

RESEARCH ETHICS & GOVERNANCE

York NeuroImaging Centre
THE UNIVERSITY *of York*

Application Form for Scientific and Ethical Approval for Research on Human Subjects, Tissues, or Samples

Instructions for applicants

Please ensure that the information which you provide is:

- *Accurate*
- *Complete*
- *Concise*

Please submit electronically to science.submission@ynic.york.ac.uk

Enter your project ID: _____

[if you do not have an ID, then do not fill in this form, complete a Project Proposal form]

Title of study: _____

Applicant: _____

Date Submitted: _____

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

Read the Guidelines for Applicants for YNiC Research Ethics & Governance Approval

Completed this form

Attached up to 2 sides of A4 describing the protocol for your study

Retained electronic and paper copies of your application

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:

Please tick this box if the contact details refer to a student supervisor

Names, positions, and qualifications of additional investigators:

If this is a collaborative project (involving institutions other than the University of York) who of the above is the University of York collaborator?

Please provide 5 of your recent publications that are most relevant to the investigation.

Section 2: Context

Date of Project Presentation:

Outcome of Project Proposal:

Complete this section if your study is being undertaken as part of an educational course:

Name and level of course/degree and Institution:

Section 3: The Study

3.1 Work leading up to the project

Briefly describe the scientific background and aims to the study (400 words max):

Clearly describe the hypotheses that will be tested in the study:

3.2 Study design and analysis

Please attach details of the protocol (a maximum of 2 sides of A4)

Briefly outline the design of the study (provide detail of the independent and dependent measures, and participant groups where appropriate):

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.)

What statistical tests or comparisons do you intend to employ?

Please list the analysis tools (software) which you plan to use to perform your analysis.

FMRI:

MEG:

Do you have experience using these tools? YES NO

Will you need assistance using these tools? YES NO

3.3 Timetable and Milestones

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

Over what period of time will you undertake the analysis of your data?

State any deadlines or contract termination dates associated with the study:

Please tick this box to indicate that the research team has sufficient time to undertake the data-gathering, analysis and write up

3.4 Study resource requirements

How many hours of scanning will be required for the study in total?

(Remember that an MEG experiment may require a structural scan for each participant requiring 0.5 hours of MRI for each participant.)

(hours)

Magnetic Resonance Imaging (MRI)

Functional Magnetic Resonance Imaging (fMRI)

Magneto-encephalography (MEG)

On which days of the week do you wish to scan participants?

MONDAY

SATURDAY

TUESDAY

SUNDAY

WEDNESDAY

THURSDAY

FRIDAY

Are you willing to use the scanners after 4pm?

YES NO

Will you require an approved operator to assist with scanning?

fMRI YES NO

If you answered NO, who is the approved fMRI operator in your research team?

MEG YES NO

If you answered NO, who is the approved MEG operator in your research team?

What imaging protocols (e.g. MR pulse sequences) will be used for the study?

fMRI:

MEG:

What stimulus delivery equipment and stimulus delivery software will you require?

fMRI:

MEG:

Do you have stimulus programmes prepared? YES NO

Will you need assistance preparing stimulus programmes? YES NO

Are the specific resources [scanning, stimulus delivery, and data analysis] required for the project available at YNiC?

YES NO

If you answered NO, outline the resources that will be needed (at YNiC or elsewhere) in order to undertake the study?

4. Participants

How will the participants be recruited?

What are the inclusion/exclusion criteria?

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

Will participants be paid for participating? YES NO

Note that YNiC will not provide funds for paying or reimbursing participants

Will participants be recruited through the NHS? YES NO

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

5. Funding

Does this study have a source of funding?

YES NO

If you answered YES, please state the source and the account number:

If you answered NO, please describe the arrangements under which the study will be conducted:

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

YES NO

If YES, please elaborate:

6. Interventions, Hazards, and Risks

Please describe the hazards and risks associated with the study and the steps that you will take to ensure the safety and welfare of participants:

Please indicate whether the study includes any of the following procedures (apart from scanning procedures):

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

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.

7. 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

8. 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

9. 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 NO

People with learning or cognitive difficulties YES NO

People who are unconscious or severely ill YES NO

People with mental illness YES NO

Prisoners YES NO

Young offenders YES NO

Individuals with motor problems YES NO

Other vulnerable groups YES NO

If you answered YES or if you intend to obtain verbal consent for whatever reason, 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?

12. Declarations

We agree that:

If approved, this study will be conducted in accordance with the protocol and other details described in this application.

The study will not start until ethical approval has been obtained from both the YNiC Research Ethics and Science Committees.

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.

In the first instance this form can be submitted electronically without signatures. The finalized approved submission will however have to be signed.

For Office Use Only

Please indicate whether the following aspects of the proposal have been discussed and that YNiC can readily provide the appropriate resources?

Imaging protocols YES NO

Stimuli for the study YES NO

Analysis procedures YES NO

Please indicate any special requirements that this project might have?

Name of SLO: