

MAKING A DECISION

WHAT IS A VOLUNTEER?

All participants in a clinical trial are volunteers who have agreed to participate in a particular study. Some volunteers seek out clinical trials, and some are referred to clinical trial opportunities by their physicians. There are research opportunities in clinical trials for persons with specific diseases and conditions and for persons in generally good health. Volunteers participating in a study are referred to as “subjects” or “participants.” Volunteers can leave a study at any time for any reason.

WHAT IS INFORMED CONSENT?

Informed consent is an understanding by the volunteer about what will happen during the study, why it is being done, how long it will take, the possible risks, the volunteer’s rights, and alternative treatment options. Before participating in any part of the study, the informed consent process begins with a discussion between the study doctor, or study coordinator, and the potential subject about the procedures in the study and the known risks. This information is written in detail in a document called a “**research consent form.**”

All studies involving human subjects are reviewed and approved by a committee of medical experts and community representatives called an Institutional Review Board (IRB) before any subject can participate in a study. The IRB reviews the scientific merit, ethics, and study documents, such as the research consent form, for concerns that may affect the subject’s safety or rights. Subjects in a study can submit complaints or concerns to the IRB. The **research consent form** will tell you how to contact the IRB.

This ongoing process of informed consent attempts to ensure that you, the volunteer, are fully informed about the study and that you have enough information to be able to make appropriate decisions about participating in a clinical trial. After discussing the study with the study doctor and reading the research consent form, you will need to sign the form to indicate that you want to participate and that you understand and accept what will happen in the study and the possible risks. All study volunteers receive a copy of the signed **research consent form.** You can continue to ask questions throughout the study and will be informed of any new developments that might affect your decision to participate. You can decide to leave the study at any time, even after you sign the research consent form.



ABOUT THE UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE

The University of Maryland School of Medicine was established in 1807. It is the first public and fifth oldest medical school in the United States and the first to institute a residency training program. The School of Medicine is the founding school of the University of Maryland, and today it is an integral part of the 11-campus University System of Maryland.

On the University of Maryland Baltimore campus, the School of Medicine serves as the foundation for a large academic health center that combines medical education, biomedical research, patient care, and community service. With the support of our patient care partners, including the University of Maryland Medical System and the Baltimore VA Medical Center, the School of Medicine offers clinical trials addressing a wide range of health problems, such as cancer, HIV/AIDS, neurologic diseases, heart diseases, kidney diseases, high blood pressure, trauma, and psychiatric problems. The School of Medicine also has active research and development programs in vaccines, complementary medicine, and in medical devices and technology.



THINKING ABOUT ENROLLING IN A CLINICAL TRIAL?

WHAT IS A CLINICAL TRIAL?

*Clinical research is a process of discovery that is intended to improve medical care. Researchers attempt to answer questions such as “Which medication works better?” or “What is the best way to treat a medical problem?” In order to find the best treatment available, researchers often set up a special kind of study called a **clinical trial.***

A clinical trial is an experimental study that can involve a few or many patients. Clinical trials evaluate the effect of a new drug or medical device on human beings. Participating in a clinical trial is **always voluntary**, that is, done with your individual permission. In many cases, the drugs and devices being tested represent potential advancements in medical science and technology that do not yet have federal approval for use by the general public. The drugs or devices being tested in the study *may* work better than the treatments that you are currently receiving. However, the study treatment may also work the same as, or even worse than, your current treatment.

There are different kinds of clinical trials, each one referred to by a “phase” (Phase I through Phase IV). New drugs or devices are first studied in humans in “Phase I” trials. Each new, progressive phase represents a larger and more intensive study of the drug or device. For example, Phase I studies involve only a few volunteers and are primarily designed to determine safety in humans. Phase II and Phase III studies involve a larger number of volunteers and are designed to determine the safety and effectiveness of the drug or device in treating the medical condition. Phase IV studies are designed to determine long-term effectiveness and safety of an already approved drug or device.

contact
information



University of Maryland School of Medicine
<http://medschool.umaryland.edu>

Center for Clinical Trials
<http://medschool.umaryland.edu/CCT>

Institutional Review Board
<http://medschool.umaryland.edu/orags/hrpo>

General Clinical Research Center
<http://medschool.umaryland.edu/gcrc>

University of Maryland
School of Medicine



PARTICIPATING IN A CLINICAL TRIAL

HOW MUCH WILL IT COST?

