

CLINICAL TRIALS FACT SHEET

About HIV/AIDS clinical trials:

Clinical trials are an important part of HIV/AIDS treatment. Without research, we could not have any of the treatments that we have today.

What is a clinical trial?

A clinical trial is a study testing experimental drugs on people to see if the drug works, is safe, and how it compares to other treatments. “Clinical trial,” “study,” and “research study” all mean the same thing. A study can also be observational or behavioral, meaning that no experimental drugs are involved. This fact sheet focuses on clinical trials of experimental medications.

What is an HIV/AIDS clinical trial?

- A study of new drugs or treatments specifically for HIV/AIDS.
- Some studies focus on medications for specific symptoms or opportunistic infections.
- Most studies focus on decreasing viral load and raising T-cell counts.
- Some focus on vaccines (both therapeutic and preventative) and microbicides.

Why do we do clinical trials?

We need to test experimental medications to make sure that they are safe and that they work. Also, research without the supervision of the government is illegal and dangerous.

What is a study protocol?

A study protocol is the “guide” of how the study will be run and describes every step of the study. The protocol lists what the comparison groups will be, what tests and/or procedures will be done, what dose of the experimental drug will be used and/or what drug combinations are being studied.

What are inclusion/exclusion criteria?

The inclusion/exclusion criteria are certain requirements that you have to meet before you are allowed to join a study. Each clinical trial has a different set of inclusion/exclusion criteria. If you do not qualify for a study, don’t get discouraged. You may qualify for a different study in the future.

What is the informed consent form?

The informed consent is a document that you must sign before joining the study. It explains the study protocol including possible risks, benefits, and procedures. The consent should be written in a language that you can understand and should not include complicated scientific or medical words.

Signing the informed consent means that you understand the study, your questions have been answered and that you agree to participate. The informed consent is NOT A CONTRACT. You may leave the study at any time. You should not feel pressured to join or stay in a study.

What is a placebo and why is it used?

A placebo is a fake, harmless pill that is given to some patients instead of the study drug. Placebos are used to compare with the study drug so that researchers know if the drug actually works. The patients and the study staff often don’t know who is getting the placebo and who is getting the study drug. This is called a “double blind study.” Most studies will eventually provide the actual drug to patients who start out taking the placebo. This information should be provided to you in the informed consent.

Why do people join clinical trials?

- They have a disease that has no cure.
- Current medication options are not working (drug resistance).
- Some people join clinical trials to get medical care, if they are uninsured or underinsured.
- Some people join clinical trials to get medical care without disclosing their HIV status to their insurance.
- Some people join clinical trials in order to help their community.

Advantages of joining a clinical trial:

- You will have access to new drugs and may continue to receive the drug after the study ends.
- Free study drugs and lab tests (sometimes includes resistance testing).
- Frequent medical follow-up with a qualified medical team, in addition to your general medical provider.
- Some studies compensate for your time. Those studies may involve higher levels of risk so you should think about it carefully before you join these studies.

Disadvantages of joining a clinical trial:

- All study volunteers need to meet the inclusion/exclusion criteria. Sometimes these criteria are strict, sometimes they are not.
- The appointment schedule can be rigid.
- You may be on the placebo instead of the actual drug.
- All of the side effects of the study drug may not be known.
- The study drug may not work.
- Some of the study procedures may be uncomfortable.

Your rights as a clinical trial volunteer:

- You have the right to have your confidentiality protected.
- You have the right to have all of your questions answered and to be informed about all known potential risks and study procedures
- You have the right to drop out of a study at any time without consequences

Your responsibilities as a clinical trial volunteer:

- You are responsible for keeping your study appointments
- You are responsible for taking the study medication as directed
- You are responsible for being honest with the study staff. This includes being honest about side effects you experienced, whether or not you have taken the study drug as directed, and any lifestyle choices (i.e., drugs and alcohol).

For more information about clinical trials in Los Angeles, you may visit the following links: