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

 **(Version 9.0; 14/02/23)**

**INTRODUCTION**

1. Neuroimaging differs from much other research with human participants in three ways: a, It may be uncomfortable and stressful for participants. b, It is expensive. c, 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 GDPR compliant privacy notice
4. a *Study-specific Consent Form*.
5. 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:
6. a *YNiC Advice of External Approval Form*,
7. 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 (Version 8)* 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. When issuing the information sheet to participants, participants should also be given a GDPR compliant privacy notice:

<https://www.york.ac.uk/records-management/dp/guidance/privacynotices/>

There is a template [here](https://vcs.ynic.york.ac.uk/ynic-public/forms/-/raw/master/ResearchPrivacyNoticeTemplate.docx).

8) 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 (V6.0)

Daniel Kaiser, Chair: YNiC Research Ethics Committee

8th July 2021 (V7.0)

Fiona McNab, Chair: YNiC Research Ethics Committee

18th July 2022 (V8.0)

**INSTRUCTIONS FOR WRITING AND SUBMITTING AN APPLICATION FOR YNIC RESEARCH ETHICS & GOVERNANCE APPROVAL**

**The process of submission**

* Information must be provided in lay language that is free from jargon, undefined technical terms, and abbreviations.
* All of the required documents must be submitted together (Research Ethics & Governance Application, Information Sheet(s), Study-specific Consent Form(s)).
* Documents **must** be submitted in **portable document format (.pdf)** to rec-submission@ynic.york.ac.uk .
* 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.
* When the application has been approved, possibly after revision, applicants and PIs/supervisors may be asked to sign a paper copy of the application and lodge it at YNiC.
* Make sure that you are using the latest version of the application form (currently version 8.0). Older forms will not be accepted.

**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. **Please note that first-time users of the YNiC facilities, as well as external users, have to submit a project proposal form first. They may be asked to present their project in a brief talk. After this, they can submit a full ethics application.**

**Section 1: The Applicant**

* 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.
* Be clear about the other investigators who are involved in the study. Give all of the details that are requested.

**Section 2: Context**

* Date of Project Presentation & Project Proposal Outcome (if these are required): first-time and external investigators may have been asked to complete a Project Proposal Form and may also be asked to give a Project Presentation. If required, enter the date of the Presentation and indicate the outcome of the Proposal, which will have been communicated to you by email.
* Please provide details of the educational course that the study may be linked to. It is essential that all student investigators are included in the Section on The Applicant (**Section 1**).
* If your application has or will need approval from another body such as the NHS ethics committee then give the details here.

**Section 3: The Study**

* 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 are clearly set out in this section.
* 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. It is also important that investigators are clear about how they intend to analyse the data they acquire. Sufficient basic detail on data analysis methods should be included.
* Participants **(Section 3.3)**. 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. Further, 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.
* Timetable and Milestones (**Section 3.4**). To fairly allocate testing and analysis resources to all researchers using the centre, we ask you to provide an approximate timetable for the key milestones of your study (data collection and data analysis).
* Study resource requirements (**Section 3.5**). It is essential that each study provides details of how much scan time is required. Once the ethical approval is granted, 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 from the YNiC ethics committee. It should be noted that some 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.

**Section 4: Funding**

* Sources of funding must be declared.
* Any conflict of interest, or apparent conflict of interest, must be declared and discussed.

**Section 5: Interventions, Hazards, and Risks**

* 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.
* Studies should not put participants at risk of harm.
* 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.

**2.8 Section 6: Data**

* Describe who will have access to the data.
* 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.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 to complete a separate Data Protection Impact Assessment (DPIA) for your study. 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/). We have completed a DPIA for standard procedures and types of data commonly processed by researchers using YNIC (DPIA\_183). If you would like anything to be added to DPIA\_183, please email a request to the YNIC Research Ethics Committee. If you will be processing any other kinds of data, or plan to deviate from the procedures outlined in DPIA\_183, you may need your own study-specific DPIA, or decide to complete one. This can be done prior to or in parallel with the YNiC ethics application.

