Guidance: The information provided in this document is a guide only. Please revise the wording in this section as necessary. The information provided in blue italics must be removed from the document before it is submitted to the HREC/HREAP ].

1. **What is the research study about?**

You are invited to take part in this research study. The research study aims to [INSERT a brief description of the purpose, aims and significance of your research study in plain English]. You have been invited because [INSERT reason for invitation], and your contact details were obtained from [Insert how their details were obtained].

1. **Who is conducting this research?**

The study is being carried out by the following researchers:[INSERT name of CI, PI and the student investigator], [INSERT School/Faculty or Organisation]**.**

**Research Funder:** This research is being funded by [list the name/s of funding organisation/s].

1. **Inclusion/Exclusion Criteria**

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

* [INSERT the inclusion criteria]
* [INSERT the inclusion criteria]
1. **Do I have to take part in this research study?**

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

* Read the information carefully (ask questions if necessary);
* Sign and return the consent form if you decide to participate in the study;
* Take a copy of this form with you to keep.

1. **What does participation in this research require, and are there any risks involved?**

Guidance: The information provided at this section needs to tell participants what they will be expected to do during their involvement in the research. Please delete any information that is not relevant to your study. [Below are examples that may be applicable to your study]

**[Completion of a Paper-Based Questionnaire]**

* If you decide to take part in the research study, we will ask you to complete a paper-based questionnaire. The questionnaire will ask you questions about [provide a description of the questions to be asked]. It should take approximately [insert approx time] to complete.

**[Participation in an Interview or Focus Group]**

* If you decide to take part in the research study, you will be asked to participate in a face to face **[interview or focus group]**. You will be asked questions about **[INSERT the nature of the questions that will be asked].** It should take approximately [insert approx time] to complete.

To ensure we collect the responses accurately, we seek your permission to digitally record the interview using an **[INSERT audio tape/videotape/photograph].**  If you would like to participate but do not wish to be recorded, you will need to discuss the options for your participation with the research team.

If you decide to take part in the research study, the research team we will ask you to [detail the steps the participants will need to follow to complete the task]. It should take approximately [insert approx time] to complete the task.

**[Participation in MRI Scanning]**

We will ask you to come to NeuRA Imaging at Neuroscience Research Australia, Barker St, Randwick for a [INSERT ANATOMY HERE] scan. This is a non­invasive, painless procedure, which involves you lying in a magnetic resonance scanner (the MRI machine). MRI equipment has been in routine clinical use for over three decades and is approved by the Australian Therapeutic Goods Administration, the European Union and the USA Food and Drug Administration for this purpose.

You will lie on a motorised bed which is then moved into an open chamber which generates the magnetic field. The chamber is small. Some people find it claustrophobic. You will required to remain still in the chamber for about [INSERT TIME HERE] minutes until the scanning is complete. Total scanning time will not exceed [INSERT TIME HERE] minutes. The scanner makes loud banging noises during this procedure, but you will be given ear-plugs to minimize disturbance. There is also a low possibility of nerve stimulation which may manifest as a tingling sensation or twitching. The scan can be stopped at any time should you feel discomfort (you will be given a buzzer to hold for this purpose). Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney, NeuRA or in any way impact the medical treatment you are currently receiving. Prior to the scan you will be screened using a questionnaire for contraindications to scanning, such as presence of a pacemaker, metal shards (e.g. from shrapnel or association with metal work) or other metal implants. Because of the powerful magnetic field, you must not bring any metal into the instrument. For your comfort, we suggest the following; wear loose-fitting, comfortable clothing containing no metal fittings or fabric. Bring only the minimum number of jewellery items (watches, rings, earrings, etc.), as all of these must be removed prior to scanning. In rare cases, certain types of eye makeup – especially eye liners – may cause problems with the MR images. You may wish to come without makeup to avoid having to remove it for the scan. For several hours prior to the scan, avoid drinking coffee and other diuretics that may require you to urinate often, as you will generally not be able to use the restroom for the duration of the scan.

Cerebral MRI is most commonly used in diagnosing neurological diseases, and rarely may find unexpected pathology. Your scans will be inspected by a qualified medical practitioner. In the event that there are adverse findings the radiologist, who will look at all the applicable images will release the report to the responsible person associated with this study [INSERT NAME HERE] who would then be responsible for any follow up. If abnormalities should be found, [INSERT NAME HERE] would be responsible for advising you of the abnormal report and liaising with you for the report to be provided to your primary health care provider.

[INSERT INFORMATION ABOUT CONTRAINDICATIONS HERE] (e.g. history of neurological disease, head trauma, etc.)

[INSERT ANY SPECIFIC INFORMATION ABOUT THE SCANNING HERE] (e.g. tasks or instructions during scanning)

MR scanning is a time-consuming and expensive procedure. To maximize the benefits to medical research we will, with your permission, allow access to your stored, de-identified data by approved researchers, subject to approval of their studies by an appropriate Human Research Ethics Committee. All data would be provided in such a way that it cannot be identified with you.

* I give my permission for my de-identified data, obtained in this study, to be used in other medical research studies.

Collection of data and recruitment of volunteers in medical research is a time consuming and potentially costly exercise. Would you be interested in potentially taking part in further medical research studies?

