

Clinical Research Trials and You

QUESTIONS & ANSWERS



What is a clinical trial?

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat diseases. Treatments might be new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. The goal of clinical trials is to determine if a new test or treatment works and is safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.

Who participates in clinical trials?

Many different types of people participate in clinical trials. Some are healthy, while others may have illnesses. A **healthy volunteer** is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention. Research procedures with healthy volunteers are designed to develop new knowledge, not to provide direct benefit to study participants.

A **patient volunteer** has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition. Research procedures with a patient volunteer help develop new knowledge. These procedures may or may not benefit the study participants.

Patient volunteers may be involved in studies similar to those in which healthy volunteers participate. These studies involve drugs, devices, or interventions designed to prevent,

treat, or cure a disease. Although these studies may provide direct benefit to patient volunteers, the main aim is to show, by scientific means, the effects and limitations of the experimental treatment. Consequently, some patients serve as controls by not taking the test drug or by receiving test doses of the drug large enough only to show that it is present, but not at a level that can treat the condition. A study's benefits may be indirect for the volunteers but may help others.

People participate in clinical trials for a variety of reasons. Healthy volunteers say they participate to help others and to contribute to moving science forward. Participants with an illness or disease also participate to help others, but also to possibly receive the newest treatment and to have the additional care and attention from the clinical trial staff. Clinical trials offer hope for many people and an opportunity to help researchers find better treatments for others in the future.

All clinical trials have guidelines about who can participate, called inclusion/exclusion criteria. Factors that allow someone to participate in a clinical trial are "inclusion criteria." Those that exclude or do not allow participation are "exclusion criteria." These criteria are based on factors such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy volunteers. Some studies need both types.

Inclusion and exclusion criteria are not used to reject people personally; rather, the criteria are used to identify appropriate participants and keep them safe, and to help ensure that researchers can find new information they need.

What are the benefits and risks of a clinical trial?

Clinical trials involve risks, just as routine medical care and the activities of daily living do. When weighing the risks of research, you can consider two important factors:

1. the chance of any harm occurring, and
2. the degree of harm that could result from participating in the study

Most clinical studies pose the risk of minor discomfort, which lasts only a short time. However, some study participants experience complications that require medical attention. In rare cases, participants have been seriously injured or have died of complications resulting from their participation in trials of experimental therapies. The specific risks associated with a research protocol are described in detail in the informed consent document, which participants are asked to read and sign before participating in research. Also, a member of the research team explains the major risks of participating in a study and will answer any questions you have about the study. Before deciding to participate, carefully consider possible risks and benefits.

POTENTIAL BENEFITS

Well-designed and well-executed clinical trials provide the best approach for participants to:

- Play an active role in their health care
- Gain access to new research treatments before they are widely available
- Receive regular and careful medical attention from a research team that includes doctors and other health professionals
- Help others by contributing to medical research

POTENTIAL RISKS

Risks to participating in clinical trials include the following:

- There may be unpleasant, serious, or even life-threatening side effects to experimental treatment.
- The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, more treatments, hospital stays, or complex dosage requirements.

If I choose to take part in a clinical trial, how will my safety be protected?

ETHICAL GUIDELINES

The goal of clinical research is to develop knowledge that improves human health or increases understanding of human biology. People who participate in clinical research make it possible for this to occur. The path to finding out if a new drug is safe or effective is to test it on patient volunteers. By placing some people at risk of harm for the good of others, clinical research has the potential to exploit patient volunteers. The purpose of ethical guidelines is both to protect patient volunteers and to preserve the integrity of the science. Ethical guidelines in place today were primarily a response to past research abuses.

INFORMED CONSENT

Informed consent is the process of learning the key facts about a clinical trial before deciding whether to participate. The process of providing information to participants continues throughout the study. To help someone decide whether to participate, members of the research team explain the details of the study. The research team provides an informed consent document, which includes such details about the study, as its purpose, duration, required procedures, and whom to contact for various purposes. The informed consent document also explains risks and potential benefits.

If the participant decides to enroll in the trial, the informed consent document will be signed. Informed consent is not a contract. Volunteers are free to withdraw from the study at any time.

IRB REVIEW

Most, but not all, clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) in order to ensure that the risks are minimal and are worth any potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected. Potential research participants should ask the sponsor or research coordinator whether the research they are considering participating in was reviewed by an IRB.

