

# Debunking Common Myths About Clinical Trials

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**MYTH:** *Clinical trial volunteers are merely human guinea pigs.*

**FACT:** You may be hesitant to participate in a clinical trial out of concern that you will be treated as a set of symptoms upon which to test an investigational drug rather than as a human being with a medical need. Or, you might worry that you will be given completely untested drugs without fully understanding the clinical trial or providing consent. In fact, strict guidelines are in place to ensure that you and all other clinical trial volunteers are treated fairly and ethically. Before an investigational drug can be given to people who volunteer to participate in clinical trials, scientists must complete a rigorous screening and preclinical testing process, which can take up to six years to complete. Additionally, every clinical trial also has a thorough informed consent process to help you understand your rights as a participant, including the right to leave the trial at any time if you change your mind about wanting to participate.

**MYTH:** *Informed consent is just reading and signing a piece of paper.*

**FACT:** Informed consent for a clinical trial involves much more than just reading and signing a piece of paper. Rather, it involves two essential parts: a document and a process. The informed consent document includes all the information you will need to help make a decision about taking part in the clinical trial, including all the known information about the safety and potential efficacy of the investigational drug being studied in the trial. The informed consent document also describes the purpose of the clinical trial, explains the visits and procedures to be done, and includes the possible risks and benefits of participating in a way that is easy to understand. The informed consent process provides you with ongoing explanations that will help you make educated decisions about whether to begin or continue participating in a trial. Researchers and health professionals know that a written document alone may not ensure that you fully understand what participation means. Thus, informed consent is an ongoing, interactive discussion, rather than a one-time informational session.

**MYTH:** *Clinical trials are dangerous because they use new practices and medicines.*

**FACT:** Clinical trials are designed for research purposes, and as a result, some level of risk is involved. However, investigational drugs are given to clinical trial participants only after the drugs have gone through a rigorous testing process and scientific evidence indicates that the drug is likely to be effective and safe for use in humans. In addition, keeping you safe when you volunteer to participate in a clinical trial is a top priority for everyone involved in the trial. For example, all clinical trials are reviewed before they start by an institutional review board (IRB), a committee made up of doctors, scientists and community members who have the responsibility to protect clinical trial participants. The purpose of IRB review is to ensure both before and during the trial that appropriate steps are taken to protect your rights and safety. During the clinical trial, researchers frequently and rigorously assess and monitor participants' safety. These are just some of the ways in which your safety and well-being are prioritized before a clinical trial begins and throughout the trial process.

**MYTH:** *If I join a clinical trial, I might get a "sugar pill" or placebo instead of a real drug.*

**FACT:** A placebo is a product that looks exactly like the investigational drug but does not cause harm or good. The decision about whether to use a placebo in a clinical trial is based on how serious the illness is, whether an existing treatment is available and other considerations that ensure a high standard of ethics. If you have a serious or life-threatening disease, the best available treatment (called "standard of care") will be used instead of a placebo.

**MYTH:** *Once I decide to participate in a clinical trial, I will not be able to change my mind.*

**FACT:** Clinical trials rely on voluntary participation. You are free to leave a clinical trial at any time, even after you have signed an informed consent and received the investigational drug or placebo. However, you should always let the clinical trial team know before you decide to leave the trial because some medicines cannot be stopped safely without a doctor's help.



**MYTH:** *Clinical trials may include painful or unpleasant parts.*

**FACT:** Like all medical interventions, clinical trials have potential benefits and risks, such as side effects or pain. Processes and procedures can be different for each clinical trial. Some, like in general medical care, may be unpleasant or carry risks. However, the doctor will talk to you about what to expect, and the procedures and risks will be listed in the informed consent document for you to consider while you are deciding whether to participate. The IRB will also ensure that the benefits and risks are carefully weighed and that the trial is reviewed for unnecessary harm or discomfort before it starts.

**MYTH:** *I have heard that some people who try to volunteer for a clinical trial are told by the research team that they are not eligible to be in the trial. The process seems unfair.*

**FACT:** Every clinical trial has a protocol, which is a plan that describes what will be done during the trial, how the trial will be conducted and why each part of the trial is necessary. The protocol for the clinical trial also includes eligibility criteria which includes guidelines for who can and cannot take part in the trial. Common eligibility criteria include age group, gender, having a certain type or stage of cancer, having received (or not received) certain medicines in the past, medical history and current health status. It is important to note that eligibility criteria are not used to reject you personally. These guidelines are used to identify the people most likely to benefit from the clinical trial. The criteria are also necessary to help ensure that researchers will be able to answer the research questions about the investigational drug that they plan to study.

**MYTH:** *Being in a clinical trial won't help me.*

**FACT:** Before you decide to participate in a clinical trial, you should speak with your doctor or the research team about the trial design and the possible risks and benefits of participating. If you choose to participate, you may have the opportunity to receive an investigational drug that is not available to people outside the trial. The clinical trial research team will watch you closely, perhaps even more closely, than your own doctor or nurse during your regular office visits. And, because trials have detailed treatment plans (called protocols), you may get additional tests and lab work that might not be part of your usual care. According to CISCRP's 2013 Perceptions and Insights study, some trial volunteers also report great personal satisfaction in the fact that they have played a key role in advancing medical science and helping scientists find new treatments that will help more people live longer, better lives.

**MYTH:** *Being in a clinical trial is expensive and isn't covered by medical insurance.*

**FACT:** Volunteers for clinical trials rarely have to pay any costs related to participating in the trial. There are two types of costs associated with a clinical trial: research costs and patient care costs. Research costs are those associated with conducting the trial, such as data collection and management, research physician and nurse time, analysis of results, and tests performed purely for research purposes. These costs are usually covered by the sponsoring organization, such as the biopharmaceutical company, and are not the patient's responsibility. Patient care costs are costs that are not covered by the research sponsors doing the clinical trial, such as the costs for routine care including doctor visits, hospital stays, clinical laboratory tests, x-rays and other clinical trial-related activities that would be done even if you were not in the trial. Many health insurance carriers will cover patient care costs, but you should ask the clinical trial research team which costs will be your responsibility and also check with your health insurance carrier about the coverage they provide for clinical trial participants before making the decision about participating in a clinical trial.

**MYTH:** *If there is a clinical trial that might help me, my doctor will tell me about it.*

**FACT:** Your doctor may not know about all available clinical trials that might benefit you. The National Institutes of Health has an online database that you, your family or doctor can search to find appropriate trials: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Alternatively, it's often worth making contact with a patient advocacy organization to help you navigate the process. Many of them have tailored services that can help you with your search and help you understand the options.

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*If you are thinking about participating in a clinical trial and have additional questions, you should talk to your doctor or a patient advocacy organization for your disease or condition.*



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