Hormone Health NETWORK

A PATIENT'S GUIDE TO
Minority Participation in Clinical Trials

What are clinical trials?

Clinical trials are scientific research studies that involve people. Their overall goal is to improve health and health care by answering specific questions about how to better prevent, detect, and treat diseases. Each clinical trial follows a study plan called a protocol. This plan is carefully designed to protect the health of the people who participate, as well as answer specific research questions. A protocol describes:

- what types of people may participate in the trial
- the schedule of tests, procedures, medications, and dosages
- the length of the study

While in a clinical trial, participants following a protocol are seen regularly by the research staff to keep an eye on their health and to check the safety and effectiveness of the study plan.

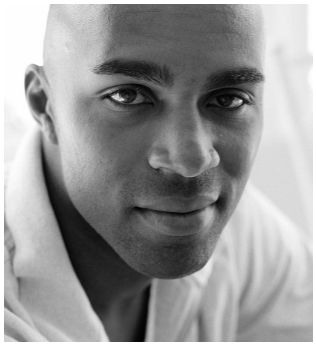
Clinical trials are important because they lead to the discovery of new prevention, diagnostic, and treatment methods for disease. Many of today's most effective ways of prevention and treatment were tested and proven in clinical trials and are now accepted to be the "standard of care." For example, current drugs that effectively treat diabetes, cancer, high blood pressure, and other diseases were first evaluated in clinical trials.

If you participate in a clinical trial, possible benefits to you include:

- Taking an active role in your own health care
- Getting new research treatments before they are widely available
- Obtaining expert medical care at leading health care facilities during the study
- Helping others by contributing to medical research

Why is minority volunteer participation important for clinical trials?

Many factors play a part in your health, including your ethnic background and race. If clinical trials are to be useful to the entire U.S. population, people from all backgrounds and races need to participate—Caucasians, African Americans, Asian/Pacific Islanders, Hispanics, and Native Americans (American Indians and Alaska Natives).



Ethnic and racial minorities make up 37.5% of the overall U.S. population, and that percentage continues to grow. Without adequate representation of minorities in clinical trials, researchers cannot learn about potential differences among groups. Also, when minority participation in clinical trials is low, researchers can't be sure that the findings of their study apply to the entire population because some ethnic and racial groups may have been understudied or never studied.

Should you volunteer for a clinical trial?

You may have heard about a clinical trial that interests you and are thinking about volunteering to participate. If you are not sure if you want to go ahead, here are some points to think about. First of all, you should know that there are safety measures in place to protect your health in a clinical trial.

There has been some distrust of medical research among people in the African American and Hispanic communities. Such feelings grew out of the Tuskegee experiments (in 1932–1972) in which African Americans with syphilis were left untreated to see if the disease affected blacks differently from whites. Another example that occurred about the same time in Puerto Rico involved the decision to sterilize women in order to control population growth.

Today, all clinical trials are conducted in a more ethical manner. No medical study is performed without your informed consent.

Informed consent is the process of learning the key facts about a clinical trial before deciding whether to participate. Informed consent is a process that continues throughout the study to provide you with needed information. To help you decide whether to participate, the doctors and others involved in the trial explain the details of the study. If your native language is not English, a translation is provided. At any time, you should ask questions about anything you don't

understand. Then researchers will give you an "informed consent" form to read that includes details about the study, including its purpose, how long it will last, required procedures, and key contacts. Most important possible risks and benefits are also explained in the form. You then decide whether to sign it or not.

Informed consent is not a contract, and you can leave the trial at any time.

Another point to consider is whether a particular clinical trial is right for you. You can go to the website at *ClinicalTrials.gov* for regularly updated information about government and private clinical trials. The information provided on this site should be used along with advice from health care providers. More information is available from the Center for Information & Study on Clinical Research Participation (CISCRP), a nonprofit organization whose goal is to educate people about taking part in clinical research. It is not involved in either recruiting people or conducting trials.

Who can participate in a clinical trial?

Before joining a clinical trial, you must qualify for the study. Some research studies look for people with illnesses or conditions to be studied in the trial, while others need healthy people. The factors that qualify someone to participate in a clinical trial are called inclusion criteria and those that restrict someone from participating are called exclusion criteria. These criteria are based on such factors as:

- Age
- Gender
- Type and stage of a specified disease
- Previous treatment history
- Other medical conditions

It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, they are used to identify the right people to participate and keep them safe. The criteria help to make sure that researchers will be able to answer the questions they plan to study.

If you meet the inclusion criteria but have other difficulties in participating, such as transportation problems or work schedule conflicts, you should talk to the researchers conducting the study. They may be able to help you to overcome these difficulties.

Before you meet with the research coordinator or doctor in charge of the clinical trial to discuss your possible participation, it's a good idea to prepare yourself so that you will get the most out of the discussion:

- Plan ahead and write down possible questions to ask.
- Ask a friend or relative to come along for support and to hear the responses to the questions.
- Bring a tape recorder to record the discussion to replay later.

What if you have concerns after you sign up?

If you decide to participate in a clinical trial and then have some concerns about your safety, your schedule, the information you've been given, or have problems understanding any part of the process, be sure to talk with the researchers so they can try to deal with these issues.

Remember, you can leave a clinical trial at any time. However, if you feel you must leave the trial, it's important that you let the research team know about it and that you give your reasons for leaving the study. That is important information that will be used by the researchers in analyzing their results.

What do I do with this information?

Clinical trials are an important part of the healthcare process, leading to the prevention, treatment and cure of many diseases and conditions. It is important that people from all races and backgrounds take part in clinical trials so that the most people possible are able to benefit from new treatments.

If you may be interested in participating, tell your doctor to let you know of upcoming trials/studies. If there's a university with a medical school in or near your community, let the clinical center at the university know you would like information on upcoming clinical trials. You can also go to *ClinicalTrials.gov* for the most complete listing of trials, including ones in your local area.

Internet Resources

http://ClinicalTrials.gov
Information on clinical trials from the National Institutes of Health

http://ciscrp.org
Center for Information and Study on Clinical Research Participation

www.hormone.org/public/clinical.cfm
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