

# **Looking for Free Medical Care?**

## **Consider Participating in Clinical Research Studies**

According to the Center for American Progress, four million people have lost health care coverage since the recession started in 2007. Even those who haven't lost their health insurance are looking for creative ways to cut medical expenses. One of the most attractive benefits of participating in a clinical research trial is free medical care. This can include free physical exams, medication, testing, education, and monitoring of your condition.

### **What is a clinical research study?**

Clinical research studies are short-term research projects that give medical professionals a better understanding of how patients respond to different medications and treatments. Researchers and physicians work with volunteer patients to evaluate the effectiveness of different dosages or combinations of medications.

### **How is a drug approved for testing in a clinical research study?**

The Food and Drug Administration (FDA) must authorize a drug company's proposal to do research studies. Once the studies have been completed, the FDA reviews the information that was collected for safety and effectiveness. The drug approval process may take many years.

### **Who can participate in a research study?**

Anyone can volunteer for participation in a clinical research study. Each study has individual eligibility requirements. These requirements are based on age, gender, type and stage of health condition (such as diabetes or arthritis), treatment history, and history of other medical conditions. The FDA has very strict requirements about patient inclusion and exclusion criteria for research studies. This means that you must meet the FDA criteria before being entered into the trial.

### **Is medical insurance required for participation in a study?**

No

### **How do I decide if I want to participate in the study?**

The FDA requires that written information about the research study is provided to all volunteers. This process is designed to give you the information you need to decide about participating in a research study. Your written and informed consent must be obtained before any research procedures begin. You should ask questions and exchange information freely with the investigator before and during the study.

### **What are the benefits of participating?**

Study participants do not pay for any study-related laboratory and diagnostic tests, physical exams, health education, study supplies or study medications(s). There is the possibility that the study drug may be as effective as or more effective than treatments

that are currently on the market. Clinical research volunteers also have the satisfaction contributing to the evaluation of effectiveness and safety of new medications and treatments.

**What are the risks of participating?**

As with any medication, research participants may experience side effects. Your primary care physician should review the participation risks with you to make sure you are comfortable with the study.

**How is the FDA involved?**

The U.S. Food and Drug Administration (FDA) must authorize a drug company's research proposal before a drug study begins. Years of laboratory research are required before an investigational drug is approved for research in people. An Ethics or Institutional Review (ERB/IRB) must also independently review and approve the study before it begins. These review boards are comprised of healthcare professionals and non-healthcare members whose goal is to protect the safety and rights of study participants. Participants in research studies are followed closely during studies through lab and other diagnostic testing, physical examinations, and evaluations of symptoms and general health. Centralized study drug safety information is regularly sent out to research investigators to keep study teams up-to-date of current findings. Any significant information is communicated to study participants as indicated during the study period.

**What are my responsibilities as a volunteer?**

It's very important to provide accurate information to the research team about your health and medications. You should be proactive about informing your other health care providers about your participation in a clinical trial study. During the study it's important to be an active participant, asking questions and sharing health information as needed with the research team, as well as following study guidelines.

**How can I find out more about the clinical research process?**

You can learn more about the clinical trial process by visiting the FDA's website at [www.fda.gov/oashi/clinicaltrials/default.html](http://www.fda.gov/oashi/clinicaltrials/default.html).

**Check these websites:**

[www.genome.gov](http://www.genome.gov)

<http://clinicalstudies.info.nih.gov/>

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

[Information Excerpted from: The Difference between Living and Living Well. *Health Matters Magazine*; April/May 2009]