Participant Information Sheet

THIS IS YOURS TO KEEP

Project Title: The formal title, or short title, of the project should appear here in bold.

Principal Investigator: Include title and name, School/Department/Centre, contact details

Co-Investigator: Include all researchers actively involved in participant engagement.

Student Investigator: Student investigators cannot be the principal investigator (ordinarily the supervisor is the PI)

Who is doing the research?

Introduce the researcher(s) by name and institutional affiliation. Briefly explain the context of the research, e.g. whether it is being conducted by university staff or as part of a student research project. If it is a student research project, clearly state the degree program being undertaken, e.g. PhD, Master of Research.

What is the research about?

In plain language, in no more than a paragraph or two, outline the aims and purpose of the research. Avoid discipline-specific jargon and acronyms. Participants should be able to understand what the research is about without any prior knowledge of the field.

Why have I been invited to participate?

Clearly state that this document is an invitation to participate in a research project. Explain why the participant has been invited, e.g. because of a particular characteristic, experience or role they hold. If there are any criteria that would exclude a potential participant from taking part, these should be identified here.

What will I be asked to do?

Clearly describe all activities the participant will be involved in, including the nature of each activity, e.g. completing an online survey, attending a focus group, where it will take place, and how it will be conducted. State the expected time commitment for each activity and the total number of stages or sessions involved.

If the research involves any topics that may be sensitive, note this here and, where possible, provide examples of the kinds of questions or discussion points that will be covered.

If there are any optional components to participation, describe them here also, e.g. follow-up interview, enter into a prize draw.

Are there any risks or inconveniences to participating?

Describe any foreseeable risks, burdens, discomforts or inconveniences associated with participation and explain how these will be minimised, mitigated or managed. Be specific, e.g. note if participants may be asked questions about personal experiences, or if fatigue is a possibility due to the length of the activity.

Where relevant, provide contact details for an appropriate support service. All research relating to domestic violence must reference 1800RESPECT at a minimum.

If there are no foreseeable risks beyond an everyday level of inconvenience, you may state: *Other than your time, there are no risks or inconveniences anticipated from your participation in this research*.

Are there any benefits to participating?

Briefly describe the potential benefits of the research both for participants directly or the broader community. These should be realistic and proportionate to the complexity of the research: avoid overstating them.

Is the research funded?

If the research has received funding, state the name of the funding body. Disclose any financial or other interests held by the researchers, sponsors or the university, including any payments or benefits to researchers arising from the project. If participants will receive any reimbursement, payment or incentive for their participation, provide full details here. Refer to the NHMRC guidance where applicable: Payment of participants in research.

If the research has no external funding, you may omit this section or state that it is not applicable.

What will happen if I say no or later wish to withdraw?

Inform participants that their involvement in this research is entirely voluntary. Make clear that choosing not to participate will have no effect on their relationship with the researchers or Macquarie University. Where a dependent relationship exists, e.g. teacher/student, clinician/patient or manager/employee, explicitly state that choosing not to participate will not adversely affect that relationship. Where relevant, describe any alternatives available to participants who choose not to take part, e.g. engagement in other classroom activities.

Advise participants that if they wish to withdraw from the research, they may do so at any time and without providing a reason. Provide the contact email address through which participants can notify the research team of their decision to withdraw.

Specify what will happen to any data already collected should a participant withdraw, e.g. their survey responses or interview transcript will be destroyed and not used in the research. Where applicable, note that after a certain point (state applicable limit) it may not be possible to withdraw data, e.g. once identifying details have been removed, or data analysis has commenced.

Reassure participants that after reading this information, they will have time to consider whether or not they wish to take part before making any decision.

What will happen to the information I provide?

Note: When addressing this section, you do not need to use the subsection headings outlined below. For simpler projects, each point can be addressed in a sentence or two. In all cases, participants should be provided with clear, direct statements explaining how their data will be securely stored, what steps are taken to minimise risk, how the data will be used in the current project, how long it will be retained and whether it may be used in future research.

** Refer to the Research Data Management webpage for more information*

Data collection and handling

Describe how data will be collected and recorded, e.g. through written notes, an online survey platform, audio or video recording. If audio or video recording will occur, this must be clearly stated. Where recording is optional, indicate this and explain what will happen if a participant declines to be recorded.

Explain where the data will be stored during the collection, analysis, and write-up phases of the research, and describe how the security of participants' personal information will be maintained throughout, e.g. through encryption, password protection, or restricted access on secure Macquarie University servers. This does not need to be exhaustive but should give participants an understanding of how their information will be handled.

