

ETHICS

York NeuroImaging Centre
THE UNIVERSITY *of York*

Application Form for Ethics Committee Approval for Research on Human Subjects, Tissues, or Samples

Instructions for applicants

Please ensure that the information provided is:

- *Accurate, complete, and concise*
- *Clear, simple, and easily understood by a lay person*
- *Free of jargon, technical terms, and abbreviations*

Please submit electronically to ethics.submission@ynic.york.ac.uk in .pdf format

Title of study: _____

Applicant: _____

Date Submitted: _____

Before submitting this form, please tick the relevant box to confirm that you have:

- | | |
|---|--------------------------|
| ▪ <i>Read YNiC Research Ethics Guidance</i> | <input type="checkbox"/> |
| ▪ <i>Read the Guidance for Preparing a Research Ethics Application</i> | <input type="checkbox"/> |
| ▪ <i>Completed this form</i> | <input type="checkbox"/> |
| ▪ <i>Included a dated copy of your Information Sheet for Participants</i> | <input type="checkbox"/> |
| ▪ <i>Included a dated copy of your Study-specific Consent Form</i> | <input type="checkbox"/> |
| ▪ <i>Separately, submitted an application for YNiC Science Approval</i> | <input type="checkbox"/> |
| ▪ <i>Retained electronic and paper copies of your application</i> | <input type="checkbox"/> |

Section 1: The Applicant

Applicant (to whom correspondence about this application will be sent)

Name, position, and qualifications:

E-mail address, telephone number, postal address:

Principal Investigator (if not the Applicant) or Supervisor (if the Applicant is an under- or post-graduate student)

Name, position, and qualifications:

E-mail address, telephone number, postal address:

Names, positions, and qualifications of additional investigators:

Section 2: The Study

Briefly describe the scientific background to the study (250 words max):

Briefly describe the aims of the study and the hypotheses that will be tested (250 words max):

Summarise the procedures (full details must be part of the application for Scientific Approval to the YNiC Science Committee. Consult <http://www.ynic.york.ac.uk> for details):

What is the design of the study (block design, parametric, randomised controlled trial...)?

How many participants will be included in the study?

What evidence suggests that this is the appropriate number of participants to include? (Give the results of a power calculation or other data suggesting that the design will find an effect if there is an effect there to be found.)

How many months do you anticipate will be required for the data-gathering phase of your study?

Section 3: Interventions, Hazards, and Risks

Please indicate whether the study involves procedures which:

Involve taking samples or introducing substances to the body YES NO

Are physically invasive YES NO

Are designed to be challenging or disturbing (physically or psychologically) YES NO

Entail discomfort or distress for participants YES NO

If you answered YES to any of the above, please describe the procedures and the steps that you will take to ensure the safety and welfare of participants

Will the study entail any hazards for participants, experimenters, or others: YES NO

If you answered YES, please describe the hazards and the steps that you will take to ensure the safety and welfare of participants:

Please explain any arrangements that have been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, any participant for negligent harm.

Section 4: Source(s) of Funding

What is (are) the funding source(s) for the study?

Do you consider accepting funds from this source raises possible ethical difficulties?
(e.g. industrial sponsorship)

YES NO

If YES, please elaborate:

Section 5: Security of Data

Who will have access to the data?

Describe the steps will be taken to safeguard the security and confidentiality of data:

Please tick the boxes to confirm the following:

Data files will be named so as to preserve the anonymity of participants

Names of participants will not be revealed when data are reported

Section 6: Security of Biological Samples

Will biological samples be gathered in the course of the study?

YES NO

If you answered YES, please answer the following questions:

Who will have access to the biological samples?

What steps will be taken to safeguard the security and confidentiality of biological samples?

Please tick the box to confirm the following:

Biological samples will be labelled so as to preserve the anonymity of participants

Section 7: Recruitment of Participants

How will participants be recruited?

What are the inclusion/exclusion criteria?

Will participants be reimbursed for expenses incurred in participating? YES NO

If you answered YES, please state which budget will be used:

Will participants be paid for participating? YES NO

If you answered YES, please explain why payment is necessary and state which budget will be used:

Will participants be recruited through the NHS? YES NO

If you answered YES, who is the contact person and referring physician? (Studies involving NHS participants require COREC approval in addition to YNiC ethics approval.)

Section 8: Consent and Debriefing

Will written consent be obtained? YES NO

Please attach a copy of the Information Sheet and Consent Form for Participants

Will any of the participants be from the following groups?

- | | | |
|--|------------------------------|-----------------------------|
| Children under the age of 18 | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| People with learning or cognitive difficulties | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| People who are unconscious or severely ill | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| People with mental illness | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| Prisoners | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| Young offenders | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| Individuals with motor problems | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| Other vulnerable groups | YES <input type="checkbox"/> | NO <input type="checkbox"/> |

If you answered YES, please describe the special arrangements that have been made for obtaining consent:

If you plan to recruit children, please submit evidence that the PI/supervisor has obtained enhanced disclosure from the Criminal Records Bureau.

What information, if any, will be given when participants are de-briefed?

Section 9: Secrecy

Is there a secrecy clause to the research?

YES NO

If you answered YES, please elaborate:

Section 10: Special Considerations

Are any ethical issues raised by the proposed study that have not already been described?

YES NO

If you answered YES, please describe the issues and explain how they will be managed:

Section 11: Declarations

We judge that this experiment will pose no risk to participants if carried out in accordance with the Guidelines of the York Neuroimaging Centre.

The information in this form is accurate to best of our knowledge and belief, and we take full responsibility for it.

We agree to advise the YNiC Ethics Committee of any adverse or unexpected events that occur during this study, to seek approval for any significant amendments to the protocol, and to provide interim and final reports. We also agree to advise the YNiC Ethics Committee if the study is withdrawn or not completed.

Applicant

Signature:

Date:

Principal Investigator (if not the applicant) or Supervisor

Signature:

Date:

Please retain electronic and paper copies of this application for yourself and, if you are a student, for your supervisor.

- Responsibilities of the Applicant following Approval***
- Report progress on an annual basis (or more frequently if requested by the Ethics Committee).
 - Seek approval from the Ethics Committee for any significant changes to the protocol.
 - Promptly report to the Ethics Committee any adverse or unexpected events that occur during the study. (Adverse events include events that involve harm or unanticipated risk to participants, damage to equipment, or breaches of confidentiality.)