

## being a trial volunteer: what happens?

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**MAKING THE DECISION** to participate in an AIDS vaccine study can be difficult. So can the participation itself. Being a trial participant takes a serious commitment—of everything from time to letting yourself be stuck with needles. You may also find yourself confronting or talking about things that are deeply personal. For some of the same reasons, volunteering can also be tremendously empowering and uplifting.

If you're thinking about volunteering for a trial, you'll probably start out with lots of questions. Other chapters in this book deal with some of the most common ones, from the safety of experimental vaccines to worries about being stigmatized as “high risk” for HIV. Here we offer a nuts-and-bolts description of what actually happens during a trial: What you will do, and what medical procedures and people are involved.

HIV VACCINE RESEARCH. REAL PEOPLE. REAL PROGRESS.

**"I'm volunteering to stop a killer."**

HIV is a killer. Four of my five close friends died of it. I volunteered to honor them. As someone who is HIV negative, volunteering in an HIV vaccine trial was a way to make a real contribution. My hope is that we will have an effective, preventive HIV vaccine someday. It's the best way to stop HIV from spreading.

Mark McLaurin  
Volunteer, HIV Vaccine Research



USA

From a series of posters by the US National Institutes of Health (NIH) announcing AIDS Vaccine Awareness Day, an education campaign about AIDS vaccine research and clinical trials.

HIV VACCINE RESEARCH. REAL PEOPLE. REAL PROGRESS.

Join me on Tuesday, May 18th  
down to form a "V" — as a sign you share my vision for an HIV vaccine research shows you appreciate all the people working to make progress to stop this killer, HIV.

**"I'm fighting to stop a killer."**

HIV is a killer. I'm a witness. I have buried babies. I have buried old people and young people. People like me, people like you. HIV is serious, so my life's work is helping others learn about it and prevent it.

Today, thousands of researchers, medical professionals and volunteers are committed to discovering a vaccine that prevents HIV and stopping this epidemic. To them, I say, 'Thank you, I'm with you.'

Mark Del Monte  
Community Worker



Join me on Tuesday, May 18th for HIV Vaccine Awareness Day. Wear your red AIDS ribbon upside down to form a "V" — as a sign you share my vision for an HIV preventive vaccine. Showing your support for HIV vaccine research shows you appreciate all the people working to make progress to stop this killer, HIV.

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**YOUR EXPERIENCE** as a trial participant will most likely follow a routine similar to this:

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Your first encounter with people connected to the trial might be an information session in your neighborhood or village where community educators talk about AIDS vaccine research, describe how *clinical trials* are done, discuss any trials that may happen at the local site and respond to any questions and concerns. Or you might start out by visiting the clinic for information after learning about an upcoming trial through an advertisement, or from another volunteer.

Once at the clinic, the first person you'll interact with will probably be an outreach worker. His or her job is to find the type of people needed for the trial and inform them about the study. While it's easy to think of outreach workers primarily as salespeople for the study, in practice many of them took their jobs because they are part of the community the trial is targeting and believe that the work they are doing is important for the community as a whole. After you get the information you need, the final decision is yours to make. No one at the trial site should pressure you one way or the other.

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The next step is a screening appointment. There you will meet with a person trained to do interviews and draw blood in a research setting. He or she should be able to describe the study in detail and answer all your questions. If not, you should have access to a project coordinator or clinical investigator. You, in turn, will be asked questions about your medical history, health and life (including personal stuff about sex and drugs, etc.) You'll have a physical exam performed by a nurse practitioner or physician, and blood will be drawn for routine clinical lab tests, to make sure your overall health is good. The blood sample will also be used for an HIV *antibody* test.



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## HAITI

Poster seeking volunteers for an AIDS vaccine trial in Port-au-Prince, Haiti. Text in speech bubble reads: "If you are between 18 and 60, and were negative for HIV when you had your last AIDS test, you can help develop a vaccine against the virus that causes AIDS." Translation from the Creole by Stephenson Jolicœur.

(Before you can participate in a vaccine study, researchers must be sure that you aren't already infected with HIV.) If you're female, you'll also be tested for pregnancy, and asked about your pregnancy plans. Being (or planning to become) pregnant disqualifies you as a volunteer, since investigators avoid intentionally exposing a fetus to an experimental product. For the same reason, women who are breastfeeding an infant are also disqualified.

At this point you might be told that you're not eligible to participate, based on the criteria for *inclusion* or *exclusion*—for example, certain medications you're taking, your medical history, your ability to return for follow-up appointments or your risk activities. Some of these criteria depend on the type of study: For example, early (*Phase I*) safety studies of a product look for volunteers with very low risk of HIV infection, while large-scale (*Phase III*) trials need people with a higher level of behavioral risk. (These different types of studies are described in chapter 11).

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One or two weeks later, you'll return for your results from the screening tests, meet with a counselor for your HIV test results and counseling, and either be accepted into the trial or told that you are ineligible. If you are eligible and still want to go forward, you will review and sign *informed consent* material with a screener or clinician and have your pre-vaccine blood drawn for lab tests, including another HIV test (to make sure you haven't become infected since the initial screening), and for storage. You might also receive your first injection, which will contain either the experimental vaccine or a *placebo* (a "blank" given to a group of participants as a basis for comparing to the *immune responses* or infection rates in people who get the real vaccine). Most trials are *blinded*, which means that neither participants nor the clinic personnel know who gets which. Women will be given a pregnancy test just before each vaccination, and are ineligible to continue if they are pregnant.

A research doctor or nurse will give the injection, and you will be asked to stay at the clinic for up to an hour for observation in case of an *adverse reaction*.

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Subsequent visits will be much the same. You will return at fixed intervals for blood draws, interviews, counseling and sometimes more injections. The number of visits is predetermined and stated in the consent form.

– 5 –

Once you have completed your visits, your responsibilities as a trial participant are over. When all the other volunteers complete theirs, the study will be “unblinded,” which means that the investigators will get a list of which participants received the vaccine and which ones got placebo. From there a team of scientists will analyze the data, which can take up to several months. When they are finished they will usually communicate with you again, letting you know which group you were in (vaccine or placebo) and explaining the results of the trial.

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#### **the site study team**

Your site will have its own principal investigator (PI), and you should have access to yours if you request it. Each PI is in charge of one or more trial sites. At each site the PI will have a group of scientists and staff working with them who you will get to know as you return for visits. Most PI's have a medical and/or public health background. You probably won't interact with him or her during your regular study visits, although some PI's look for opportunities to interact with the volunteers.

In addition to the PI, most sites also have a coordinator who is responsible for the day-to-day running of the trial. The whole process at a site is often colored by the PI and site coordinator, so you may want to get a sense about them before agreeing to participate.

The person you will interact with most will be your counselor or study nurse. He or she is usually chosen in part for their good people skills. Often these relationships can grow to

be warm and supportive. You will also get to know the study's lead physician, whose job is to monitor the clinical results and overall health of the participants and to follow up and provide care if needed in the case of adverse events.

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what next?

**THE END OF A TRIAL** means one less obligation on your schedule. But some volunteers also describe it as a letdown; a loss of the sense that you're "doing something" about the epidemic.

It's important to realize that volunteers, past and present, are a fast-growing and potentially potent group of advocates for AIDS vaccines. Worldwide, there are over 20,000 of us.

If you're in a trial that is about to end, you might want to find other ways to stay involved—for example, by serving on a *Community Advisory Board (CAB)*, or doing advocacy work (see chapter 34 for a discussion of this by one former volunteer). Your trial site may know about some others, and perhaps this book and some of the resources it lists will also give you ideas.