**RESEARCH**

**ETHICS & GOVERNANCE**

**York NeuroImaging Centre**



#### 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*** rec-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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Version number of Guidelines for Applicants you consulted (must be current): \_\_\_\_\_\_\_***

***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* [ ]

*Included an information sheet for participants* [ ]

*Included a study-specific consent form* [ ]

*Retained electronic and paper copies of your application* [ ]

**Section 1: The Applicant (see *Guidelines* Section 2.3)**

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 (see *Guidelines* Section 2.4)**

Date of Project Presentation:

Outcome of Project Proposal:

Not relevant for TMS-only studies where no SLO will be assigned

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

Name and level of course/degree and Institution:

Complete this section if your study requires additional ethical approval from an external body (e.g., NHS)

Name of external ethics board:

Do you have ethical approval from the above board? Choose an item.

If you answered YES then you should include a YNiC Advice of External Approval Form along with you approval letter in this application. If you answered NO, then YNiC approval will be conditional on the presentation of these documents at a later date.

**Section 3: The Study (see *Guidelines* Section 2.5)**

**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, protocol and analysis**

**Expand this space to describe your study, giving all details that are relevant for ethical review (normally, a maximum of 2 sides of A4)**

Outline the design and protocol of the study, providing relevant detail of the independent and dependent measures, stimuli, participant groups, trial structure, scanning parameters, timecourse and durations of session(s), and so on:

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? Choose an item.

Will you need assistance using these tools? Choose an item.

**For TMS studies only:**

Will the study involve:

On-line TMS Choose an item.

Off-line TMS Choose an item.
Single pulse TMS Choose an item.

Repetitive TMS Choose an item.

What stimulation parameters do you propose to employ?

Intensity of stimulation (e.g., 120% of active motor threshold):

Frequency of rTMS:

Duration of trains of rTMS:

Interval between trains of rTMS:

Maximal number of TMS pulses applied in any single testing session:

Sites for stimulation:

In case of on-line TMS only: are TMS trials [ ]  blocked

 [ ]  intermixed with control trials

What is the evidence indicating that the proposed stimulation parameters are safe? Applicants should refer by specific citation to previous unharmful studies or to published safety guidelines (e.g., Wasserman, 1998; Rossi et al., 2009).

**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) \_\_\_\_\_\_\_\_\_\_

TMS lab \_\_\_\_\_\_\_\_\_\_

For MRI, do you have a need for a particular scanner? Choose an item.

If you need a particular scanner, briefly say why:

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? Choose an item.

Will you require an approved operator to assist with scanning?

fMRI Choose an item.

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

MEG Choose an item.

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

TMS

TMS is not a supported service at present. Investigators will have to be fully trained before undertaking TMS studies.

Who is the **trained TMS 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? Choose an item.

Will you need assistance preparing stimulus programmes? Choose an item.

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

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

**4. Participants (see *Guidelines* Section 2.6)**

How will the participants be recruited?

What are the inclusion/exclusion criteria?

Will participants be reimbursed for expenses incurred in participating? Choose an item.

Will participants be paid for participating? Choose an item.

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

Will participants be recruited through the NHS? Choose an item.

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 (see *Guidelines* Section 2.7)**

Does this study have a source of funding? Choose an item.

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)

 Choose an item.

If YES, please elaborate:

## 6. Interventions, Hazards, and Risks (see *Guidelines* Section 2.8)

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 Choose an item.

Are physically invasive Choose an item.

Are designed to be challenging or disturbing (physically or psychologically) Choose an item.

Entail discomfort or distress for participants Choose an item.

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. Data**  **(see *Guidelines* Section 2.9)**

Who will have access to the data?

Describe the steps will be taken to safeguard the security and confidentiality of data. *(Make sure that your Participant Information Sheet is consistent with this statement).*

[Data Protection Impact Assessment](https://www.york.ac.uk/records-management/dp/dataprivacyimpactassessments/) (DPIA):

For data processing likely to be “high risk” to individuals’ interests, Principal Investigators are required to complete a DPIA. You must consider the need for a DPIA prior to submission of your ethics application.

Please indicate the status of the DPIA for this application: Choose an item.

In cases where a DPIA is required, please state the reason:

Any YNiC Research Ethics & Governance Approval is conditional on approval of the DPIA by the University’s Data Protection Officer.

Please tick the boxes to confirm the following:

The project collects the minimum amount of personal data required for the research [ ]

Data files will be pseudonymised or anonymised to protect participants’ identities [ ]

Names of participants will not be revealed when data are reported [ ]

Any collaborations that involve data sharing or intellectual property arrangements have been dealt with in consultation with the University Information Governance Office and/or IP and Legal Manager [ ]

Research Data Management (RDM):

Your research must adhere to the research data management policies of all relevant bodies, including the University of York and any funding body.

Please tick the boxes to confirm the following:

The applicants are aware of the [University RDM Policy](https://www.york.ac.uk/about/departments/support-and-admin/information-services/information-policy/index/research-data-management-policy/) and will comply with it [ ]

The applicants are aware of any funder RDM policy and will comply with it [ ]

**8. Security of Biological Samples** **(see *Guidelines* Section 2.10)**

Will biological samples be gathered in the course of the study? Choose an item.

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** **(see *Guidelines* Section 2.11)**

Will written consent be obtained? Choose an item.

###### 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 Choose an item.

People with learning or cognitive difficulties Choose an item.

People who are unconscious or severely ill Choose an item.

People with mental illness Choose an item.

Prisoners Choose an item.

Young offenders Choose an item.

Individuals with motor problems Choose an item.

Other vulnerable groups Choose an item.

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?

**10. Secrecy** **(see *Guidelines* Section 2.12)**

Is there a secrecy clause to the research? Choose an item.

If you answered YES, please elaborate:

**11. Special Considerations** **(see *Guidelines* Section 2.13)**

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

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

**12. Declarations** **(see *Guidelines* Section 2.14)**

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.

TMS studies will be conducted in accordance with the “Rules of TMS operation” document.

**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?**

(Not relevant in case of TMS-only studies)

Imaging protocols Choose an item.

Stimuli for the study Choose an item.

Analysis procedures Choose an item.

**Please indicate any special requirements that this project might have?**

**Name of SLO:**

(Not relevant in case of TMS-only studies)