PARTICIPATING IN A CLINICAL TRIAL

WHAT IS A CLINICAL TRIAL?

The Food and Drug Administration (FDA) approves new drugs and other treatments based on the results of laboratory tests, animal tests, and tests in humans (clinical trials). Before new drugs can be sold to treat HIV disease, they must be proved to be safe and effective.

New treatments are tested in humans only if there were good results from laboratory tests and animal studies. There is a process in which specific treatments or drugs are tested. First, the treatment is tested for safety in a small group of people. Later trials with many more participants test how well the treatment works. InfoNet Fact Sheet 105, How HIV Drugs Get Approved, has more information on the phases of clinical trials.

There are other types of clinical trials, including vaccine trials (see fact sheet 159), strategy and management trials, and observational studies.

A ***strategy or management trial*** does not test a new treatment. Instead, it evaluates an approach to treatment. For example, the SMART (Strategies for Management of Anti-Retroviral Therapy) trial examined whether taking antiretroviral therapy continuously led to better health than taking therapy only until a target level of CD4 cells (see fact sheet 124) was reached.

Observational studies collect information on the long-term effects of HIV and its treatments by seeing what happens to a large number of patients as time goes by.

A clinical trial is a carefully planned medical experiment. The guidelines for a clinical trial are called a 'protocol'. Similar to a recipe for cooking, the protocol is a document that describes exactly how the trial will be carried out.

WHO CAN PARTICIPATE IN A CLINICAL TRIAL?

The protocol explains the rules for participation in a clinical trial. Each trial has different requirements. For example, some trials require certain viral loads or CD4 cell counts in order to participate.

You normally cannot participate in a clinical trial if you have any opportunistic infections, or are using any treatments that might make it difficult to measure how well the test treatment is working. You also cannot participate if the study treatment might harm you. For example, women sometimes cannot participate in trials during the first three months of pregnancy, because of the risk of birth defects for their newborn child.

Trials are carried out at different hospitals, research centers and clinics throughout the world. Some trials will reimburse your travel costs to a study center or pay you to be in the study.

WHAT ARE THE BENEFITS OF PARTICIPATING?

- You could get a new treatment before it is available to the public.
- Your health will be watched very carefully.
- You might get some or all of your medications paid for. You might get some lab tests or other care for free.
- You will be helping others by contributing information about new treatments or vaccines, or about the long-term effects of HIV and how it is treated.

WHAT ARE THE RISKS?

- In drug trials, new treatments are compared to the best available medication or to a dummy medication (a "placebo"). **You might not get the new treatment.** Patients and health care providers in these trials are not told who is getting the new treatment.
- You might have to stop taking other medications during the trial.
- Study treatments might not work.
- Study treatments might have serious side effects.
- Participating in a study might take a lot of time. It could require special record-keeping or many trips to the study location.

HOW ARE PARTICIPANTS PROTECTED?

There are strict laws on research using human participants. The main tool to protect you is called "Informed Consent." You will be given a full, written description of the clinical trial to read and sign before you agree to participate. Take your time to review the Informed Consent before you sign it. If you need an interpreter to help you understand it, ask for one. If you have questions, be sure you get the answers before you sign. Do not feel pressured to sign the Informed Consent until you understand the study.

There are also local and national boards that review and monitor each clinical trial before it starts and while it is in progress. Trials can be stopped early if they are harming participants.

You can decide to drop out of a clinical trial **at any time, for any reason**.

SHOULD I PARTICIPATE?

You and your health care provider should discuss the possible benefits and risks of taking part in a clinical trial. Here are some of the questions you should consider:

- What is the purpose of the study?
- How long will it last?
- Where is it being conducted?
- How will I take the medication (pills, shots, intravenous infusion, other)?
- What else do I have to do (records to keep, office visits, etc.)?
- What will I have to pay for?
- Can I be reimbursed for travel expenses?
- Is childcare available?
- Will I be able to stay on the study treatment after the trial is over? Who will pay for it?
- What was learned in previous studies of this treatment?
- Will I have to stop any drugs or other treatments I am now using?
- Will taking part in this study exclude me from other clinical trials?

TO FIND OUT MORE ABOUT CLINICAL TRIALS:

For information about participating in clinical trials or trials availability throughout the US, call the **AIDSinfo Service** at 1-800-448-0440 or visit their Internet web site at http://aidsinfo.nih.gov

The FDA website has information on the drug development process at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm

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