NIH News in Health

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Get Involved in Clinical Research

Because Lives Depend on it

Gene Gary-Williams began participating in a **clinical research** study in 1996. Why? "African-American people in general have not been involved in many of the medical studies," she explains. "For a long time, we weren't invited and then, when the opportunity presented itself, we were too suspicious.... As women of color, we need to participate so that we can provide information researchers would not be able to get otherwise."

Are you playing your part in clinical research? Doctors and scientists are conducting clinical studies in every state of the union. They're looking for volunteers of all ages, from all cultures, with different lifestyles. You may be able to help them learn how to improve the health of hundreds, thousands or millions of people.

In clinical research—also known as clinical trials or clinical studies—volunteers participate in carefully conducted investigations designed to uncover better ways to treat, prevent, diagnose and understand human disease. The studies can be sponsored by foundations, medical institutions, pharmaceutical companies and federal agencies such as NIH. Sites as varied as hospitals, universities, doctors' offices or community clinics can host trials.

Definitions

Clinical Research
Medical studies that involve people.

Protocol
The research plan, carefully designed to answer medical questions while safeguarding the participants' health.

The idea for a study often begins in a laboratory, hospital or clinic. Researchers first develop new therapies or procedures in the laboratory and then test them in animal studies. The treatments that prove most promising move into clinical trials.

Two types of volunteers are needed for clinical research. A healthy volunteer is a person with no known significant health problems. Healthy volunteers don't directly benefit from their participation, but they help researchers develop new knowledge that may indirectly help them and people they know. Healthy volunteers might be needed for several reasons. For example, when developing a new technique, such as a blood test or imaging device, healthy volunteers help define the limits of what is considered normal.

The other type of volunteer, a patient volunteer, has a known health problem and is needed to better understand, diagnose, treat or cure that disease or condition. The research procedures may or may not benefit the patient volunteer, but clinical studies are always designed to help researchers learn something about the disease or condition and to one day help others. Researchers can learn more about the disease process by comparing patient volunteers to healthy volunteers, so they often need both types of volunteers.

Clinical studies all have a research plan, known as the **protocol**. A protocol describes who is eligible to participate; details about any tests, procedures, medications and dosages that will be used; and the length of the study and what information will be gathered. The protocol is carefully designed to safeguard the participants' health.

Every clinical trial protocol in the

continued on page 2

Inside News

continued from page 1

U.S. must be approved and monitored by an independent committee of physicians, statisticians and members of the community to ensure that the risks are minimal and are worth the potential benefits. Federal regulation requires that all institutions in the U.S. conducting or supporting medical research involving volunteers have such a committee to approve the protocol before it begins and to periodically review the study. Members of the research team also regularly monitor the participants' health during the study to determine its safety and effectiveness.

All clinical studies have guidelines about who can participate. The participants are selected according to factors such as age, gender, the type and stage of a disease, previous treatment history and other medical conditions. These criteria aren't personal. They're used to ensure that researchers identify appropriate participants to help them answer the questions they want answered.

If you consider participating in a trial, members of the research team will explain the details of the study to you in a process called **informed consent**. They will give you a document to sign that includes details about the study, such as its purpose, length, required procedures and who to contact for further information. The document also explains the risks and potential benefits of the study. If you decide to sign, you're still free to withdraw from the study. Informed consent is not a contract; it's to ensure that you understand enough about the study to decide whether or not to participate.

After a study is completed, the researchers carefully examine the information they've collected. The results are often published in scientific journals. If the new approach has been proven safe and effective, it may become standard practice.

Paul Covington, a retired basketball coach from Jackson State University, knew he hadn't always followed a healthy diet even though he was quite active. So he decided to volunteer for a clinical study looking into blood pressure and heart disease. "At first, I did it for selfish reasons," he said. "I had been coaching so long, I thought maybe getting in the program would help me find out if I had done any damage to my body."

But then, he said, "After thinking about all of it, I found out in the long run this will help a lot of people. So what started out to be selfish will end up helping others."

Many people might benefit from your participation in clinical research: your relatives, your friends and even you. Talk to your doctor or visit http://clinicaltrials.gov to find a clinical study near you. ■

Web Sites

- **http://clinicalresearch.nih.gov**
- **http://clinicaltrials.gov**
- **www.cancer.gov/clinicaltrials/conducting/informed-consent-guide**
- **www.cancer.gov/clinicaltrials/understanding/childrensassent0101**
- **www.nimh.nih.gov/publicat/clinres.cfm**

Definition

Informed Consent

The process of providing key facts about a clinical study to potential participants before they decide whether to participate.

Wise Choices

Things to Consider

If you're considering taking part in clinical research, learn as much as possible about the study before committing. Here are some questions you might want to ask:

- What is the purpose of the study?
- What types of tests and experimental treatments are involved?
- Why do researchers think the treatment being tested may be effective? Has it been tested before?
- Will the study directly benefit me?
- What are the risks?
- How do the possible risks, side effects and benefits of the experimental treatment compare with my current treatment?
- How much of my time will be involved? Will hospitalization be required? What about outpatient visits?
- Who pays for the experimental treatment? Will I be reimbursed for other expenses?
- Who is responsible for my care during the study? What type of follow-up care will be provided?
- How will I learn about the trial results?

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Understanding Clinical Research

Learn the Basics

You hear about the results of clinical research all the time. You've probably made a few changes to your behavior—what you eat or how much you exercise—based on some study. Whether you want to understand how to put those news reports in perspective or are thinking of participating in a clinical study yourself, it's time you learned more about clinical research.

