**RESEARCH ETHICS & GOVERNANCE**

**York NeuroImaging Centre**



#### Application Form for Scientific and Ethical Approval for Research on Human Subjects, Tissues, or Samples (Version 10)

*When filling out this form, please make sure you read the guidance (in italics) carefully. For detailed information, consult the Guideline for Applications document. Please ensure that all information in this form is accurate and complete.*

**Title of study:**

**Principal applicant:**

**Date submitted:**

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

**If you already have a project number, enter it here:**

**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 [x]

Completed this form [x]

Included an information sheet for participants [x]

Included a study-specific consent form [x]

Retained a copy of your application [x]

Once you have provided all information, submit the final application electronically to:

rec-submission@ynic.york.ac.uk

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

*Note that all external projects require at least one investigator from York.*

**Applicant details:**

Name:

Position:

Contact Details:

Work Address:

**Principal investigator or supervisor (if different from the applicant):**

Name:

Position:

Contact Details:

**Other investigators:**

Name:

Position:

Contact Details:

**Section 2: Context (see *Guidelines* Section 2.4)**

**Project proposal:**

*Note that project proposal forms are mandatory for first-time and external users. These users may be asked to give project presentations prior to submitting an ethics form. Experienced users from the University of York can directly submit their ethics without a proposal from.*

[x]  I do not need to complete a project proposal form

[x]  I have completed the project proposal form and given a project presentation if this was required

**Studies as part of educational courses:**

*If this study is part of an educational activity, please specify the name of the course and the Institute / Department where the course takes places below.*

[x]  This study is not part of an educational activity

[x]  This study is part of the following course:

**External ethical approval:**

*If this study requires approval from an external ethics board (e.g., NHS), place specify below. If you have obtained approval from this ethics board, please include a YNiC Advice of External Approval Form. If you have not yet obtained external approval, but it is required, ethical approval from this board will depend on the submission of an YNiC Advice of External Approval Form at a later date.*

[x]  External ethical approval is not required

[x]  Ethical approval has already been obtained from the following board:

[x]  Ethical approval from the following board is pending:

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

**3.1 Study Overview**

**Background:**

*In this section, briefly describe the theoretical background of the work.*

**Objectives / Hypotheses:**

*In this section, briefly state what the study aims to investigate and which specific hypotheses you are planning to test.*

**3.2 Methods Summary**

**Study design:**

*In this section, describe your study, giving all details that are relevant for ethical review. Particularly, outline key aspects of the study design, such as independent and dependent measures (collected both in and outside of the scanner), stimuli, trial structure. If any special equipment is used during the experiment, please outline this here.*

**Scanning parameters (MRI studies only):**

*In this section, provide the details of your neuroimaging protocols. Mention the types of sequences you will be using, the relevant scanning parameters of these sequences, and the duration of individual scanning runs.*

**Neurostimulation parameters (TMS studies only):**

The study will involve:

[x]  On-line TMS

[x]  Off-line TMS

[x]  Single-pulse TMS

[x]  Repetitive TMS

General TMS parameters:

Stimulation intensity:

Number of pulses in a session:

Time between pulses:

For rTMS only:

rTMS frequency:

Duration of rTMS trains:

Interval between rTMS trains:

Finally, please provide literature that shows that your TMS protocol has been safely used before:

**3.3 Participants**

**Which population will you recruit your participants from?**

**What are the inclusion and exclusion criteria?**

**How will you recruit your participants?**

**How many participants will you test? How was this sample size determined?**

**How will participants be compensated for their participation (see the guidance)?**

*If you plan to recruit participants through the NHS, please provide details of the NHS contact person for recruitment. Note that recruiting participants through the NHS additionally required NRES ethics approval (see section on external ethical approval).*

[x]  I will not recruit participants through the NHS

[x]  I will recruit participant through the NHS. My NHS contact for recruitment is:

**3.4 Study resource requirements**

*In this section, please provide information which YNiC labs you will need to use and for how long.*