Normally, the study drug or device is provided free-of-charge and many of the procedures that accompany the study visit are paid for by the sponsor, such as lab tests, x-rays, etc. However, the cost of some procedures, depending on the protocol, may be your responsibility (or your health insurance provider's) if the procedures were going to occur anyway as part of routine treatment (standard of care). You or your insurer *may* also be responsible for costs due to medical complications that result from your participation in a study or for complications that occur which are unrelated to the study. Specific information about costs can be found in the **research consent form**.

WHAT IS A PROTOCOL?

A protocol is the detailed set of rules and procedures that describe the study. The protocol describes what type of patient can take part in the study ("eligibility"), the study tests, the number of visits that will be done, how long the study will last, and how the information from the study will be processed and analyzed. *Not everyone will be eligible to participate in a clinical trial.* The study doctor and study coordinators use the protocol as a technical guide for conducting the study. The procedures in the protocol are summarized for you in the **research consent form**.

WHAT IS A PRINCIPAL INVESTIGATOR?

The principal investigator (PI) is the study doctor in charge of the study. The PI, or a physician working with the PI on the study, will be responsible for your care while participating in the study. The PI may be the physician you see for your routine (or standard) care. The study doctor is usually assisted by a study coordinator, who is often a nurse. The study coordinator may have a great deal of contact with you as a study volunteer (subject). The study doctor and the research team members will work closely with you in making decisions about your treatment, but the final decision is always yours.

WHAT IS A SPONSOR?

Each study, or clinical trial, has a sponsor (for example, a pharmaceutical company or a federal agency such as the National Institutes of Health) that provides the drug or device, funding for the study, and sets of rules and procedures (the "protocol") that the research team and volunteers are required to follow. Based on the information gathered from clinical trials, the U.S. Food and Drug Administration (FDA) will ultimately determine whether the drug or device will be approved for use by the general public. The sponsor will then determine whether and when to market the drug or device.

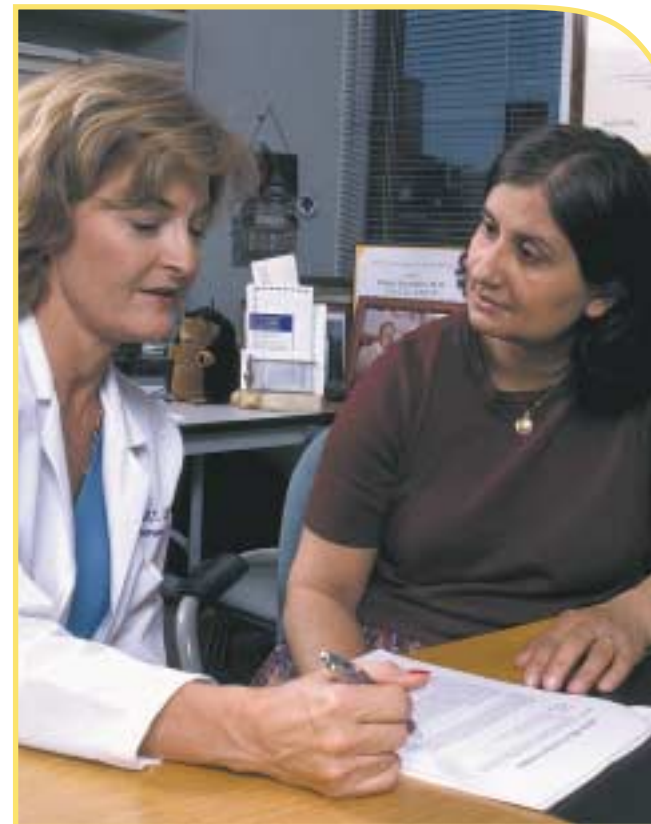
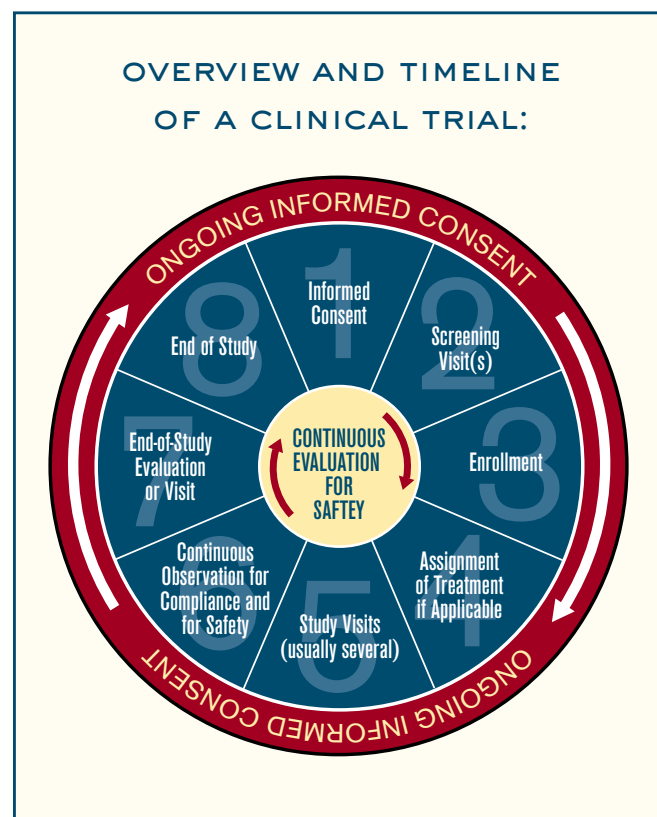
WHAT MEDICINES WILL YOU TAKE?

