Participant Information Sheet and Consent Form

Title
Short Title
Project Sponsor
Coordinating Investigator
Principal Investigator
Location **HREC Reference Number**

Part I – What does my participation in the study involve?

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1. Introduction

"You are invited to take part in XXX, which may be suitable for you. Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used."

2. What is the purpose of this research?

Brief description of the purpose and aims of this research.

3. Why have I been chosen?

"You have been chosen to participate in this research because XXX."

4. Do I have to take part in the research?

"It is up to you to decide whether or not to take part in this study. If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep. If you decide to take part you can change your mind later and withdraw from the study at any stage, for any reason."

5. What do I have to do?

Brief outline of the participants role in the study.

6. What are the possible benefits of taking part?

Identify if there are any or no clear benefits for the patient or community for participating in this research.

7. What do I do if I wish to withdraw from the research?

Identify what the patient must do or who to contact to withdraw

Part II – How is the study being conducted?

8. What will happen to information about me?

Outline what will happen and how information will be used and stored

9. Who has reviewed the study?

Identify the HREC who has provided approval of this study.

10. Further information and who to contact

Provide contact details of who participants can contact for questions and information

Study Subject Number ##

PARTICIPANT CONSENT FORM

Title
Protocol No
Location
Principal Investigator

1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

4. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future health care.

Name of Participant	Signature of Participant	Date
Name of Member of Study Team	Signature of Member of Study Team	Date