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]

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?**

If you agree to participate you will be asked to complete the following research procedures.

**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].

**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  |
|  |  |

**Questionnaire/Survey:** An [insert online/email/paper/verbal] questionnaire/survey asking you to answer questions about [provide details]. You will be asked to complete this survey on [insert number] of occasions. The survey should take approx. [specify time] to complete. [if applicable, you will be asked to complete additional rounds of questionnaires/surveys, the research team will contact you via [insert method of contact] to remind you when to complete the next round. You will receive an initial reminder and one follow up reminder.

**Interview:** A [specify face to face, online video, telephone] interview, and you will be asked questions about [provide details]. The interview will take place [insert the location or note the type of video software being used] and will take approximately [specify the expected time]. With your permission the research team would like to [audio/video] record the interview. If you do not wish to be recorded but you would like to participate you advise the research team and written notes will be taken.  [if applicable, you will be asked to complete a follow up interview, the research team will contact you via [insert method of contact] to organise the time. You will receive an initial reminder and one follow up reminder.

**Focus Group:** All focus group sessions will take place [insert the location] and will take approximately [specify the expected time]. During the focus group you will be asked questions about [provide details]. With your permission the research team would like to [audio/video] record the interview. 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. [if applicable, you will be asked to complete a follow up focus group, the research team will contact you via [insert method of contact] to organise the time. You will receive an initial reminder and one follow up reminder.

 **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.

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 approved research investigators.
* Information collected from you using paper-based measures will be stored in the following [insert the school/faculty address] and only the approved research investigators will have access to this information.
* Audio or video recordings will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators [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 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] |

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]  |

**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] |

**Consent Form – Participant providing own consent**

**Declaration by the participant**

* 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/focus groups; 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;
* I understand that I will be given a signed copy of this document to keep.
* I understand that the results of the research will be made available on the [insert school/faculty/organisation] website.
* 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 6 of this document.
* I provide my consent to be identifed 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.

**Participant Name**

|  |  |
| --- | --- |
| Name of Participant (please type) |  |
| 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] |