Participating in a Clinical Trial

WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study done to evaluate new medical approaches in people. New approaches can include:

- New medicines or new combinations of medicines
- New medical devices or surgical procedures
- New ways to use an existing medicine or device
- New ways to change behaviors to improve health

Clinical trials are conducted to determine whether new medical approaches are safe and effective in people.

New medical approaches 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. Read more about how HIV drugs get approved.

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

WHAT IS AN HIV/AIDS CLINICAL TRIAL?

HIV/AIDS clinical trials help researchers find better ways to prevent, detect, or treat HIV and AIDS. For example, all of the medicines used to treat HIV/AIDS in the U.S. were first studied in clinical trials.

Examples of HIV/AIDS clinical trials underway include:

- Studies of new medicines to prevent or treat HIV
- Studies of vaccines to prevent or treat HIV
- Studies of medicines to treat infections related to HIV

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 (ART) continuously led to better health than taking therapy only until a target level of CD4 cells 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 people with HIV as time goes by.

WHO CAN PARTICIPATE IN AN HIV/AIDS 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. Some HIV/AIDS clinical trials enroll only people who have HIV. Other studies include people who don't have HIV. Participation in an HIV/AIDS clinical trial may also depend on other factors such as age, gender, HIV treatment history, or other medical conditions.

You normally cannot participate in a clinical trial if you have any opportunistic infections (OI), or if you 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, pregnant people sometimes cannot participate in trials during the first 3 months of pregnancy because of the risk of birth defects for their newborn child.

WHAT ARE THE BENEFITS OF PARTICIPATING IN A CLINICAL TRIAL?

Participating in an HIV/AIDS clinical trial can provide benefits. For example, many people participate in HIV/AIDS clinical trials because they want to contribute to HIV/AIDS research. They may have HIV or know someone who has HIV.

People with HIV who participate in an HIV/AIDS clinical trial may benefit from new HIV medicines before they are widely available. HIV medicines being studied in clinical trials are called investigational drugs.

Participants in clinical trials can receive regular and careful medical care from a research team that includes doctors and other health professionals. Often the medicines, medical care, and laboratory tests are free of charge.

Sometimes people get paid for participating in a clinical trial. For example, they may receive money or a gift card or they may be reimbursed for the cost of meals or transportation.

WHAT ARE THE RISKS OF PARTICIPATING IN A CLINICAL TRIAL?

In drug trials, new treatments are compared to the best available medication or to a dummy medication (known as a placebo). **You might not get the new treatment.** Participants and researchers in these trials are not told who is getting the new treatment and who is getting the placebo.

You might have to stop taking medications for other conditions during the trial. This can be dangerous for people with medical conditions such as cardiovascular disease (CVD) or diabetes.

Researchers try to make HIV/AIDS clinical trials as safe as possible. However, volunteering to participate in a study that is testing an experimental treatment for HIV/AIDS can involve risks of varying degrees. Risks can include unpleasant, serious, or even life-threatening side effects from the treatment being studied.

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. Before enrolling in a clinical trial, potential volunteers learn about the study in a process called informed consent. The process includes an explanation of the possible risks and benefits of participating in the study. Once enrolled in a study, participants continue to receive information about the study through the informed consent process.

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**.

WILL MY PERSONAL INFORMATION BE SHARED?

The privacy of study volunteers is important to everyone involved in an HIV/AIDS clinical trial. The informed consent process includes an explanation of how a study volunteer's personal information is protected.

SHOULD I PARTICIPATE?

You and your healthcare 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?

MORE INFORMATION

To find an HIV/AIDS clinical trial call an HIVInfo health information specialist at (800) 448-0440 or email ContactUs@HIVinfo.NIH.gov

National Institutes of Health: NIH Clinical Research Trials and You

ClinicalTrials.gov

FDA: Informed Consent for Clinical Trials

FDA: How Drugs are Developed and Approved

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