

**York Neuroimaging Centre**

**“Title of Project”**

***Participant Information Sheet (Version 10)***

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve. Please read the following carefully and ask any questions if you wish.

***What is the purpose of the study?***

Study explanation.

***Why have I been chosen?***

Insert here.

***Do I have to take part?***

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw any time and without giving a reason.

***What will happen to me if I take part?***

Insert here.

***Benefits of taking part in the research***

Insert here.

***Is there a chance that the brain scan will detect something wrong with my brain?***

Yes, neuroimaging research can detect brain anomalies (abnormal structural features). Such anomalies are uncommon (~3% of volunteers scanned). Most frequently anomalies are benign and will not affect daily life or health prospects. More uncommonly (~1%), anomalies that are a risk to an individual’s health are detected. (Figures were obtained from an article by [Morris et al](http://www.bmj.com/content/339/bmj.b3016.full) published in the British Medical Journal.

***What are the potential benefits and harm that could arise from a brain anomaly being detected?***

The chance finding of the anomaly may allow for action to be taken quickly that may benefit your health directly. In contrast, there is the possibility that a brain anomaly would have to be declared if you were to be seeking health insurance or other types of insurance and could affect how insurance is provided to you. Knowing that a brain anomaly has been detected may also make you worry about your own health in a way that you didn’t before. It is important to consider these issues in the context of volunteering for the study.

***If no anomaly is detected, do I have a ‘clean bill of health’?***

No. Almost all the research procedures undertaken at YNiC are not the same as the scans that are routinely used for clinical diagnosis. Therefore, you should not consider the absence of the detection of an anomaly as an indication of ‘a clean bill of health’.

***What procedures are used if an anomaly is suspected?***

Under the circumstances that an anomaly is detected in your brain the scans will be sent to a qualified Radiologist to give a clinical opinion. You and the principal investigator of the research project will be informed, in writing, that this has been done. Your GP will also be informed and will be supplied with the report given by the Radiologist. You will also be informed, in writing, that your GP has been sent the report on your scan. Your GP may contact you to discuss the appropriate course of action. Even if your GP does not contact you, you may wish to see him/her to discuss the report on the scan. You may give your permission for your data to be released for research purposes, by completing a data release form. You can read the [policy on Diagnostic Imaging](https://www.ynic.york.ac.uk/information/policies#ynic-clinical-diagnostic-policy) for further information if you have any concerns. It is important for you to weigh up the potential benefits and harm that may result from an anomaly being detected.

***Are there any other risks of taking part?***

Research at YNiC is always planned and conducted in a way that minimises any risk of harm to participants. However, MRI involves high magnetic fields. For this reason, participants must not take any metal objects into the scanner room. In addition, certain groups of people are unable to

take part for safety reasons: these include individuals with dental braces, pacemakers, cochlear or brainstem implants, any other surgical implants involving metal, and pregnant women. If you have any

questions about whether it will be safe for you to take part, please ask the researchers. MRI also involves high sound levels. We will ask you to wear earplugs during testing to protect your hearing. In some cases, participants may find the enclosed nature of the MRI scanner to be claustrophobic. You

can stop the experiment at any time if you experience discomfort. Finally, participants are required to stay still for the duration of the experiment; cushions, knee rests and blankets are provided to assist comfort during the scan.

As part of the MEG scanning procedure, you will see a bright flashing light. Please do not take part if you are sensitive to a bright flashing light.

***What will happen if I don’t want to carry on with the study?***

If you feel uncomfortable about any aspect of the study, please let the researcher know straight away. S/he will be discuss your concerns with you and may be able to help. You are free to withdraw from the study at any time without giving a reason. If you decide to withdraw, please tell the researcher.

***On what basis will you process my data?***

Under the UK General Data Protection Regulation (UK GDPR), the University has to identify a legal basis for processing personal data and, where appropriate, an additional condition for processing special category data.

In line with our charter which states that we advance learning and knowledge by teaching and research, the University processes personal data for research purposes under Article 6 (1) (e) of the UK GDPR:

*Processing is necessary for the performance of a task carried out in the public interest.*

Special category data is processed under Article 9 (2) (j):

*Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes.*

Research will only be undertaken where ethical and data protection approval has been obtained, where there is a clear public interest and where appropriate safeguards have been put in place to protect data.

In line with ethical expectations and in order to comply with common law duty of confidentiality, we will seek your consent to participate where appropriate. This consent will not, however, be our legal basis for processing your data under the UK GDPR.