* I would be interested in receiving information via mail about other potential research studies. I understand that this would involve information only and would not oblige me to take part in these studies. I understand that this information would be limited to two potential studies per year.

**[Reimbursement and Incentives] –** If applicable indicate whether participants will be provided with reimbursement or an incentive. Describe how they can claim following participation. Further information about incentives can be found on the frequently asked questions [page](https://research.unsw.edu.au/frequently-asked-questions-faqs).

If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time. You can also tell a member of the research team and they will provide you with assistance or alternatively a list of support services and their contact details are provided below.

1. **What are the possible benefits to participation?**

We hope to use information we get from this research study to benefit others who [INSERT realistic potential future benefits. Please do not overstate the benefits]

1. **What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for:

* A minimum of 5 years after the publication of the research results;
* A minimum of 7 years after the completion of the research;
* A minimum of 15 years after the publication of research results;
* Other [insert the retention period]

The information about you will be stored in an/a:

* Identifiable format, where your identity will be known.
* Re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code.
* Non-identifiable format where your identify will be unknown.

You will be asked to provide your consent for the research team the share or use the information collected from you in future research that:

* Will be specific to the aims of this research;
* Will be an extension of, or closely related to, the original project; or is in the same general area of research;
* Will be used in any future research.

Your information will only be shared in a format that will not identify you.

* Information collected from you in an electronic format stored on a UNSW password protected OneDrive only accessible to the investigators listed at section 2 of this document.
* Information collected from you using paper-based measures will be stored in the following [insert the school/faculty address] only the investigators listed at section 2 of this document will have access to this information.
* Audio or video recordings will be stored on a UNSW password protected OneDrive only accessible to the investigators listed at section 2 of this document.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [**UNSW Privacy Management Plan**](https://www.legal.unsw.edu.au/compliance/privacyhome.html).

1. **How and when will I find out what the results of the research study are?**

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will or will not identify you.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

1. **What if I want to withdraw from the research study?**

If you do consent to participate, you may withdraw at any time. You can do so by completing the ‘Withdrawal of Consent Form’ which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or any of the organisations involved in this research. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

[Focus groups]

If you decide to participate in the focus group, your comments along with other participants will be recorded during the group discussions. Because of the way in which the focus group discussions are recorded, the research team will not be able to withdraw or destroy individual participant responses.

1. **What should I do if I have further questions about my involvement in the research study?**

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

**Research Team Contact Details**

|  |  |
| --- | --- |
| **Name** | [INSERT full name] |
| **Position** | [INSERT position title] |
| **Telephone** | [INSERT work telephone number. Please do not use personal mobile numbers]  |
| **Email** | [INSERT work email address. Please use only UNSW email addresses]  |

**Support Services Contact Details**

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

|  |  |
| --- | --- |
| **Name/Organisation** | [INSERT name/organisation]  |
| **Position** | [INSERT position title] |
| **Telephone** | [INSERT work telephone number] |
| **Email** | [INSERT work email address] |

**What if I have a complaint or any concerns about the research study?**

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

**Complaints Contact**

|  |  |
| --- | --- |
| **Position** | UNSW Human Research Ethics Coordinator |
| **Telephone** | + 61 2 9385 6222 |
| **Email** | humanethics@unsw.edu.au  |
| **HC Reference Number** | [INSERT HC reference number] |

**Consent Form – Participant providing own consent**

**Declaration by the participant**

* [add or remove checkboxes as required]
* I understand I am being asked to provide consent to participate in this research study;
* I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
* I understand the purposes, study tasks and risks of the research described in the study;
* [Recordings] I understand that the research team will audio/video record the interviews; I agree to be recorded for this purpose.
* [Collection of Biospecimens] I understand that the research team will collect [INSERT type of speciment to be collected]; I provide my consent for this to happen.
* I provide my consent for the information collected about me to be used for the purpose of this research study only.
* I have had an opportunity to ask questions and I am satisfied with the answers I have received;
* I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
* I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* I understand that I will be given a signed copy of this document to keep.

**Participant Signature**

|  |  |
| --- | --- |
| Name of Participant (please print) |  |
| Signature of Research Participant  |  |
| Date |  |

**Declaration by Researcher\***

* I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

**Researcher Signature\***

|  |  |
| --- | --- |
| Name of Researcher (please print) |  |
| Signature of Researcher  |  |
| Date |  |

**+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.**

**Note: All parties signing the consent section must date their own signature.**

**Form for Withdrawal of Participation**

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, [other participating organisation[s] or other professional(s)].

In withdrawing my consent, I would like any information which I have provided for the purpose of this research study withdrawn. [I understand that the information collected about me during my participation in the focus group cannot be withdrawn given the nature of the focus group ].

**Participant Signature**

|  |  |
| --- | --- |
| Name of Participant (please print) |  |
| Signature of Research Participant  |  |
| Date |  |

**The section for Withdrawal of Participation should be forwarded to:**

|  |  |
| --- | --- |
| CI Name: | [insert CI name] |
| Email: | [insert work email address] |
| Phone: | [insert work mobile number] |
| Postal Address: | [insert work postal address] |