The most common kind of clinical trial compares two different medications to treat a condition. You will probably not be able to choose which of the medications you will take. This assignment is done randomly, like the flip of a coin, and there is usually a 50% chance of receiving either medication. To make sure the results are as objective as possible, neither you nor your physician will know which medication you are receiving (called a "double-blinded study"). Then, as your condition is monitored during the study, your doctor will see if your condition changes over the study period.

Your physician will discuss your current medications and whether you will be able to continue on those medications while on the study. Also, instructions about whether you can take certain medications while on the study will be found in the **research consent form**.

WHAT IS A PLACEBO?

It is occasionally necessary for some volunteers in a clinical trial to receive a "placebo." A placebo is an inactive substitute for the real drug (or device). For example, if the study drug is a pill, the placebo looks and tastes like the real drug, but it is made of something ordinary like sugar (often referred to as a "sugar pill"). A placebo is normally used in a clinical trial only when there is no established treatment for the condition.



THINKING IT OVER...WHAT YOU NEED TO KNOW...

IS A CLINICAL TRIAL RIGHT FOR ME?

There are several questions that you should ask as part of the **informed consent process** when considering whether to participate in a clinical trial:

- What is the purpose of the study?
- What are the study treatments and procedures?
- How might the study treatment help me?
- What are my other treatment options?
- What are the possible risks or side effects of the study treatment or procedures and how likely are they?
- What costs am I responsible for?
- Who will be treating me during the study?
- Will I see the same nurse or doctor each time?
- Will I be able to see my test results or the results of the study?
- Can I keep seeing my regular doctor?
- Is there any payment to help with parking costs and meals during the study visits?
- What happens if I am injured because of the study?

IS A CLINICAL TRIAL RISKY?

A clinical trial is designed to test new drugs or devices that have not yet been approved for use by the general public or approved drugs that may be used in a new way. Investigators in some cases have limited information about how these products work in humans. Such unknowns do create risk. All studies carry some risk, which can range from minimal to significant. Drugs that are being tested in humans for the first time, however, have had prior testing in animals or in the laboratory.

As a volunteer, you may have access to new treatments for your condition—options that may not exist outside of the study setting. Often you will undergo procedures such as blood draws (or other tests) while participating in a study that you normally would not experience in your routine care. These additional procedures carry their own risk. As a volunteer, you have to consider whether the potential benefits from participating outweigh the potential risks.

Some reasons why people decide to participate in a clinical trial:

- To gain access to possible new treatments that are not widely available
- To help find a better treatment for a known condition
- To help future patients
- To play an active role in their own health care
- To obtain medical care that is paid for by the study

Some reasons why people decide NOT to participate in a clinical trial:

- There is no guarantee that the treatment will work for them
- They are concerned about possible risks or that the study procedures may be unpleasant
- The trial may require more visits to the doctor, or the treatment takes more time than standard care
- It is possible that their condition will worsen while on the study
- They may be placed in a "placebo" group in the study

HOW DOES MY CONTRIBUTION HELP?

Knowledge gained from clinical research can lead to improved treatments, assist in the development of new drugs and vaccines, help prevent disease, and improve quality of life for you or future patients. Volunteering for a clinical trial is an important contribution to science and medical care. While you may not benefit from participating in a clinical trial, clinical research is a necessary part of developing new drugs and devices.