**AH&MRC HUMAN RESEARCH ETHICS COMMITTEE**

**MODEL PARTICIPANT INFORMATION SHEET**

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| --- | --- |
| **PROJECT TITLE:**  |  |
| **HREC REFERENCE NUMBER:** |  |
| **CHIEF INVESTIGATOR:**  |  |
| **ASSOCIATE INVESTIGATORS:** |  |
| **INSTITUTION RESPONSIBLE FOR THE RESEARCH:**  |  |
| **PROJECT SPONSER/ FUNDER:** |  |
| **SITE:** |  |

**Introduction:**

The purpose of this section is to state the reason the participant is being invited to take part in the research project and to explain the purpose of the form and the nature of informed consent.

**The purpose of the research:**

* Aim of the project and its significance
* How the project is intended to fill any gap in knowledge
* How it may contribute to care or education or research in the future
* Any relevant background including what is already known
* Whether the research is for the purpose of obtaining a degree or other educational qualification, is funded by a grant, or has sponsorship of some other sort.

**What does participation involve?**

* Consent form will be signed prior to any study assessments being performed
* Initial steps:
	+ Screening for eligibility
	+ Randomisation and/or the use of a control group
* Procedures:
	+ All procedures
	+ Nature, number, timing and time commitment of procedures, visits, and questionnaires
	+ Nature of follow-up
	+ Duration of participant’s involvement (including follow-up)
	+ Duration of the research project (if this is different from their involvement)
* Reimbursement and costs (if applicable) [NS 2.2.6(j), 2.2.10]
* How the research will be monitored [NS 2.2.6(b)]
* The commitment required by the participant
* Access to personal records that may be required
* Whether any part of the research project will be recorded (video/audio)
* Details on the use of interpreters in the consent and/or data collection process
* Venue details and a statement whether participants may choose the venue
* Do I have to take part in this research project?
* What are the possible benefits of taking part?
* What are the possible risks and disadvantages of taking part?
* What if I withdraw from this research project?
* What happens when the research project ends?
* What will happen to information about me?

**Information should be provided regarding the following:**

* Whether the data collected or used is individually identifiable, re-identifiable (coded) or non-identifiable
* Where the data will be kept and who will have access to it
* How long it will be stored and what will happen to the data at the end of the storage period (Refer to your institution’s policy on retention of study data)
* Whether the participant is being asked to provide consent for the use of their data for this project only, or for extended (related research) or unspecified (any future research) use of their data
* Whether the research project involves the establishment of a databank

**Complaints**

The Chairperson

AH&MRC Ethics Committee

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**Further information and who to contact**