The full DPIA\_183 can be found [here](https://vcs.ynic.york.ac.uk/ynic-public/forms/-/raw/master/YNICDPIA183.pdf) and there is a summary in Appendix 1 below. Please check that document to determine whether your study is covered by DPIA\_183. A summary is given in Appendix 1 below.

In this section you should state whether or not you will complete a separate DPIA, and whether this has been instigated. Crucially, if DPIA approval is pending when you submit your ethics application, any ethical approval is conditional on receiving DPIA approval from the University.

* 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.
* 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).
* If your study collects biological samples:Participants are entitled to confidentiality, and to know who will use any biological samples which they provide and for what purpose.
1. The steps that will be taken to ensure the security and confidentiality of biological samples must be described.
2. The people who will have access to the biological samples must be named.

**Section 7: Consent and Debriefing**

* Consent: Competent healthy adult volunteers must give written consent to participate. Applicants should follow the advice in Section 3 for obtaining consent from the other groups of participants listed in the Application Form.
* 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.

**Section 8: Secrecy**

Any constraints on the conduct of the research or the way it is reported must be declared.

**Section 9: Special Considerations**

This section provides an opportunity for an applicant to raise any issues that have not been addressed elsewhere in the form.

**Section 10: 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 may be asked to sign a paper copy of the approved version of the application and submit it to YNiC before starting the study.

**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.

**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 is 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.

Appendix 1

The full DPIA\_183 can be found [here](https://vcs.ynic.york.ac.uk/ynic-public/forms/-/raw/master/YNICDPIA183.pdf). Please check that document to determine whether your study is covered by DPIA\_183. Below is a summary of the key points.

1. We routinely collect “special category personal data” (in particularly data relating to health) when screening participants during recruitment, when deciding whether it is safe for the participant to be scanned or when deciding whether a person belongs to a population of interest. DPIA\_183 covers:

i) Standard questions we usually include when screening participant during recruitment, (check the list in Appendix 2 below to see what’s included),

ii) The general consent form issued by and held at YNIC (for full details of the procedure, check the full version of [DPIA\_183](https://vcs.ynic.york.ac.uk/ynic-public/forms/-/raw/master/YNICDPIA183.pdf)),

iii) Standard study-specific questions and other behavioural / additional experiments (check the list (Appendix 2) to see what’s included),

iii) The three safety screening forms (MRI, MEG, TMS). The data from these are held at YNIC (for full details of the procedure, check the full version of [DPIA\_183](https://vcs.ynic.york.ac.uk/ynic-public/forms/-/raw/master/YNICDPIA183.pdf)),

**If you wish to collect any kind of data that is not covered by DPIA\_183, you will need to determine whether you need to complete your own DPIA, which must be approved by the University data protection officer before the study can begin**.

1. For your initial screening questions to be covered by DPIA\_183, **you must gather this data using a Google form** (managed by the individual research group), **either filled in by the participant or by the researcher on behalf of the participant**. If the questions are asked verbally, the answers will be read back to the participant to ensure that errors have not been introduced. If the participant seeks further clarification from the researcher or YNiC staff, they may be asked necessary follow-up questions verbally. The data should be stored using Google Sheets on Google Workspace under the University’s Google Licence.

It is your responsibility to ensure that the data are held securely. Advice can be found here: <https://www.youtube.com/watch?v=OwZ0Nq-f1qI>

[https://support.google.com/docs/answer/2839588?ref\_topic=6063592#zippy=%2Cshow-a-summary-of-responses](https://support.google.com/docs/answer/2839588?ref_topic=6063592" \l "zippy=%2Cshow-a-summary-of-responses)

<https://subjectguides.york.ac.uk/howdoiguide/collaborate-google-files>

When giving the initial screening questions, participants must be told the following:

*“Magnetic Resonance (MR) research takes place in a strong magnetic field. Therefore, no metallic items can be taken into the scanner since they will get attracted by the magnet. They may also be heated up by the radio waves. For the same reason, people with metallic implants or other items cannot be scanned. There may be other reasons why a person cannot take part in the research. For example, we may need certain people to be able to answer our specific research questions. If you wish to take part in the research, we need answers to the following questions so we can establish whether or not you can take part in the research. Please remember that participation is purely voluntary. “*

Researchers should ask the potential participants to read the YNiC safety forms relevant to the modality of scanning to be carried out (i.e. MRI, MEG or TMS, or any combination of them) and ask the participant/potential participant to confirm that there are no contraindications on those forms that mean that they cannot safely take part in the study.