Key things to include, as appropriate:

- Name any digital device or online tools or platforms that will be used to initially collect or generate the data, e.g. video camera, Zoom, REDCap, Gorilla, etc. Note: When referring to storage on OneDrive and SharePoint, describe these as "restricted-access secure Macquarie University servers" rather than naming the products.)
- Clearly state if collection is done by a collaborator or entity outside of Macquarie University, what happens to the data after, including if held by them, transferred in original form or processed to Macquarie University, etc.
- State when personal data is held, even temporarily, on platforms or servers outside of Australia. Include the country it will be held in. If your participants are located in the EU or UK, you must also include a direct tick-box acknowledgement – refer to GDPR consent requirements.
- Include a clear statement if audio and/or video recording will occur, or photographs will be taken, e.g. of the participant or something they produce.

- State whether and how transcription will occur and what will happen to recordings once they are transcribed.
- If a re-identification key is created, clearly state this and identify who will have access to the key.

Data retention

State where data will be stored once the project is complete. In most cases this will be at Macquarie University for a minimum of five years, or longer for certain types of research (per NSW General Retention and Disposal Authority: GA47) in order to substantiate findings. If parts of the data will be deleted sooner, state when this will occur e.g. identified interview data that is captured through note-taking or audio/video recording will be deleted after verifying transcription.

If the research is conducted in partnership with other agencies or institutions, different storage locations or longer retention periods may apply. Identify these where relevant, particularly if the other party will be responsible for data custodianship. State clearly what will happen to the data at the end of the retention period, e.g. data that has not been deposited in a repository or retained for future use will be securely deleted.

Use of results

Explain how the findings of the research will be used and disseminated. This may include theses, published journal articles, conference presentations, reports, or use in teaching. Where findings will be published or presented, describe the form in which participant data will appear, e.g. de-identified, aggregated, or anonymised. Be specific if using quotes, videos or photographs, and specify if they have an option to remain identifiable.
If a project is sponsored or involves an external party, state any specific use of the data that they have planned.

Data sharing and future use

Note: Consent documentation should not unnecessarily preclude the sharing or preservation of data, for example by promising to destroy data without good reason. Unnecessary destruction does not recognise the burden that data collection places on participants and may lead to avoidable repeat data collection. However, even where consent for data sharing has been obtained, you retain an obligation to exercise judgment in the interests of participants. If a material risk is identified that participants may not have considered, and that would reasonably have caused them to decline consent, you should err on the side of not sharing the data.

Specify the type of consent being sought regarding future use and/or sharing of the data from the three options below. This should align with the scope of consent selected in HREA Q2.2.2.1.

- Specific consent – data will be used for this project only. This means not even the current research team can re-use the data.
- Extended consent – data may be used in future research related to this project or area of research, with separate ethics approval.

- Unspecified consent – data may be used in future research more broadly, with ethics approval. This is required if the data may be shared in a data repository.

Where extended or unspecified consent is sought, clearly inform participants of the following:

- What part of the data (if relevant) and the form in which the data may be reused or shared, e.g. identifiable, re-identifiable or de-identified, and whether it includes raw data (such as recordings) or processed data (such as transcripts).

- Who will be permitted to reuse the data, e.g. the current research team only, named collaborators, the broader research group, or any genuine researcher. Where an external party has rights to the data, explain what those rights entail.

- The mechanism for sharing data, e.g. upon request to the research team, via a data repository, or through a managed database.

- Whether access will be open or restricted. For restricted access, outline the conditions that must be met, e.g. a requirement for separate HREC review, evidence of legitimate research intent. For open access (i.e. CC-0 or CC-BY) on a repository, clearly state that anyone can access the data for any purpose.

If your research involves Aboriginal or Torres Strait Islander peoples, communities or data, decisions about data access, reuse, retention and disposal should be made in accordance with the AIATSIS Code of Ethics and the CARE Principles.

Note: De-identified data is data that is no longer reasonably identifiable to an individual person. De-identification of data must be considered in context, it requires more than just removing direct identifiers – it ensures that data is not reasonably identifiable in a given context.

How will you protect my privacy?

Identify who will have access to the data provided by participants. For example, named members of the research team, or external parties such as a transcriber or project sponsor. All relevant parties should be identified or described, along with the form in which they will access the data, e.g. identifiable, coded, de-identified.

State whether participants' will be identifiable in any theses, publications or conferences etc. arising from the research, and explain the steps taken to protect their identity if relevant. For example, this might include the use of pseudonyms or the removal of identifying details.

If participants may be reasonably identifiable in certain contexts, such as in small group settings or focus groups, you should acknowledge this openly and describe what steps will be taken to minimise any risks to participants' privacy.

What if I have concerns or a complaint?