***What type of data are collected or processed in this study?***

We are collecting and processing two types of personal data (data that could potentially identify you) in this study. Personally Identifiable Information (PII) refers to data that can easily identify you (for example, your name, address, or date of birth). For some MEG studies, this will also include images of your face. These are needed when MEG and MRI are aligned during data analysis. Research data refers to information you provide as part of this study, for example answers to questionnaires and scans of your brain. Based on these data, it is often difficult to identify you personally. We treat these two types of information differently, as outlined below.

***How will you keep my data secure?***

The University will put in place appropriate technical and organisational measures to protect your personal data and/or special category data. The University is committed to the principle of data protection by design and default and will collect the minimum amount of data necessary for the project. In addition, we will use data in anonymised (all personally identifying information removed) or pseudonymised (using participant IDs) form wherever possible. No names, or images of an individual’s face will be used when the research is written up. We shall comply with the terms of the UK GDPR and other current data protection law.

***What happens to my PII (identifiable information, such as my name and contact details)?***

We shall store names and addresses (and any other type of information that can easily identify you, with the exception of any images of your face that are required for MEG / MRI data alignment) separately from research data. Only three members of our research team will know the contact details of the participants. They are Professor Alpha Beta, Dr Gamma Delta, and Dr Epsilon Zeta. In addition, staff of the York Neuro-imaging Centre have privileged access to the computer systems and can link the names of participants with their data and any images of your face created for MEG / MRI data alignment. Those people are under a professional obligation not to abuse this privilege. Names and addresses will never be transferred internationally. If an anomaly is detected in your scan, staff at the York Neuroimaging Centre will have to share PII data with your GP, as described in the “***What procedures are used if an anomaly is suspected?”*** section of this document. Images of your face acquired to allow alignment of MEG and MRI data will not be available to researchers, and will only be available to YNIC staff.

***What happens to my research data?***

Your research data will be stored separate from your PII in an anonymous or pseudonymous format.

Conducting research is expensive and it relies on volunteers generously contributing their time. To make the most of your participation, we plan to retain your research data indefinitely and may use these data to answer research questions beyond those for which your data were originally collected. This may include combining research data from this study withresearchdata from other studies in which you have been involved.

In addition to potentially sharing your research data with other researchers at the York Neuroimaging Centre, we also plan to share some research data more broadly with researchers across the UK and globally. This is important for the scientific process, so that other researchers have the opportunity to check our data and findings or to conduct new analyses.

In some cases, these research data can be shared in a fully anonymous format, with no connection to any personal data you provided. However, your data might be shared in pseudonymised format. In this case, the research data themselves are saved and shared with an anonymous ID code that cannot identify you but there remains a link with your YNiC ID code *within YNiC*. This connection cannot be made by researchers outside YNiC.

When sharing MRI data, there is a small chance the research data themselves could identify you. For instance, there is a very small chance that you could be identified (by yourself or another person) based on a brain scan. However, we will always take great care to minimise the chances of identification, for example by removing the face from an fMRI scan before sharing the data outside of YNIC.

In some cases, people will be required to agree to a “data usage agreement” in order to access research data. However, in other instances, data might be made fully “open”, in which case we cannot control how that information is used.

[We plan to share the following types of research data:]

**You should only agree to participate in this study if you have understood and consent to this re-use and sharing of research data.**

***Will you transfer my data internationally?***

PII data will never be shared internationally. Research data may be shared internationally through open data sharing.

In cases where collaborators are based outside the University, pseudonymised or anonymised data may be shared using the University’s cloud storage solution provided by Google, which means that data can be located at any of Google’s globally spread data centres. The University has [data-protection compliant arrangements](https://www.york.ac.uk/it-services/google/policy/privacy/) in place with this provider. As stated above, we may make research data freely available through other platforms too.

***How long will you keep my data?***

Data will be retained in line with legal requirements or where there is a business need. Retention timeframes will be determined in line with the University’s [Records Retention Schedule](https://www.york.ac.uk/library/info-for/researchers/data/sharing/). When research data are shared publicly, they are retained indefinitely.

***What rights do I have in relation to my data?***

Under the UK GDPR, you have a general right of access to your data, a right to rectification, erasure, restriction, objection or portability. You also have a right to withdrawal. Please note, not all rights apply where data is processed purely for research purposes. For further information see this [For further information, please see the University's guidance on rights requests.](https://www.york.ac.uk/records-management/dp/individualsrights/)

You can request to have your PII/YNiC account removed at any time by contacting YNiC staff. You can request to have your research data for this study deleted by contacting the project leader. It may not be possible to delete your research data if they are already processed and/or published.

***What will happen to the results of the study?***

Insert here.

***Who has reviewed the study?***

This study was given a favourable ethical opinion by the Research Ethics Committee of the York Neuroimaging Centre.

***What if there is a problem? How can I make a complaint?***

‘If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. They may be reached using the contact details given at the end of this sheet. If you remain unhappy and wish to complain formally, you can do this through the complaints procedure of the University of York. Details can be obtained from the email address: [registrar-and-secretary@york.ac.uk](mailto:registrar-and-secretary@york.ac.uk). If you are dissatisfied with the way your personal data have been handled please contact the lead researcher in the first case, or the University’s Data Protection Officer at [dataprotection@york.ac.uk](mailto:dataprotection@york.ac.uk). If you are unhappy with the way in which the University has handled your personal data, you have a right to complain to the [Information Commissioner’s Office](http://www.ico.org.uk/concerns).

The York Neuroimaging Centre takes pride and care in ensuring that no harm, or risk of harm, occurs to participants in research. In the event that something does go wrong and you are harmed during the research study and this is due to someone’s negligence, then you may have grounds for a legal action for compensation against The University of York.

***Who is organising and funding the research?***

The study is being organised by Professor Alpha Beta, Dr Gamma Delta, and Dr Epsilon Zeta. They work in the Department of Psychology at the University of York. Alpha Beta is a Professor of Psychology. Gamma Delta is a Reader in Psychology. Epsilon Zeta is a Research Fellow in Psychology.

The study is being funded by The University of York and a charity, the Pi Rho Sigma Foundation.

Professor Alpha Beta can be contacted on…

***Recompense***

To recompense you for taking part in this research

[You will be assigned x hours of course credit]

[You will be paid £x using [cash/vouchers/bank transfer/other form of payment] ]

[The research team will pay for expenses associated with your involvement in this research.]

**[If you are paying participants through e.g., vouchers, please also include the following information (see participant payment information sheet on the wiki). Collection of personal data for payment is not needed for studies on Prolific or for course credit]:**

In order to pay participants, we are now required to ask for their home address (in addition to their name and email address) to meet HMRC requirements. To be paid for this study, we therefore ask you to provide us with this information. If you do not want to share this, we kindly ask you not to take part.

Your data (name, email address, and home address) will be shared with the administration team in the Department of Psychology so that they can process the payment. In line with HMRC retention requirements, these data will be kept for seven years. Your data will not be shared with others and will not be used for any other purposes. They will also be saved separately from the data collected in this study. For more information about processing of personal data, please see [this key information about UK GDPR.](https://wiki.york.ac.uk/display/PsySharedDocs/Key+information+about+GDPR)

**Further information about payments:**

Please be aware that if you are paid more than £1000 over the course of a year, you will need to complete a Self-Assessment form for HMRC. Being paid for involvement in research is likely to have implications for you whether you are currently employed, unemployed, receiving state benefits or retired. The payment you receive will be treated as earnings by HMRC. There are a number of ways in which receiving payment for involvement may affect your current financial situation. You can find more information about this here: https://www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-public-considering-involvement-in-research/27372#Section\_8\_-\_Sources\_of\_information\_and\_advice

For information and guidance concerning your personal tax obligations, please see the following resources:

**NIHR Payment guidance for members of the public considering involvement in research**<https://www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-public-considering-involvement-in-research/27372#The_implications_of_being_paid_for_involvement>

**Benefits Advice Service**

This free, confidential and personalised service is coordinated by the Bedford Citizens Advice Bureau to support members of the public whose welfare benefits may be affected by payment for involvement.

The service:

* provides advice based on the benefits you are receiving, to help you decide if and how you want to get involved in research or receive payment for your involvement
* supports you should you need to make contact with the Department for Work and Pensions, or other benefits agencies about payments for involvement

#### **How to access the Benefits Advice Service**

For more information on how to access this service, please contact the NIHR Centre for Engagement and Dissemination ced@nihr.ac.uk or call 020 88437117.

* tell us the name of the NIHR organisation you are involved with, or the name of the NIHR programme funding the research project you are involved with
* we do not need to know anything about your benefit situation
* we will give you an email address (or telephone number) so that you can contact the Benefits Advice Service directly
* We will also give you a code – please give this code to the service when you contact them
* the service prefers that the first contact is by email if possible – the service will then arrange a time to call you.
* if you do not know if the organisation you are involved with is part of the NIHR, please contact the person who asked you to get involved

Taken from: NIHR Payment guidance for members of the public considering involvement in research, (March 2021)

<https://www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-public-considering-involvement-in-research/27372#Section_8_-_Sources_of_information_and_advice>