There are two general types of clinical research studies. In an observational study, scientists observe people to learn more about the cause or progression of a disease or condition. They might compare a group with a particular condition to another similar group without the condition to figure out what factors play a role in the disorder. Or they might select participants based on their exposure, say, to a particular pollutant, and then try to find a similar group of people who haven't been exposed. By comparing the two groups, they might discover whether the factor in question is causing any health problems.

In an intervention study, researchers test a particular treatment. The best-known type of intervention study, the randomized clinical trial, is considered the gold standard. People are assigned to 2 or more study groups by chance (randomly). The different groups receive different treatments. One, the control or comparison group, receives a sham treatment or a pill that looks just like the drug being tested but actually does nothing (called a placebo). Only the pharmacist knows who is getting which medication so that observations by the research team won't be biased.

Comparing treatment groups to control groups is the best way to see if a treatment is really effective. But that's not always possible. Placebos can't be used if a patient would be put at risk by not having effective therapy. In these situations, studies compare the experimental therapy with an approved one.

You may hear about clinical trial "phases." Each phase has a different purpose and helps researchers answer different questions. In phase I trials, researchers test an experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects, not to see if it's effective.

In phase II trials, the experimental drug or treatment is given to a larger group of people (100–300) to start testing its effectiveness and further evaluate its safety. In phase III trials, the experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with other treatments and collect information about how to use the experimental treatment safely.

After a treatment is licensed (approved by the U.S. Food and Drug Administration), researchers track its safety in phase IV trials, seeking more information about its risks, benefits and optimal use. Large groups of participants are needed for these long–term studies to detect any unexpected side effects that might occur in a small percentage of people. ■

Wise Choices
Questioning Research Study Results

- Was the study done in the laboratory, in animals or in people?
- Does the study include enough people like you?
- What kind of trial was it? A randomized clinical trial involving thousands of people gives scientists the most reliable results.
- Where was the research done and who paid for it?
- If a new treatment was being tested, were there side effects?
- Who is reporting the results? Is it from a source you can trust?
- If you're not sure what a finding means for you, ask your health care provider.

Web Sites

- **clinicalresearch.nih.gov**
- **www.nih.gov/news/WordonHealth/aug2004/story03.htm**
- **www.nih.gov/news/WordonHealth/apr2004/risk.htm**

Health Capsules

Migraines Tied to Heart Attack Risk

Men who suffer from migraine headaches may be at greater risk for heart attack and other types of **cardiovascular** disease, according to a new study funded by NIH. The findings parallel last year's report that women with a history of migraines also face a higher risk of cardiovascular disease.

More than 28 million Americans suffer from intense migraine headaches, often described as a pulsing or throbbing in one area of the head. Symptoms can include nausea, vomiting and extreme sensitivity to light and sound. Migraines affect about 18% of women and 6% of men.

Researchers studied more than 20,000 men for about 16 years. None had a history of cardiovascular disease or other major illnesses when they first enrolled in the study. About 1,500 of the men suffered from migraines.

Over time, the men with migraine had a 24% greater risk of developing major cardiovascular disease compared with men who did not have migraine. The men with migraine also had a 42% increased risk for heart attack.

The relationship between migraine and heart health is complex and unclear. Migraines may simply be a sign of an underlying cardiovascular problem. In any event, because of the apparent link to heart disease, migraine sufferers might be wise to take steps to reduce traditional cardiovascular risk factors, like high blood pressure, obesity, smoking and high cholesterol. ■

Definition

Cardiovascular
The system of heart and vessels that circulates blood throughout the body.

Web Sites

■ **http://health.nih.gov/result.asp?disease_id=303&terms=migraine**

■ **http://health.nih.gov/result.asp?disease_id=312&terms=cardio**

Heart Health for Women

Learn how to protect your heart health by reading the newly updated booklet *The Healthy Heart Handbook for Women*. This easy-to-use guide is packed with the latest information on heart disease, the #1 killer of women.

Read practical advice on reducing the major heart disease risk factors: high blood pressure, high cholesterol, diabetes, smoking and being overweight. You'll find tips on following a nutritious eating plan, creating a physical activity plan, working in partnership with your doctor and getting the whole family involved in heart-healthy living. Quizzes, charts and the latest health statistics provide information you'll need to estimate your risk and control and prevent heart-related problems.

The full-color booklet is available for $4 or can be viewed online without charge. Go to http://emall.nhlbihin.net/product2.asp?sku=07-2720 or call 301-592-8573. ■

Wise Choices
Warning Signs of Heart Attack

For many women and men, the first symptom of heart disease is a heart attack. Recognizing the warning signs and getting help quickly can save your life.

- Heart attacks don't always begin with sudden, crushing pain; many start slowly as mild pain or discomfort.
- Most involve discomfort in the center of the chest that lasts more than a few minutes.
- You may feel discomfort in other areas of the upper body, including one or both arms, the back, neck, jaw or stomach.
- You may feel short of breath.
- Other symptoms include nausea, light-headedness and breaking out in a cold sweat.

Featured Web Site
Cancer.gov en Español

www.cancer.gov/espanol

A new Spanish language Web site provides Hispanic/Latino communities with accurate and up-to-date cancer information. Visitors can learn about different types of cancer, treatments, detection and prevention as well as read about the experiences of Latino cancer survivors. *From NIH's National Cancer Institute.*