This project has been approved by the Macquarie University Medical Sciences/Humanities and Social Sciences [*delete one*] Human Research Ethics Committee, include your Project ID number. If you have any concerns or complaints about the conduct of this research, please contact the Human Research Ethics Manager on +61 2 9850 4194 or email: ethics@mq.edu.au.

How do I take part?

Provide clear instructions explaining what participants need to do if they wish to take part, e.g. signing and returning a consent form, responding to an email, or completing an online survey. Make this as straightforward and actionable as possible.

Consent Form

PLEASE SIGN AND RETURN

Project title: Insert the formal or short title of the project

Principal Investigator: Title, Name, School/Department/Centre

Before you sign this form

Please tick the box to confirm:

☐ I have read and understood the Participant Information Sheet for this project. I have been given a copy to keep and have had the opportunity to ask questions before deciding to participate.

What you are agreeing to

By signing this form, I am agreeing to:

☐ Describe activity 1

☐ Describe activity 2

☐ Etc.

If participation involves optional components, include the following.

Please indicate your preferences by ticking each box that applies to you:

☐ I agree to participate in *describe component, e.g. an online survey*

☐ I agree to participate in *describe component, e.g. a one-on-one interview*

☐ I agree to be audio recorded

☐ I agree to be video recorded

☐ I agree to direct quotations from my responses being used in research outputs, e.g. publications, reports, presentations

☐ I agree to be identified in research outputs (if you do not tick this box, you will not be directly identified and a pseudonym will be used)

Risks associated with participation

Include a brief statement identifying any major or foreseeable risks associated with participation in this research. For example, 'I understand that I may be asked questions about sensitive topics, which I may find uncomfortable'.

Consent for data use

Please indicate the type of consent you are requesting for the use of participant data and include only the relevant statement(s) below.

Specific consent *(use if data will be used for this project only)*

- ☐ I understand that the data collected from me will be used only for the purposes of this research project.

Extended consent *(use if data may be used in future research related to this project – include opt-in checkbox)*

- ☐ I agree that my [*specify whether identifiable/de-identified/anonymous*] data may be used in this current project and in future research related to this project or area of research. I understand that any future use will require separate Human Research Ethics Committee approval.

Unspecified consent *(use if data may be used in future research more broadly or if open access – include opt-in checkbox)*

- ☐ I agree that my [*specify whether de-identified/anonymous*] data may be used in future research more broadly. I understand that any future use will require separate Human Research Ethics Committee approval.

Open access sharing of research data *(use if data may be– include opt-in checkbox)*

In addition to the consent options above, we are also asking your permission to make a de-identified version of the research data publicly available through an open access data repository (e.g. [name of repository]). This is increasingly required by research funders and journals to support transparency and reproducibility in research.

- ☐ I agree to a [*specify whether de-identified/anonymous*] version of my research data being made publicly available through an open access data repository, with the understanding that future use will not require Human Research Ethics Committee approval and the data cannot be withdrawn once released.

Note: Extended, unspecified and open access consent options must be presented as clearly labelled opt-in checkboxes so that participants are actively agreeing to this additional use of their data. Do not pre-tick these boxes or present them as default options.

Note: De-identified data is data that is no longer reasonably identifiable to an individual person. De-identification of data must be considered in context, it requires more than just removing direct identifiers – it ensures that data is not reasonably identifiable in a given context. Anonymous data is data that was collected without any identifying information being recorded in the first place.

Voluntary participation and right to withdraw

I understand that my participation is voluntary and I may withdraw at any time by contacting [*insert email address]*. I understand that if I withdraw after *[state applicable limit, e.g. data* *analysis has commenced/ identifying details have been removed]* it may not be possible to withdraw my data from the project.

Participant declaration

By signing below, I confirm that I have read and understood the information above and I freely consent to participate in this research project.

Participant's full name:

Participant's signature:

Date:

Researcher declaration *(recommended)*

Researcher's full name:

Researcher's signature:

Date:

Parent/Guardian consent *(include where participants are unable to consent for themselves)*

If your research involves participants who are unable to consent independently, such as children or individuals with impaired decision-making capacity, include a separate section for parent or guardian consent. This should mirror the participant consent section above and clearly identify the relationship of the person providing consent to the participant.

Name of parent/guardian:

Relationship to participant:

Signature:

Date:

Child assent *(include where appropriate)*

Where the research involves children who are capable of expressing a view about their participation, include an age appropriate assent statement in addition to the parent/guardian consent section above. This should be written in simple, accessible language suited to the child's age and understanding.

Example: I know that I am being asked to be part of a research project. I understand that I will be asked some questions about what I like to eat and I am happy to take part. I know I can stop at any time if I want to.

Child's name:

Child's signature (if applicable):

Date: