

Example of Statement in Plain English for Project Participants

This plain English statement is provided by the Bolton Clarke Human Research Ethics Committee to applicants as an example of the scope and style of information to inform potential project participants.

- Do not use acronyms
- Use every day words to describe medical or other technical concepts
- Avoid a technical project description
- Provide context for the project. Why is this subject worthy of research?
- Provide a clear user-friendly project description in simple language that addresses the potential participant
- Provide a statement of what is required of the participant and for how long
- Explain what the project aims to achieve
- Aim for a short document (no more than 2 pages, if possible)

Research Project Participant Information Sheet

NAME OF PROJECT (Project A is being used in example)

Project A is a significant medical condition affecting 180,960 Victorians. There is a need to identify the best ways of providing good quality health care to all.

You are invited to be part of a research project that aims to identify more effective approaches in the provision of care provided to Type 2 diabetes patients by a Transition Diabetes Team after they leave hospital and return to home. The aim is to provide better quality of care for more people with poorly controlled Type 2 diabetes by providing home-based support by an expert team to people needing regular insulin injections.

The investigations will be conducted by researchers from the AAA Hospital and the Bolton Clarke.

The project involves 65 patients with Type 2 diabetes who have never had their diabetes managed by using insulin and would benefit from one or a maximum of twice daily injections. You will need to be over 54 years old, contactable by phone and live within 30 minutes of the AAA Hospital.

You will be supported by a Transition Diabetes Team who visit you at home. You will require insulin injections as part of your care plan. You will be supported until you are comfortable to give injections to yourself.

If you agree to be part of this project we will:

- Visit you at home soon after your discharge from hospital to explain the project and make sure that you are well supported
- Provide you with required medication and a blood glucose meter at no cost
- Give you an education kit
- Teach you how to give insulin injections to yourself.

A Diabetes Specialist and a Diabetes Educator will be available for support.

After 12 weeks, a progress review will be undertaken with a Diabetes Specialist. This will require you to attend an appointment at the hospital.

If you are managing well after that time, your medical management will continue with your local doctor, who can also request the assistance of the Diabetes Specialist if needed.

There is no particular risk in participating in this project.

Data from this study will be compared with a profile taken from the records of 100 Type 2 diabetes patients who received care in the hospital.

It is expected that the Transition Diabetes Team approach will produce better outcomes.

Important information:

- You do not have to be part of this research project
- Participation in the project does not affect any other services you receive
- You will be free to withdraw from the project at any time
- You will not be paid for your participation
- Information collected about you will be kept confidential
- A project report will be prepared. A copy will be available if you request it.
- If you wish to be part of the project you will be asked to sign the attached Consent Form.

This project has been approved by the Bolton Clarke Human Research Ethics Committee.

Contact person:

Insert name, position and phone number

Complaints:

Any person involved in the project has the right to complain. The contact person is:

Insert name, position and phone number

Consent Form

Name of study:

Project A

Participant details:

Name:
(in block letters)

SRS Name:

I hereby agree to take part in the above study and confirm that:

- The details of the study have been explained to me, and
- I have received a copy of the Participant Information Sheet, and
- I understand that my health information collected by the Bolton Clarke nurse will be used as part of this study, and
- Any questions I have asked regarding this study have been answered.

I agree to take part in this study and know that I can stop being a part of it whenever I want.

I agree that my data may be used as a case study or report or presented at conferences or published on the condition that my name or any other identifying information is not used.

I understand that any information I provide will be strictly confidential.

Signature of participant _____
(Print name) (Signature)

(Date)

Witnessed by _____
(Print name) (Signature)

(Date)