

## Frequently Asked Questions About Clinical Trials

### **What is a clinical trial?**

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial. The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

### **Why should I join? What do I get out of this?**

The treatment being tested may work for you. Clinical trials may be the only way to get a promising new drug. Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available "underground," or by prescription, you may not be able to afford it). You can help speed the development of new treatments for HIV.

### **Will I be used as a "guinea pig"?**

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time. In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that it may prevent you from getting sick.

### **What if the drug makes me sicker?**

The researchers who design the trials always plan for what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

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### **Will I have to take a placebo ("sugar pill")?**

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled" study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug or would have happened without treatment. Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

### **How can I tell which trial might be good for me?**

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

### **What are my rights as a patient?**

The people involved in your care must treat you with consideration and respect.

You have the right to:

- Be told all the important details about your care
- Ask questions and have them answered
- Say no to any test, procedure or medication
- Go to another health care provider to get more information
- Know the names of anyone you talk with
- Read your medical records with your health care provider
- Make your own decisions about your health care
- Know that your medical records will be kept confidential

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### **What are my responsibilities as a patient?**

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- Be honest about your medical history and anything in your lifestyle which may affect your health
- Follow instructions and take the study drug(s) as requested
- Keep appointments or reschedule them at least 24 hours in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

### **What is informed consent?**

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving informed consent. When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

### **What should I know before I sign the consent form?**

Before you sign the consent form, you should know:

- The reasons for using the experimental treatment
- The risks and benefits of taking part in the study
- If there are any extra costs, doctor visits, lab tests, etc.
- What drugs you will have to take
- Before you decide to join a trial, you may also want to know
  - How will information about me be handled to protect my privacy?
  - Can I take the drug after the trial is over? Will I have to pay for it?
  - If I get sick or develop health problems while on the trial, will I be taken off the trial?
  - How can I find out the results of the trial?
  - Are there other studies of this drug I should know about?
  - (For women) Do I have to use birth control? If so, what kind?
  - If I become pregnant will I have to leave the study?

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### **Why do some studies pay people to participate?**

Do not sign the consent form until you understand everything in it. Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions. Some research studies pay people who volunteer to participate in them. Usually, studies only pay when there is no expected medical benefit to participants, such as when a new drug is being tested for only a short amount of time. Sometimes studies pay when they ask a lot of time and energy from participants, such as overnight stays in the hospital, or long surveys about personal issues.

Some researchers feel that the offer of money is not always ethical because it may tempt some people to take risks that they would not take otherwise. Ask and understand why the study is paying participants before you decide whether to join. Keep in mind that studies that pay usually do not pay until the study is over. When studies do not pay, it is because the potential benefit of the study is felt to be enough compensation for the effort and risk of participating in it. If a study gives you free medication, checkups, lab tests and helps you to be healthier by curing or preventing disease, then you do get something out of your participation.

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### **How to Enroll in a Clinical Trial**

If you want to find out more about a specific clinical trial, call the person listed under the location for that trial. This is usually a research nurse or study coordinator; they will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

### **Finding out if you're eligible: The screening visit**

If the research nurse thinks you may be eligible, she will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

### **Giving "informed consent"**

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join.

### **The first study visit**

After you have signed the consent form, you can join the study during a "baseline" visit, the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

### **Follow-up visits**

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects you may be having. If everything seems to be all right, you will be asked to come back for regular follow-up visits. Frequency of visits may vary from daily to every few months, depending upon the study.

### **Keeping in touch**

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

## Frequently Asked Questions About Clinical Trials

### **Women and Clinical Trials**

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

#### **Can women with HIV join clinical trials?**

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men. Women often don't get enough information about clinical trials and think that they cannot join simply because they are women. Using Trials Search, you can do a "Keyword Search" for a list of studies that are open only to women, but women may also join nearly all of the other studies listed.

#### **Are there special rules about birth control and pregnancy?**

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

#### **What happens if a woman becomes pregnant while in a trial?**

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant. Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion. If you choose to have the baby, it may affect your continued participation in the trial.



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### Youth and Clinical Trials

#### **What does "youth" mean?**

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

#### **Why are youth treated differently in clinical trials?**

Youth are different physically and emotionally from both children and adults. Health care and support programs for youth take these differences into account.

#### **Are there special clinical trials for youth?**

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both child and adult clinical trials. Age restrictions are listed for trials in the trial description.

In many places, there are programs to provide health care and support for youth with HIV.

#### **Do youth need permission to join a clinical trial?**

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial. Even if you get medical care at a clinic without permission, you usually cannot join a trial without your parents' or guardian's consent. There are people working to change the laws in this area, and they may be able to help you join a trial without your parent's permission in certain situations. See the section "Common questions about clinical trails" for an explanation of what it means to give informed consent.

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### Children and Clinical Trials

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older. Children's research is done by doctors and nurses who are experts on children's bodies and health.

#### Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in a child. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

#### Is it Is it Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called "informed consent".

#### Where can I find out more about clinical trials for children with HIV?

In the Bay Area, there are several places where you can get information about children with HIV and clinical trials. You can do a [Trials Search](#) keyword query to get a list of all current studies.

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### **Injection Drug Users and Clinical Trials**

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory do not exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial

#### **Damaged liver or kidney**

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the screening visit. If any of the tests are outside normal limits, you may not be able to join the trial. This is done to protect your health.

#### **Dangerous drug interaction**

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know every drug you are taking, to prevent harmful side effects.

#### **Unable to comply with the rules of the study**

Some trials have very complicated rules, and some people find it hard to follow them. If your doctor thinks you are unreliable, you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.