

healthsmart!

Should You Participate in a Clinical Research Study?

What is a clinical research study?

A clinical research study (or clinical trial) is a research study that uses human volunteers to answer specific health questions and find new treatments and ways to improve health. Clinical research studies help physicians and scientists develop improved treatments and even cures for many medical problems. Typically conducted in hospitals, clinics or physicians' offices, clinical research studies rely on patients who volunteer to try the new treatments. UK HealthCare is the setting for more than 900 active clinical research studies each year. You can browse clinical research studies that are recruiting for volunteers at www.UKclinicalresearch.com.

What are the potential benefits to you?

While there is no guarantee that you will benefit from participating in a clinical research study, there are numerous potential benefits, including possible health improvements from new treatments not available to the public, interaction with physicians and nurses who are at the leading edge of medical science, and close medical monitoring of your condition. In addition, you may feel satisfaction from participating in studies that may contribute to new medical knowledge and that have the potential of helping others

with similar illnesses. Most clinical research studies provide study-related procedures and treatments at no cost to the volunteer.

Types of clinical trials

Clinical research studies may test new treatments, new combinations of drugs, medical devices or new medical approaches. Some research studies look for better ways to screen, diagnose or prevent disease. Others may look at the influence of genetics or at the outcomes of medical treatments, such as improved quality of life or cost effectiveness.

Clinical research studies of new drugs are conducted in three phases:

Phase One: Tests a new drug's safety in the human body. A small number of healthy volunteers are needed for this phase.

Phase Two: Tests for effectiveness and dosage in several hundred patients. Often there are two groups: One receives the standard treatment or placebo (inactive pill), and the second receives the new treatment.

Phase Three: Measures the drug or procedure against the best standard treatment. This is the last phase before submission to the Food and Drug Administration (FDA) for approval. If approved, the drug will be available in pharmacies.

What risks are involved in clinical trials?

Side effects and risks exist with almost any treatment, whether it is a traditional, conventional treatment or a clinical research study. Some treatments that are being tested have side effects that can be unpleasant, serious or even life-threatening. However, many safeguards exist to make clinical research studies as safe as possible and to protect patient rights. Before a new treatment is given to patients, it is carefully studied in the laboratory. Laboratory research establishes how best to use the new methods or treatments effectively in people while minimizing risks. However, because the treatment being studied is new, doctors don't always know what side effects may occur. All known risks including non-physical risks such as inconvenience, emotional risk, financial

risks or risk from confidentiality breach should be fully explained to you by the researchers.

Cost is an important consideration for a patient thinking about entering a clinical research study. Most studies provide the product being studied and any research-related procedures at no cost to the participant. Clinical research studies that test a treatment may require clinic or hospital visits, X-rays, blood tests or other medical procedures. Some studies may have a sponsor that pays some or all of the costs. Sponsors could be federal agencies or the company that makes the new drug or device.

Health insurance and managed care providers do not always cover all patient costs in clinical research studies. Before making any decisions, you should call your insurance company to learn what their coverage would be for a specific clinical study. In addition, UK HealthCare patient account representatives are available to work with you and your insurance company on reimbursement

Where to find information about clinical trials

www.UKclinicalresearch.com

Browse UK's listing of currently enrolling clinical research studies by category

www.research.uky.edu/ori/human/participants.html

Office of Research Integrity research participant Web site

EmergingMed.com

Matches patient's personal profile to enrollment criteria for studies

ClinicalTrials.gov

Government listing service of 55,000-plus trials in 155 countries

CenterWatch.com

Searches 25,000 industry and government-sponsored studies

SearchClinicalTrials.org

Searches multiple Web sites for listings, study results and study news

Cancer.org

American Cancer Society no-cost studies-matching service

To learn more about clinical trials at UK HealthCare, call **859-257-7856** and speak to someone in our Clinical Research Office. Office hours are Monday through Friday, 8 a.m. to 5 p.m.

issues for clinical research studies. In many cases, patients do not pay out-of-pocket for participating in a clinical research study.

What protections are afforded to clinical trial participants?

The FDA and the National Institutes of Health oversee much of the medical research in the United States. Clinical research studies with drugs or devices must be conducted according to rules and guidelines set forth by the FDA as well as state laws and institutional policy.

Clinical research studies must be approved by the organization's Institutional Review Board (IRB) prior to beginning. The IRB is a board of scientists and laypeople not connected with the study who provide ongoing review and oversight to ensure that the rights, safety and welfare of study participants are respected and protected. The IRB is authorized to review, require changes to, approve or disapprove studies. Studies are monitored on an ongoing basis to ensure safety and if obvious problems are noted, changes are made.

Clinical research studies must be conducted under the supervision of a qualified investigator, usually a medical doctor, who along with his or her team will provide close medical monitoring to ensure the volunteer is not exposed to any to unnecessary risks.

Before you agree to take part in a clinical research study, you must be given complete information about the study, including possible side effects and benefits. All of the study information will be documented in an informed-consent form, which will be reviewed with you and which you will sign if you choose to participate. The informed-consent form is not a contract: You should know that you can withdraw at any time without any effect on how you would be treated in the future.

If you have questions about your rights as a clinical research study participant at the University of Kentucky, you may contact the Office of Research Integrity, which is the

administrative office for UK's IRB, at **1-866-400-9428**.

Questions to ask

- What is the time commitment?
- Compared to my current treatment, what are the risks? Side effects? Benefits?
- What safeguards are built into the trial?
- Who will pay for the research-related treatment?
- How will patients be informed about new risks identified during the trial?
- Will results of the trial be provided to me?
- Who are the primary investigator and coordinator involved in conducting the trial?

Health information

In need of health information? We can help.

At UK HealthCare, it's part of our mission to be Kentucky's health information resource. Our goal is to give you information on wellness practices, illnesses and treatments, and health consumer issues so that you can live the healthiest life possible and make the best possible health care decisions.

Information on a wide variety of health topics can be found on our Web site, and printed versions may be requested by calling UK Health Connection, **859-257-1000** or **1-800-333-8874**.

Publications

Here are just a few publications that are available:

Advances & Insights

Advances & Insights is a publication that highlights a recent medical discovery or development and provides the insights of a UK HealthCare expert. Issues are available in the following categories:

- Women's Health
- Cancer
- General Health
- Pediatrics
- Heart Health
- Neurosciences

HealthSmart!

We also produce *HealthSmart!*, a series of publications designed to help you be a good health care consumer and get the most out of the health care system.

HealthSmart! topics include:

- Genetic Counseling and Testing
- Preventing and Solving Medical Billing Problems
- Managing Multiple Medical Problems
- Patient Safety (Adult)
- Pediatric Patient Safety
- How to Avoid Medication Errors
- Getting a Good Second Opinion
- Protecting Yourself Against Identity Theft

Individual issues of all of our publications can be found online at ukhealthcare.uky.edu/publications and new topics are added regularly.

Want to make sure you never miss a new one? Sign up for a subscription on the Web site or by calling UK Health Connection.

On the Web

Extensive information on various illnesses, conditions and treatment methods can be found on our Web site, ukhealthcare.uky.edu. From the home page, select the box on the left-hand side labeled "Need health information?" and select "Illnesses and Conditions" from the drop-down menu.

*Health*Click*

Visit our Web site, ukhealthcare.uky.edu to subscribe to our *Health*Click* service, which allows you to receive notification of new publications as well as special events in areas that interest you.

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Call UK Health Connection at (859) 257-1000 or toll free (800) 333-8874 to make an appointment or request a referral. Visit us online at www.ukhealthcare.uky.edu.

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