What questions should I ask before deciding if I want to take part in a clinical trial?

If you are offered a clinical trial, feel free to ask any questions or bring up any issues concerning the trial at any time. The following suggestions may give you some ideas as you think about your own questions.

THE STUDY

- What is the purpose of the study?
- Why do researchers think the approach may be effective?
- Who will fund the study?
- Who has reviewed and approved the study?
- How are study results and safety of participants being checked?
- How long will the study last?
- What will my responsibilities be if I participate?

POSSIBLE RISKS AND BENEFITS

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my short-term risks, such as side effects?
- What are my possible long-term risks?
- What other options do people with my disease have?
- How do the possible risks and benefits of this trial compare with those options?

PARTICIPATION AND CARE

- What kinds of therapies, procedures, and/or tests will I have during the trial?
- Will they hurt, and if so, for how long?
- How do the tests in the study compare with those I would have outside of the trial?
- Will I be able to take my regular medications while participating in the clinical trial?
- Where will I have my medical care?
- Who will be in charge of my care?

PERSONAL ISSUES

- How could being in this study affect my daily life?
- Can I talk to other people in the study?

COST ISSUES

- Will I have to pay for any part of the trial, such as tests or the study drug?
- If so, what will the charges likely be?

- What is my health insurance likely to cover?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or child care costs that I need to consider while I am in the trial?

TIPS FOR ASKING YOUR DOCTOR ABOUT TRIALS

- Consider taking a family member or friend along for support and for help in asking questions or recording answers.
- Plan ahead what to ask, but don't hesitate to ask any new questions you think of while you're there.
- Write down your questions in advance to make sure you remember to ask them all.
- Write down the answers, so that you can review them whenever you want.
- Ask about bringing a tape recorder to record what's said (even if you write down answers).

Where can I find a mental health clinical trial?

AROUND THE NATION AND WORLDWIDE

The National Institutes of Health (NIH), the nation's medical research agency, conducts clinical research trials for many diseases and conditions, including a variety of mental disorders.

To search for other diseases and conditions, you can visit ClinicalTrials.gov. This is a searchable registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals.

AT THE NIH CLINICAL CENTER IN BETHESDA, MARYLAND

The National Institute of Mental Health (NIMH) is the lead federal agency for research on mental disorders. NIMH is one of the 27 Institutes and Centers that make up the NIH. Researchers at the NIMH conduct a large number of research studies with patients and healthy volunteers. The studies are conducted at the NIH Clinical Center (CC), a hospital dedicated to the highest quality research and located in Bethesda, Maryland, near Washington, D.C. Some studies enroll locally, others regionally or nationally. Adult, children, and healthy volunteer study descriptions and other information are provided on the NIMH website

at <http://www.nimh.nih.gov/labs-at-nimh/join-a-study/index.shtml>, or visit www.nimh.nih.gov and enter “Join a Study” in the Search box.

If you qualify for a study, then a study-related evaluation, treatment, and transportation to NIH (in some cases) are provided without cost to you or your health plan.

What is the next step after I find a clinical trial?

Once you find a study that you might want to join, contact the clinical trial or study coordinator. You can usually find this contact information in the description of the study. The next step is a screening appointment to see if you qualify to participate. This appointment also gives you a chance to ask your questions about the study.

Let your doctor know that you are thinking about joining a clinical trial. He or she may want to talk to the research team about your health to make sure the study is safe for you and to coordinate your care while you are in the study.

*This content is brought to you by the **National Institutes of Health (NIH)**.*

For More Information

NIH CLINICAL TRIALS AND YOU WEBSITE

Basic information about clinical trials, such as the benefits and risks, who is responsible for which research costs, and how your safety is protected, is available online to help you understand what’s involved in taking part in a clinical trial. There are also promotional and education resources for health care providers, patients, and their families. Visit the NIH Clinical Trials and You website at <https://www.nih.gov/health-information/nih-clinical-research-trials-you>.

Contact Us

For all mental health-related questions; requests for copies of publications; and inquiries concerning NIMH research, policies, and priorities, please contact a health information specialist at the NIMH Information Resource Center using the contact information provided below.

TELEPHONE

1-866-615-6464 (toll-free)

1-301-443-8431 (TTY)

1-866-415-8051 (TTY toll-free)

Available in English and Spanish

Monday through Friday

8:30 a.m. to 5:00 p.m. ET

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