OFFICIAL

CALHN Research Services

Survey - Participant Information Sheet

Overview

This guidance is intended for surveys where implied consent may be considered.

The purpose of the Survey - Participant Information Sheet (PIS) is to provide prospective participants with detailed information about the research and its requirements, enabling them to make an informed decision regarding their participation. The PIS is designed with the participant's perspective in mind and must be tailored to their demographic characteristics, including factors such as age, language proficiency, literacy level, and educational background.

This document serves as a guideline and should not be utilised as a template. It emphasises the importance of using concise sentences and paragraphs to ensure clarity. The PIS should adopt an active voice and employ personalised language ('we' and 'you'). It is recommended to avoid complex legal and medical terminology whenever possible. Additionally, the presentation of the PIS should be carefully considered, with information structured logically, clear headings and numbering, well-spaced paragraphs, and the use of numbered or bulleted lists. Key points should be highlighted for emphasis, either through formatting or distinct separation from other content.

PLEASE NOTE: All documents submitted for review must contain the document label, version number, date, page number, and total number of pages in the footer. The logo of the organisation that will own the study results is inserted in the header.



Health Central Adelaide Local Health Network

Project Title:	[Insert Title]
Principal Investigator:	[Insert Name]
HREC Reference:	[Insert Reference]

1. Introduction:

You are invited to participate in a research study conducted by [Insert Principal Investigator's Name] at [Insert Institution/Organisation]. Before deciding whether to participate, it is important for you to understand why the research is being conducted and what your involvement will entail. Please take the time to read the following information carefully.

2. Purpose of the Study:

The purpose of this study is to [Briefly describe the aims and objectives of the research].

3. What does participation in this research involve?

- This section should describe, in plain language, exactly what the participants will experience when participating in the study. Each aspect of participation should be explained separately.
- If participants are required to attend a site as part of the study, the exact location must be provided in the PICF.
- Where information from participants' medical (or other) records is required for the study, the following information must be provided in the PICF:
 - The source of the records
 - The type of information that will be extracted from the records
 - Who will be accessing it
 - How it will be accessed (e.g. any transfer between institutions).

4. Risks and Benefits:

- Many studies do not have any direct benefit to participants. If this is the case, it must be clearly stated.
- Note: financial/other reimbursement for participation is not a benefit of the study.
- Explain the potential risks participants may face, and any disadvantages they may experience from participating in the study. Consider:
 - Physical harm
 - Psychological distress
 - Financial harm
 - \circ $\,$ Harm to reputation.
- As research is never 100% risk free, the phrase 'no foreseeable risks' should be used rather than 'no risks.

Potential benefits of participating in this study include [Describe any potential benefits to participants or society, such as contributing to knowledge in the field, personal reflection, etc.].

5. What will happen to information about me? Confidentiality and data security

- State whether data collected will be de-identified, re-identifiable, identifiable but confidential or anonymous.
- Explain the study's data confidentiality and security measures:
 - Form of stored data
 - o Location of storage
 - Who has access
 - o How it is secured
 - Duration of storage
 - Method of destruction.
- Describe the method of dissemination of study results (for example academic journal publication, conference, internal institutional publication).
- Clearly state whether participants will be identifiable in any publications.

6. Voluntary Participation:

Participation in this study is entirely voluntary. You have the right to refuse to participate or withdraw from the study at any time without any consequences. Your decision will not affect your relationship with [Insert Institution/Organisation].

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7. Who has reviewed the research project?

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies. The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee.

8. Further Information and who to contact:

The person you may need to contact will depend on the nature of your query.

If you have any questions concerning this project or your participation, contact the following person:

Research Contact:

Name	[Insert Name]
Position	[Insert Position]
Phone	[Insert Number]
Email (institutional email)	[Insert email address]

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or if you have any complaints about any aspect of the project or about the conduct of the study, you may contact:

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

Consent:

By continuing with the survey, you indicate that you have read and understood the information provided in this Participant Information Sheet. Your participation in this study is voluntary, and you consent to take part under the conditions outlined above.

If you are obtaining consent, attach the consent form to the information sheet.

If you are obtaining implied consent, include the following statement in this information sheet: By completing this survey you are providing your implied consent.

Thank you for considering participating in this study.

INTERNAL USE ONLY: (remove this section when creating PIS)

CALHN Research Services Contact information

T: (08) 7117 2224 E: <u>Health.CALHNResearchLNR@sa.gov.au</u> W: <u>https://www.rah.sa.gov.au/research/for-researchers/health-medical-research-project-submissions/expedited-review</u>

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