

**York Neuroimaging Centre**

**“Title of Project”**

***Participant Information Sheet***

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?***

Insert here.

***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 General Data Protection Regulation (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 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 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 GDPR.

***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 will be used when the research is written up. We shall comply with the terms of the GDPR and other current data protection regulations. We shall store the information and the measurements in pseudonymous or anonymous computer files and in locked filing cabinets. We shall store names and addresses separately from other 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. Those people are under a professional obligation not to abuse this privilege.

Pseudonymised data may be shared with our collaborators working in other institutions but the source data that could be used to identify individuals will never be shared. With the approval of the Research Ethics Committee of the York Neuroimaging Centre, other researchers may be allowed access to the pseudonymised data for use in research and teaching. Fully anonymised data may be made publicly available to allow full use of the research data, once the source data that can be used to identify individuals has been removed.

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

Personal details such as names and addresses will never be transferred internationally. 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 open access data available, which would be shared internationally, but only in fully anonymised form.

***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/).

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

Under the 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 [link](https://www.york.ac.uk/records-management/dp/individualsrights/).

***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…