CLINICAL TRIAL INFORMATION AND CONSENT FORM

PART A

GENERAL INFORMATION

Clinical trials

What is a clinical trial?

Clinical trials are research investigations in which people volunteer to help evaluate new procedures, interventions or tests that prevent, detect, treat or manage various diseases or medical conditions. This helps to determine if an intervention works, if it is safe and if it is better than the interventions that are already available

Clinical trials serve a number of purposes. Some clinical trials look at how people respond to a new intervention and what side effects might occur. Clinical trials might also compare existing interventions, test new ways to use or combine existing interventions, or observe how people respond to other factors that might affect their health.

Clinical trial interventions could include:

- preventive care strategies
- vaccines, cells and biological products behavioural therapies
- surgical and medical treatments and procedures
- medical devices
- experimental drugs
- health service changes education.

Who reviews and approves clinical trials?

An independent Human Research Ethics Committee (HREC) reviews and approves clinical trials. The HREC makes sure that the trial complies with the National Statement on Ethical Conduct in Human Research (2007). The National Statement ensures that the interests, safety and wellbeing of people who agree to take part in trials are protected.

Clinical trials

Participant information and consent

Everyone taking part in a clinical trial must give informed consent, or have a parent, legal guardian or other person responsible give informed consent on their behalf, before entering a trial.

To help decide whether or not to be part of a trial, members of the research team will explain the details of the trial.

The researchers will also give a participant information and consent form.

The person taking part in a clinical trial, is referred to as a participant. Their involvement and consent to participate must be freely and voluntarily given after reading the participant information and consent form and talking with the researchers. To enter a trial, a consent form must be signed.

After signing the form, the researchers will provide a signed copy of the information and consent form for participants to keep.

The participant information and consent form has three parts:

A General information

This booklet introduces clinical trials. It gives information about the informed consent process and provides some questions to ask the clinical trial team.

B Trial details

An information sheet with details about a specific trial, including its purpose, duration, required procedures, risks and any potential benefits.

C Consent form

A form that a participant, a parent/legal guardian or a person responsible, signs to consent to take part in a clinical trial.

What is informed consent?

Informed consent means that potential participants are given information about the key facts of a clinical trial before deciding whether or not to take part. Informed consent also means that participants are provided with information on new developments throughout the trial.

If a person is asked to take part in a clinical trial, they are free to say yes or no at any time. There is no pressure to enter or stay in a trial. Ask questions about anything that is not clear. Take time, and talk it over with family and friends, or a regular General Practitioner before making a decision.

After making a decision, the consent form needs to be signed. The consent form is not a contract, and a participant may leave the trial at any time without losing any of their normal rights. If there are any changes during a trial, participants are kept informed and may be asked to give consent again before continuing with the trial.

Signing the consent form means the person(s) signing:

- Understands what they have read
- Consents to take part in the trial
- Consents to the tests and procedures described in the participant information and consent form
- Consents that personal and health information can be accessed by the researchers
- Consents that a general practitioner and/or treating specialist may be notified of participation in the clinical trial as well as any clinically relevant information noted by the researchers during the trial.

What happens to information about the participant?

By signing the consent form, the researchers will collect and use information about the participant for the trial in the ways described in the Participant information and consent form. This could include information that identifies the participant, and details about their health now, in the past or in the future, as well as information about the collection and use of samples. A trial code (e.g. AA01) may be used to link participants identifying information to the trial.

Can a participant leave a trial?

Yes, a participant can stop taking part in a trial at any time, for example if their condition is getting worse, they are finding it difficult to participate or they have concerns about the intervention.

Participants can choose to leave a trial at any time without giving a reason. Withdrawing from a clinical trial will not affect any future care or the patient/doctor relationship. It is important to discuss any decision to leave a trial with the research team before leaving, so they can advise about any safety or follow-up requirements of leaving the trial.

They will discuss what happens to personal health information that has been collected for the trial.

Sometimes a trial maybe stopped early if, for example the intervention is found to be unsafe or if it is found to be effective and does not need further study. A participant will have their treatment and care followed up if this happens.

Asking questions

Before signing a consent form, find out as much as possible about the trial. Some of the answers to questions may be found in Part B of the participant information and consent form.

Some questions to ask

△ **About the trial**

- What is the aim of the trial and how will it help people?
- Has the intervention been tested before? What was the outcome?
- Will the trial use a placebo (a substance not containing an active agent), standard care or another established intervention as the control to compare with the new intervention?
- Who is conducting and paying for this research?
- What are the alternatives to participation?
- Will any samples will be collected? How often? Are there any risks associated with the collection of the samples? What will happen to the samples after the trial? Will any trial tests provide information about the current or future health of me or my family members?

△ **About your involvement**

- How might this trial affect daily life? How much time will be needed?
- What kinds of tests and experimental interventions are involved?
- Who can be contacted for support and information during the trial? Will someone be available 24 hours a day?

△ **About risks**

- What are the risks of taking part in this trial?
- What are the possible side effects of the trial intervention?
- How do the possible risks, side effects and any potential benefits of the trial compare with current treatment or care?

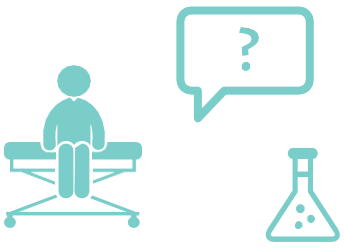
△ **About costs**

- Who will pay for the experimental intervention?
- Will any expenses be covered?
- If complications arise from the trial, who is responsible for paying any costs that are associated with them?

△ **About what happens after the trial**

- What follow-up care is available after the trial?
- How long will it be before the results of the trial are known?
- How do participants find out the results of the trial?
- Will participants have access to the experimental intervention after the trial?

The Australian clinical trials website (www.australianclinicaltrials.gov.au/how-be-part-clinical-trial) also lists some things you might want to discuss.



The clinical trial team

Part B of the participant information and consent form will contain contact details for various people involved in the trial.

There are normally three key contacts:

- the research team
  - trial doctor and research staff
- the research site
  - clinic or hospital where the trial is being conducted
- the Human Research Ethics Committee
  - which reviews the trial for its scientific merit and protects the interests of trial participants.

Please keep the participant information and consent form, and the contact details of these people.

Contact these people at any time during a trial to:

- ask questions about the trial or the treatment
- ask for advice about anything that concerns you
- make suggestions about the trial or the treatment
- compliment the trial staff or organisation
- complain about any aspect of the trial.

Notes

For further information about clinical trials, visit the Australian clinical trials website:
www.australianclinicaltrials.gov.au/consumers