CLINICAL TRIAL PARTICIPANT 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.

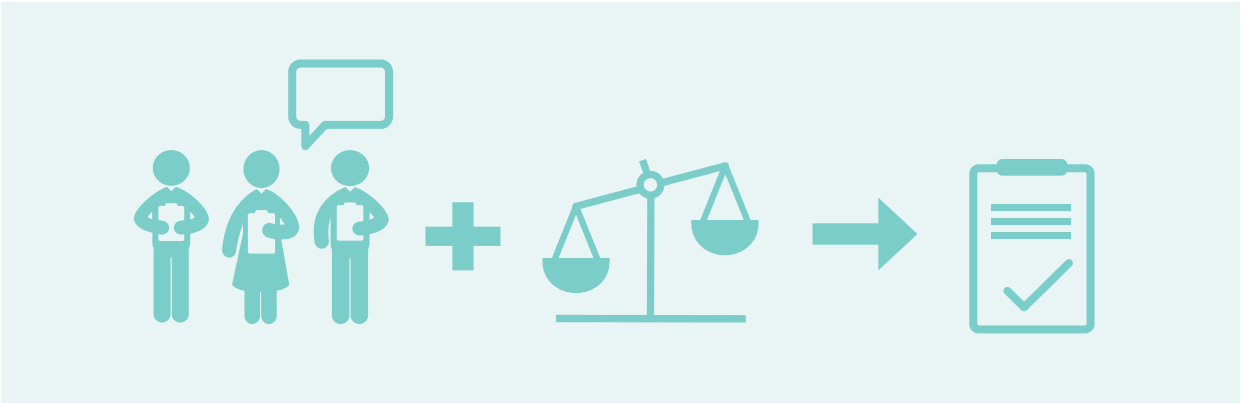
Clinical trials serve a number of purposes. Some clinical trials look at how people respond to a new intervention and what side effects might occur. Clinical trials might also compare existing interventions, test new ways to use or combine existing interventions, or observe how people respond to other 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 has reviewed and approved this clinical trial?

An independent Human Research Ethics Committee (HREC) reviewed and approved this trial . 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 and you

Participant information and consent

Everyone taking part in a clinical trial must give informed consent, or have a parent, guardian or other legally authorised person give informed consent on their behalf, before they enter the trial.

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

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

If you take part in a clinical trial, you are referred to as a participant, and your involvement and your consent to participate must be freely and voluntarily given.

After reading the participant information and consent form and talking with the researchers, you can decide whether to participate. You do not have to agree to participate in the trial. If you do agree to enter the trial, you will be asked to sign a consent form.

After you sign the form, the researchers will give you a copy of the three parts as one complete document to keep in your records.

The participant information and consent form has three parts:

A General information

This booklet introduces you to clinical trials. It guides you through 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 you, a parent/guardian or a person responsible, sign if you wish to participate in a trial, to show that you voluntarily agree to take part and understand what your involvement will be.

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 you are asked to take part in a clinical trial, you are free to say yes or no at any time. There is no pressure on you to enter or stay in a trial.

If you are under 18, you must consent to participate and a parent or guardian must also give consent on your behalf.

You are encouraged to ask questions about anything that is not clear to you or that you do not understand. Take your time, and talk it over with family and friends, or your regular GP before deciding whether to take part.

If you decide to take part, you will be asked to sign the consent form. The consent form is not a contract, and you may leave the trial at any time without losing any of your normal rights. If there are any changes to the trial, you will be kept informed and you may be asked to give your consent again before continuing with the trial.

Signing the consent form means that you:

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

What happens to information about me?

If you sign the consent form, you are agreeing that the researchers may collect and use information about you for this trial in the ways they have described in this document. This could include information that identifies you, and details about your health now, in the past or in the future. As well as information, the researchers may collect and use samples.

Can I leave a trial?

You can stop taking part in a trial at any time. You may decide to stop taking part in a trial for example if your condition is getting worse, you are finding it difficult to participate or you have concerns about the intervention.

You can also choose to leave the trial at any time without giving a reason and without any effects on the care that you will continue to receive.

If you do withdraw from a clinical trial, the relationship between you and your doctor will not be affected. It is important to discuss your decision to leave a trial with the research team before you leave, so that they can advise you about any safety or follow-up requirements of leaving the trial and what will happen to information about you that has been collected for the trial.

If there are signs that the intervention in a trial could be unsafe, the research team or the regulators monitoring the trial will stop the trial. In addition, if the new intervention is found to be clearly superior or inferior during the trial, the trial may be stopped. Your care will always be followed up.

Asking questions

If you are thinking about being part of a clinical trial, you should know as much as possible about the trial, your involvement in it and the commitment you are making. You might find some of the answers to your questions in Part B of the participant information and consent form.

You can also discuss your questions with your doctor and the research team. Consider taking a family member or friend along to the discussion for support and help in asking questions or recording answers.

Plan what to ask ahead of time, but don't hesitate to ask any new questions that you think of during the trial.

Some questions that you may want 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 my daily life? How much of my time will be needed?
  - ☐ What kinds of tests and experimental interventions are involved?
  - ☐ Who can I contact 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 my current treatment or care?
- About costs
  - ☐ Who will pay for the experimental intervention?
  - ☐ Will my 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 I find out the results of the trial?
  - ☐ Will I have access to the experimental intervention after the trial if I wish to continue with it?

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, in case you would like to talk to any of these people. You can contact them at any time during the trial to:

- ☐ ask questions about the trial or your treatment
- ☐ ask for advice about anything that concerns you
- ☐ make suggestions about the trial or your 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