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].

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]

Participants who meet the following criteria will be excluded from the study:

[INSERT the exclusion 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]

**Screening:** A screening questionnaire asking about [provide details]; this will determine if you are eligible to take part. Completing the screening measures will take approximately [specify expected time]. The screening questionnaire will be administered to you in a [provide details e.g. online platform, paper version, telephone or online interview]. If the screening questionnaire shows that you meet the criteria for inclusion, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, [insert what will happen].

**[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.

**Randomisation:** The aim of the research is to compare the outcomes of the [insert research intervention] and the [insert the research control],to ensure that each participant has an equal chance of being placed in any group to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Once randomised participants will be allocated to one of the following participant groups. An overview of the difference in research procedures that you will be asked to complete is described in the table below.

|  |  |
| --- | --- |
| Intervention  | Control  |
|  |  |

**Sample Collection:** Samples of blood taken from a vein will be required. The amount of blood taken will be equivalent to [insert number] of millilitres (or [insert number] of teaspoons) taken on [insert number] occasions. The research team will provide you with a request for and you will be asked to attend the [insert details] pathology clinic for sample collection. The research team will cover the cost of blood collection. Any blood samples collected will be analysed for the purpose of this research and will be destroyed following testing.

**Intervention:** [Name of treatment/therapy] used to treat [Name of condition] will be used in this research. OR [Name of treatment/therapy] is an experimental treatment. Therefore, it is an experimental treatment for [Name of condition]. This means that it must be tested to see if it is an effective treatment for [Name of condition].

**Medical Drugs or Devices:** Medical Medications, drugs and devices have to be approved for use by the Australian Federal Government before they are used within Australia. The following medical drugs, devices or placebos will be used in this research:

[Name of investigational product] is approved in Australia to treat [Name of condition] will be used in this research. OR [Name of investigational product] is an experimental treatment. This means that it is not an approved treatment for [Name of condition] in Australia. Therefore, it is an experimental treatment for [Name of condition]. This means that it must be tested to see if it is an effective treatment for [Name of condition].

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the research team immediately about any new or unusual symptoms that you get. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. The research team will discuss the best way of managing any side effects with you.

**[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.

Your MRI scan is solely for the purposes of research and the imaging performed is tailored to that research. The scan does not constitute a clinical imaging scan and will not include the scope of imaging that is typically taken for clinical scans for the purpose of a diagnosis. Therefore the research MRI scan should NOT be regarded as a diagnostic imaging scan, should not be in lieu of clinically appropriate imaging looking for pathology and it will not be inspected by a qualified medical practitioner or a medical report produced.

In the event of an incidental finding by research staff, the finding will be disclosed to the participant by the research team. You may be advised to discuss any findings with your G.P who may suggest additional and appropriate clinical imaging.

[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.

**Additional Costs and Reimbursement:** There are no costs associated with participating in this research project, nor will you be paid. However, you will receive a [provide details] to reimburse you for any reasonable travel, parking, meals and other expenses while completing the [provide details].

**Psychological Distress:** You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Alternatively, a number of free contactable support services are included at section 9. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

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.

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.

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

Guidance: Do not attempt to build up participant hope in this section. Reference to the potential benefit to future patients may be appropriate but should not be exaggerated.

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include [describe any likely benefits to participants or other people in the future].

1. **What are the alternatives to taking part in the research?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include *[give examples of standard treatment]*. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

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. [if applicable, will be made available to a professional transcription service. Recordings will only be made available after a confidentiality agreement has been signed]

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.

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

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**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]  |
|  |  |

**Chief Investigator**

|  |  |
| --- | --- |
| **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] |

**Complaints Contact**

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:

|  |  |
| --- | --- |
| **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 understand that I will be given a signed copy of this document to keep.
* I give my permission for my de-identified data, obtained in this study, to be used in other medical research studies.
* I understand that the results of the research will be made available on the [insert school/faculty/organisation] website.
* 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.
* 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Optional Consent for reuse of data and future research:

* I provide my consent for the information collected about me to made available to other researchers as described at section 7 of this document.
* I provide my consent to be identified in publications relating to this research.
* I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future.

**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)].

* I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
* I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.
* I am withdrawing my consent and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

[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] |