



Drug Information

Participating in Clinical Trials

What is a clinical trial?

A clinical trial is a medical experiment or study designed to find answers to some questions about medical treatments. It is usually set up to find out if a new, untested treatment is safe and effective, or to compare the effectiveness of different treatments.

Trials are usually set up with a **study group** and a **control group**. The participants in the study group get the treatment being tested or compared. The participants in the control group either get a placebo (a sugar pill with no effect) or another kind of treatment that is being used for comparison with the study treatment. The participants usually do not know whether they are in the study or control group. This is done to avoid biases from participants knowing what outcome may be expected.

Each clinical trial must follow special guidelines. These guidelines are usually called a protocol and they describe how the whole clinical trial should be set up and carried out.

Who can participate in a clinical trial?

Each clinical trial has special rules that define who can or cannot participate.

The rules that define who **can** participate in a clinical trial are called **inclusion criteria**. Inclusion criteria are set up to select participants who:

- will most likely benefit from the treatment, or
- have certain characteristics or conditions that will help answer certain questions about the effectiveness of the treatment.

The rules that define who **cannot** participate in a clinical trial are called **exclusion criteria**. Exclusion criteria are set up to prevent participation of people who:

- are most likely to be at risk for having problems or bad effects from the treatment, or
- have certain characteristics or conditions that will make it hard to determine the effect of the treatment being tested.

What are the benefits of participating in a clinical trial?

Benefits of participating in a clinical trial may include:

- the chance to try a new treatment before it is available to the general public
- getting potential health benefits from the treatment being tested
- getting a free supply of the medications
- having more regular health examinations and tests done to monitor your condition
- helping others by contributing to information and knowledge about new treatments



What are the risks of participating in a clinical trial?

Risks of participating in a clinical trial may include:

- getting the placebo and not the actual new treatment being tested
- the new treatment being studied may not work
- the new treatment may cause bad side effects
- more visits to doctors and more blood tests
- not being able to take some other treatments as a condition of the clinical trial

What should happen when I enroll in a clinical trial?

Before participating in a clinical trial, you will be interviewed by the researchers doing the experiment to see if you meet the specific inclusion or exclusion criteria. If the researchers decide you can participate, they should provide you with detailed information about the process of the clinical trial and answer any questions you have about the trial. If there is something you don't understand, ask them to explain it to you again. When you are satisfied with the answers to all your questions, you will be asked to sign an informed consent form. This is a legal document that says you agree to participate in the clinical trial after understanding all the information you need to know about the trial.

What questions should be answered before I sign an informed consent form?

- What treatment is being studied? What questions about this treatment will be answered by the study? What questions will not be answered?
- What exactly will happen during the trial? What do I have to do during the trial?
- Who is responsible for the study? Who will have access to the information about me? How will my privacy be protected?
- What are the potential benefits of the treatment? What are the potential risks and side effects?
- Can I get the treatment another way if I do not participate in the trial?
- If I choose not to participate in the study, will it have a bad effect on the care and services I receive?

What are my basic rights in a clinical trial?

- You have the right to receive all the information necessary to help you make an informed decision about participating in a clinical trial.
- The researchers must answer all your questions honestly and in ways or languages that you can understand. If you need the help of an interpreter, it is the responsibility of the researchers to provide you with one.
- You can decide to stop participating in a clinical trial at any time for any reason.

Your decision to stop participating in a clinical trial must not cause any harm to the care you receive from your health service providers.

- You should be informed of the outcomes or results of the clinical trial when it is completed. If the trial is terminated early because it has become clear that there are significant risks or benefits, you should be informed about this.



Where can I find out more about clinical trials?

You can ask your health care providers, AIDS service agency staff or other people with HIV/AIDS about what clinical trials are currently taking on participants. In Canada, you can get information about all the current HIV/AIDS-related clinical trials at the Canadian HIV Trials Network: Call toll-free at 1.800.661.4664 or check their website at <http://www.hivnet.ubc.ca/ctn.html>.

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