These data are held by the investigators and must only be used to determine whether or not the person can take part in the research, or whether they meet the criteria for a certain experimental group or control group.

Health data from the screening questions may be shared with YNiC staff or other members of the research group who are internal to the University, but only in anonymised form.

Google forms containing the health-related screening information must be deleted when a participant decides not to participate or when it has been decided that they do not meet the criteria for participation. If a participant meets the criteria and decides to take part, the Google form will be retained if the information may be required for data analysis. In this case, data will be held for a minimum of 10 years. Data will not be deleted unless by explicit request from the participant. It may not be possible to delete data if they are already processed and / or published - participants must be made aware of this when they consent to take part in the study.

Following the initial screening procedure, study-specific data may be collected from the participant (eg. using a study-specific consent form, specific behavioural/psychological assessments). Consent information will be necessarily stored in a non-anonymised format; all other behavioural / assessment information relating to any individual participant will be stored with reference to their pseudo-anonymised ID only. These data will be held for a minimum of 10 years. Data will not be deleted unless by explicit request from the participant. It may not be possible to delete data if they are already processed and / or published - participants must be made aware of this when they consent to take part in the study.

When issuing the information sheet to participants, participants should also be given a GDPR compliant privacy notice:

<https://www.york.ac.uk/records-management/dp/guidance/privacynotices/>

There is a template on the [YNIC ethics webpage](https://www.ynic.york.ac.uk/forms).

**If you wish to deviate from the procedure outlined here, you need to assess whether a study-specific DPIA is necessary: https://www.york.ac.uk/records-management/dp/dataprivacyimpactassessments/**

1. MR data, even when stored in a pseudorandomised manner, may be considered “**special category personal data**”. Some MRI data can be reconstructed in such a way that they could be considered to reveal “biometric information”. It is also possible to reconstruct head shape (and thus face) in 3D from an MRI scan, so that a participant could be identified from their their pseudo-anonymised MRI data. Also, as sulcal and gyral folding patterns and the configuration of the brain are unique to each person, they can be considered as representing a potential “brain fingerprint”.

Recovering the identity of a participant in this way would be contrary to all data protection policies already in place at YNiC. It could also represent a breach of section 171 of the Data Protection Act 2018:

*It is an offence for a person knowingly or recklessly to re-identify information that is de-identified personal data without the consent of the controller responsible for de-identifying the personal data.*

i, Data from the scanners are transferred to the YNiC servers and stored in a pseudo-anonymised format. These data can be accessed by investigators who agree to abide by all YNiC data protection policies and procedures. These policies include a declaration signed by each investigator, which confirms that investigators will not use pseudo-anonymised data to try to determine the identity of the person from whom it was obtained.

**All researchers and staff who have access to the centre must sign the** [**YNiC Appropriate Data Usage Declaration**](https://vcs.ynic.york.ac.uk/ynic-public/forms/-/raw/master/AppropriateDataUsageDeclaration.pdf) **when they register to have access to data stored at YNiC (NB - all active users of the centre will have to sign this declaration retrospectively if they are currently using the center, both for newly acquired data and data acquired in the past). The signed form must be submitted to the YNIC reception.**

ii, Data are held at YNiC. **Researchers can only copy data from YNiC servers if they a) have obtained approval from the YNIC Research Ethics Committee (by emailing** rec-submission@ynic.york.ac.uk) **and 2)** **do this in a way that does not allow others to reconstruct biometric data that could be used to reveal the identity of an individual participant’s data from that participant’s pseudo-anonymised data set.** If they do need to share data outside of the organisation that would allow such a representation to be constructed, **a separate DPIA will be needed**. In this case researchers will also need to work with the University’s Research and Knowledge Exchange Contracts Team to ensure an appropriate agreement is in place (eg. a Memorandum of Understanding to cover Intellectual Property etc.