**I will require the following resources:**

[x]  MRI lab (both are fine): hours

[x]  MRI lab (only Siemens): hours

[x]  MRI lab (only GE): hours

[x]  MEG lab: hours

[x]  TMS lab: hours

*Please note that if you do not have a certified operator in your team, you will only be able to scan in operator-covered time slots . Note that TMS studies can currently only be conducted if you have a fully trained TMS operator in your team.*

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

*Please specify how this study will be funded. If funded by an external body, please specify the funder and the workorder (R-code) and state whether there are any conflicts of interest.*

[x]  There is no funding available for this study

[x]  This study is funded by:

**If the study is funded by an external body:**

[x]  There is no conflict of interest

[x]  The following conflict of interest is declared:

## 5. Interventions, Hazards, and Risks (see *Guidelines* Section 2.7)

**The study yields the following potential risks and hazards:**

*In this section, specify all potential risks of the study and the steps you take to ensure the safety and welfare of participants. Please make sure all risks are appropriately described in your study information sheet, too. For TMS studies, please specifically outline how you will meet TMS safety guidelines (e.g., Wasserman, 1998; Rossi et al., 2009).*

**Additionally, please indicate whether your study fulfils any of the following criteria:**

[x]  The study takes samples or introduces substances to the body

[x]  The study is physically invasive

[x]  The study is designed to be challenging or disturbing (physically or psychologically)

[x]  The study entails discomfort or distress for participants

If you ticked any of the above boxes, please explain in detail how you ensure the safety in welfare of your participants throughout the experiment:

**6. Data** **(see *Guidelines* Section 2.8)**

**Will anyone else apart from the investigators have access to the data?**

[x]  No

[x]  Yes

If yes, please specify:

**Please confirm the following statements:**

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

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

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

[x]  The researchers will not copy any images of the participant’s face created during MEG acquisition. These images will only be available to YNIC staff.

[x]  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

[x]  The steps to safeguard the security and confidentiality of data are clearly outlined in the participant information sheet

[x]  The applicants are aware of the [University Research Data Management (RDM) Policy](https://www.york.ac.uk/about/departments/support-and-admin/information-services/information-policy/index/research-data-management-policy/), as well as any RDM policies of their external funders and will fully comply with these policies

[x]  The need for a separate study-specific [Data Protection Impact Assessment](https://www.york.ac.uk/records-management/dp/dataprivacyimpactassessments/) (DPIA) has been considered. If a separate DPIA is being completed, please specify the reason for the separate DPIA below, and the whether this has been submitted / approved. Note that ethical approval is conditional on the DPIA approval.

**Will your study collect biological samples?**

[x]  No

[x]  Yes

If yes, please specify who will have access to these samples and how you will ensure that the samples are kept confidential:

# **7. Consent and Debriefing** **(see *Guidelines* Section 2.9)**

*In this section, please provide information about participant consent and debriefing (where applicable). Note that the consent and information sheets need to be attached to the application.*

**Will written consent be obtained?**

[x]  Yes

[x]  No (please specify below)

**Please indicate whether any of the participants are from one the following groups:**

[x]  Children under the age of 18

[x]  People with leaning or cognitive difficulties

[x]  People who are unconscious or severely ill

[x]  People with mental illness

[x]  Prisoners

[x]  Young offenders

[x]  Individuals with motor problems

[x]  Other vulnerable groups (please specify below)

If you ticked any of the above boxes, 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.

**Which information will be given to debrief participants (if relevant)?**

**8. Secrecy** **(see *Guidelines* Section 2.10)**

**Is there a secrecy clause to this research?**

[x]  No

[x]  Yes

If yes, please specify:

**9. Special Considerations** **(see *Guidelines* Section 2.11)**

**Please describe any other ethical issues that are relevant for assessing this proposal:**

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

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 the YNiC Research Ethics Committee and a separate DPIA (if necessary) has been approved.
* TMS studies will be conducted in accordance with the “Rules of TMS operation” document.

**Applicant**

Signature:

Date:

**Principal Investigator or Supervisor (if not the applicant)**

Signature:

Date: