CLINICAL STUDY PARTICIPANT INFORMATION AND CONSENT FORM

PART A

GENERAL INFORMATION

2018 edition

Clinical studies

What is a clinical study?

"We do studies to find out the best way to provide medicine – we are trying to see if they are safe and that they work".

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

Clinical studies can be used for different purposes.

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

Clinical study interventions could include:

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

Who has approved this clinical study?

A Human Research Ethics Committee (HREC) approved this study.
The HREC checks that the study meets with the standards of the Australian *National Statement on Ethical Conduct in Human Research* (2007). The National Statement ensures that the interests, safety and wellbeing of people who take part in studies are protected.

Clinical studies and you

Participant information and consent

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

To help you decide whether or not to be part of a study, members of the study team will explain the details of the study to you. They will also give you information to read (the participant information and consent form).

After talking with the researchers and reading the study details, you can decide whether to participate. You do not have to agree to participate in the study.

If you do agree to enter the study, you will be asked to sign a consent form.

After you sign the form, the researchers will give you a copy to refer to during or after the study.

The participant information and consent form has three parts:

A General information

This booklet introduces you to clinical studies and informed consent, and provides some questions that you might want to ask the clinical study team.

B Study details

An information sheet with details about a specific study, 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 study, 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 study before deciding whether or not to take part.

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

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 study at any time without losing any of your normal rights. If there are any changes to the study, you will be kept informed and you may be asked to give your consent again before continuing with the study.

Signing the consent form means that you:

- understand what you have read
- consent to take part in the study
- consent to the activities 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 may be notified of your participation in the clinical study as well as any clinically relevant information noted by the researchers during your participation in the study.

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 the study in the ways they have described in the 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.

What happens if I leave a clinical study?
Can a clinical study be stopped?

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

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

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

If you do withdraw your consent during the clinical study, the research team will stop collecting personal information about you.

Asking questions

Some questions you may want to ask after you have read Part B

If you are thinking about being part of a clinical study, you should know as much as possible about the study, 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 discuss your questions with the study team and your doctor. 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.
Don't hesitate to ask any new questions that you think of during the study.

- About the study
  - What is the aim of the study? Will it help people? Will it help me?
  - Has the intervention been tested before? What was the outcome? Can it help others?
  - Will the study use a placebo (a substance with no clinical effect)?
  - Who is conducting and paying for this research?
  - What are the alternatives to participation?
  - Will any samples be collected? How often? Are there any risks associated with the collection of the samples? What will happen to the samples after the study?
  - Will any of the study tests provide information about the current or future health of me or my family members?
- About your involvement
  - How might this study affect my daily life? How much of my time will be needed?
  - What kinds of tests and procedures are involved?
  - Who can I contact for support and information during the study? Will someone be available 24 hours a day?
- About costs
  - Who will pay for the experimental intervention?
  - Will my expenses be covered?
  - If complications arise from the study, who is responsible for paying any costs associated with them?
- About what happens after the study
  - What follow-up care, if any, is available after the study?
  - How long will it be before the results of the study are known?
  - How do I find out the results of the study?
  - Will I have access to the experimental intervention after the study if I wish to continue with it?

The Australian clinical trials website lists some other things you might want to discuss and suggests additional information sources: www.australianclinicaltrials.gov.au/how-be-part-clinical-trial.

The study contacts

Part B of the participant information and consent form will contain contact details for people involved in the study. There are normally three key contacts:

- the study team
  (the researchers and support staff)
- the research site
- the Human Research Ethics Committee
  (this committee reviews the study for its scientific merit and protects the interests of study participants, and may provide independent advice).

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 study to:

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

Notes

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