Appendix 2

To determine whether a potential participant meets the safety criteria for participating in a research study, the participant may be asked any of the following questions (any questions that are not needed for a certain study must be removed by the researcher). It will be made clear to the individual that we need answers to these questions only if they still wish to take part, and they will be reminded that participation is purely voluntary.

* Do you have any metallic implants or items including cardiac pacemakers, pacing wires, cochlear implants, metallic aneurysm clips, metallic fragments in the eye, certain types of bio-mechanical implants and fixed dental braces?
* Do you have a programmable hydrocephalus shunt?
* Have you ever had any operations on your heart, head or spine?
* Do you have or have ever had a spinal or other neuro stimulator?
* Have you had any surgery which involved the use of medical implants? (e.g., hip or knee replacements, breast or penile implants, or any procedure using metal stents e.g., coronary arteries)?
* Do you have a fixed dental brace?
* Have you had any surgery in the last 3 months?
* Have you, at any time, had an injury to your eye involving metal fragments?
* Do you have any shrapnel in your body?
* Do you have any medicinal patches? including nicotine, hormone
* Do you have epilepsy? / Have you ever had a fit or seizure?
* Do you have any diseases/disorders related to the eye or brain?
* Do you have an Intra-Uterine Contraceptive Device?
* Are you claustrophobic?
* Do you have normal or corrected to normal vision?
* Do you wear glasses? / If yes, what prescription lenses do you wear?
* Do you have normal hearing?
* Are you neurologically healthy? / Do you have a history of neurological disease?
* Do you have / have you had any neurological problems?
* Do you have/ have you had any psychiatric problems (including anxiety or depressive disorders)?
* Do you have any history of mental illness?
* Do you have / have you had a developmental disorder?
* Do you have dyslexia?
* Do you have Attention Deficit Hyperactivity Disorder (ADHD)? / Do you have Attention Deficit Disorder (ADD)?
* Are you taking certain prescription medications?

*(we may specify certain medications, for example we might ask “Do you use medications/drugs with potential vascular or central nervous system effects?”)*

* Are you pregnant or do you believe you could be pregnant?
* Have you ever had a Cerebrovascular Accident (CVA) / stroke?
* Can you tell me when you had your stroke/ most recent stroke?
* Do you have any brain damage e.g., Parkinsons, Alzheimers?
* Other than your stroke, have you ever experienced any other form of brain damage? Do you think it's possible you have dementia or Parkinson's disease, for instance? Or have you ever suffered a traumatic brain injury?
* Do you experience fatigue?
* When you had your stroke, can you remember which hospital you were admitted to? If so, do you remember which consultant you were seen by/had contact with?
* Did you have any speech and language therapy following your stroke? If so, how often did you have these sessions and for what period of time? Are you taking part in any speech and language therapy at the moment?
* Since your stroke do you experience any weakness on one side of your body? If so, which side?"
* If possible, it's useful for us to know which areas of your brain were affected by your stroke. Can you remember having an MRI scan while in hospital following your stroke? If so, do you remember which hospital this scan took place at? Would you be happy for us to try and obtain some images of this scan from the hospital? If so, we can submit a request together with you, and can make sure you have access to these images as well if that's something you'd like?
* Have you ever been diagnosed with any form of sleep disorder?
* Have you ever been diagnosed with any form of hormonal disorder?
* Are you a smoker?

If the following questions are needed, the participant will be asked to tick one box to confirm that all the statements they are given are true. They will not be asked to answer these questions separately.

*During the past three months, I have not used any illicit drugs for recreational purposes
During the past three months, I have not regularly consumed in excess of 14 units of alcohol (equivalent to six pints of beer or seven glasses of wine) per week*

We may also ask participants to complete: The Pittsburgh Sleep Quality Index (PSQI), the Beck Depression Inventory (BDI-II), and the Beck Anxiety Inventory (BAI).

If they are in doubt about how to answer a question, they can contact the researcher or YNiC for further clarification. The researcher / YNiC staff may ask necessary additional questions as part of this process.