guidance for completing the YNiC Research Ethics and Governance Form**

 **(Version 6.0; 25/5/18)**

**1. INTRODUCTION**

* 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.
	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.
	3. All applications to YNiC REC must include the following:

1. a *YNiC Research Ethics & Governance Application Form*,
2. an *Information Sheet* for Participants,
3. a *Study-specific Consent Form*.
	1. An application for research that involves patients or employees of the National Health Service should normally have received prior approval from IRAS. This type of application consists of the three components above, plus:
4. a *YNiC Advice of External Approval Form*,
5. an *IRAS Approval Letter*.

If the applicant wishes to seek YNiC conditional approval *prior to* IRAS application (to avoid having to put amendments through IRAS), then the application can be submitted without items 4 and 5, with YNIC approval being conditional on the submission of these items subsequent to IRAS approval (along with a description of any amendments to the original application required by IRAS).

* 1. 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.
	2. The *Information Sheet* should provide information that 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 and a template is available for download.
	3. 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 and a template is available for download.

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

6th May 2011

1st February 2014 (V03)

25th February 2015 (V04)

Gareth Gaskell, Chair: YNiC Research Ethics Committee

10th November 2017 (V5.0)

25th May 2018 (V.6.0)

**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 rec-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.

2.1.5 Make sure that you are using the latest version of the application form (currently version 4.0). Older forms will not be accepted.

**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**).

2.4.3 If your application has or will need approval from another body such as the NHS ethics committee then give the details here.

**2.5 Section 3: 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 In **Section 3.2**, you should outline the design, protocol and analysis plan for your study. The content of this section depends on the nature of the experiment, but should provide information about the structure of a test session including the type of stimuli presented, the parameters of the functional and/or structural imaging sequence and so on. In cases where the experiment is based on an established protocol previously approved by the YNiC REC, this document may only need to be half a page or so. Think carefully about what details need to be provided for proper ethical scrutiny and provide these details, but avoid unnecessary overspecification. 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 no more or less than the appropriate number of participants. Thus, 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 analyse 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 data protection regulations 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: Data**

2.9.1 Describe who will have access to the data.

2.9.2 Describe how you will ensure data securing and confidentiality in the light of data protection regulations such as the GDPR. The template participant information sheet has some suggested text that describes in more detail how confidentiality should be dealt with, and you may wish to base your description on that text.

2.9.3 Current data protection regulations require consideration of the impact of data collection. You should consult the [University’s guidelines](https://www.york.ac.uk/records-management/dp/dataprivacyimpactassessments/) about whether any aspect of your data could be considered high risk in this respect. Further information is available from the [Information Commissioner’s Office](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/data-protection-impact-assessments-dpias/examples-of-processing-likely-to-result-in-high-risk/). It is expected that most research conducted using YNiC’s facilities will not involve high risk personal data. In cases where data processing is considered high risk, the Principal Investigator must conduct a Data Protection Impact Assessment (DPIA) in consultation with the University’s Data Protection Officer. This can be done prior to or in parallel with the YNiC ethics application. In this section you should state whether or not you have instigated a DPIA. Crucially, if DPIA approval is pending when you submit your ethics application, any ethical approval is conditional on receiving DPIA approval from the University.

2.9.4 You should confirm that you are aware of and are acting according to current [data protection regulations](https://www.york.ac.uk/records-management/dp/dataprivacyimpactassessments/) that apply to research. You must collect only the personal data that is essential to the success of your research, and consider how best to protect participants’ privacy using pseudonymisation (e.g., YNiC R codes) by default, and anonymization where possible. Making your data publicly accessible via an online repository is considered good practice, and is often a funder requirement, but you must ensure that any data you make publicly available is fully anonymised and cannot be linked back to individual identity. In practice this will often mean stripping the data of any pseudonymised participant ID that could be linked back to identify the participant. MRI data may also need to be processed to obliterate facial identity cues. If your research involves collaborative or data processing links outside the University then you should consider in consultation with the University [Information Governance Office](https://www.york.ac.uk/records-management/dp/dataprivacyimpactassessments/) whether contracts need to be drawn up to cover the data sharing and/or intellectual property implications.

2.9.5 You must ensure that the research is conducted in accordance with any research data management policies that apply in your case. You will need to read and comply with the [University of York policy](https://www.york.ac.uk/about/departments/support-and-admin/information-services/information-policy/index/research-data-management-policy/), and may also need to comply with your funder’s policy (e.g., grant, studentship).

**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 participants’ 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 10: 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, and retained by the participant. Before writing their information sheet(s), applicants should consult the [documentation](http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/) produced by HRA, which provides plentiful [advice](http://www.hra-decisiontools.org.uk/consent/index.html) and [templates](http://www.hra-decisiontools.org.uk/consent/) to adapt.

A template participant information sheet is provided for download on the [YNiC website](https://www.ynic.york.ac.uk/forms). This is the minimum requirement for competent healthy adult volunteers and is tailored towards an experiment involving MRI. You should adapt this template for your purposes, taking careful note of the comments in the margin and deleting these prior to submission. In the more technical sections you are encouraged to leave the text as is rather than reword. Applicants intending to write information sheets for other groups (e.g. children, parents/guardians) should study the HRA guidance.

**4. Guidance on writing a CONSENT FORM for a study at YNiC**

A template example consent form is available for download from the [YNiC website](https://www.ynic.york.ac.uk/forms). This 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.