

Clinical Research Trials and You:

Questions and Answers

From the **NATIONAL INSTITUTE of MENTAL HEALTH**

What is a clinical trial?



A clinical trial is a research study that involves people like you.

Researchers conduct clinical trials to find new or better ways to prevent, detect, or treat health conditions.

Often, researchers want to find out if a new test, treatment, or preventive measure is safe and effective. Tests can include ways to screen for, diagnose, or prevent a disease or condition. Treatments and preventive measures can include medications, surgeries, medical devices, and behavioral therapies.

Clinical trials are important because they serve as the foundation for most medical advances. Without clinical trials, many of the medical treatments and cures we have today wouldn't exist.

Why should I volunteer for a clinical trial?



People volunteer for clinical trials for many reasons. Some want to advance science or help doctors and researchers learn more about disease and improve health care. Others, such as

those with an illness, may join to try new or advanced treatments that aren't widely available.

Whatever your reason for joining a clinical trial, researchers generally need two types of volunteers: those without specific illnesses or conditions and those with them.

A **healthy volunteer** is someone in a clinical trial with no known related health problems. Researchers need healthy volunteers to establish a healthy or optimal reference point. They use data from healthy volunteers to test new treatments or interventions, not to provide direct benefit to participants.

A **patient volunteer** is someone in a clinical trial who has the condition being studied.

Researchers need patient volunteers to learn if new tests, treatments, or preventive measures are safe and effective. Not all trial participants will receive experimental medications or treatments; sometimes,

participants may receive a placebo. Researchers need to vary medications and treatments so they can compare results and learn from their differences.

While a study's treatment or findings may help patients directly, sometimes participants will receive no direct benefit. However, in many cases, study results can still serve as building blocks that are used to help people later.



What would I experience during a clinical trial?

During a clinical trial, the study team will track your health. Participating in a clinical trial may take more time than standard treatment, and you may have more tests and treatments than you would if you weren't in a clinical trial. The study team also may ask you to keep a log of symptoms or other health measures, fill out forms about how you feel, or complete other tasks. You may need to travel or reside away from home to take part in a study.



What are the risks and benefits of my participation in a clinical trial?



Clinical trials can provide many benefits to participants and society. However, before volunteering for a clinical trial, you should talk with your health care provider and the study team about the risks and benefits.

Potential Risks

When weighing the risks of volunteering, you should consider:

- The likelihood of any harm occurring
- How much harm could result from your participation in the study

Researchers try to limit patient discomfort during clinical trials. However, in some cases, volunteers have complications that require medical attention. In rare cases, volunteers have died when participating in clinical trials.

Potential Benefits

The benefits of volunteering can include:

- Treatment with study medications that may not be available elsewhere
- Care from health care professionals who are familiar with the most advanced treatments available
- The opportunity to learn more about an illness and how to manage it
- Playing an active role in your health care
- Helping others by contributing to medical research

Where can I find a mental health clinical trial?



The National Institute of Mental Health (NIMH) is the lead federal agency for research on mental disorders. While NIMH supports research around the world, it also conducts many clinical trials at the National Institutes of Health (NIH) campus in Bethesda, Maryland.

To learn more about NIMH studies conducted on the NIH campus, visit www.nimh.nih.gov/joinastudy. These studies enroll volunteers from the local area and across the nation. In some cases, participants receive free study-related evaluations, treatment, and transportation to NIH.

To learn more about NIMH-funded clinical trials at universities, medical centers, and other institutions, visit www.nimh.nih.gov/clinicaltrials.

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



To learn more about a specific clinical trial, contact the study coordinator. You can usually find this contact information in the trial's description.

If you decide to join a clinical trial, let your health care provider know. They may want to talk to the study team to coordinate your care and ensure the trial is safe for you. For more tips on talking with a health care provider, visit www.nimh.nih.gov/talkingtips.



How do I know if I can join a clinical trial?



People of all ages, ethnicities, and racial backgrounds can volunteer for clinical trials. If you want to join a clinical trial, you must be eligible

to participate in that specific trial. Your eligibility can usually be determined by phone or online screening.

All clinical trials have eligibility guidelines called inclusion and exclusion criteria. These criteria may include:

- Age
- The type and stage of an illness
- Treatment history
- Other medical conditions



Researchers use these guidelines to find suitable study participants, maximize participant safety, and ensure trial data are accurate.

How is my safety protected if I choose to take part in a clinical trial?



Strict rules and laws help protect participants in research studies, and the study team must follow these rules to conduct research. Below are some measures that can help ensure your safety.

Ethical Guidelines

Ethical guidelines protect volunteers and ensure a study's scientific integrity. Regulators created these guidelines primarily in response to past research errors and misconduct. Federal policies and regulations require that researchers conducting clinical trials obey these ethical guidelines.

Informed Consent

Before joining a trial, you should understand what your participation will involve. The study team will provide an informed consent document with detailed information about the study. The document will include details about the length of the trial, required visits, medications, and medical procedures. It will also explain the expected outcomes, potential benefits, possible risks, and other trial details. The study team will review the informed consent document with you and answer any questions you have. You can decide then or later if you want to take part in the trial.

If you choose to join the trial, you will be asked to sign the informed consent document. This document is not a contract; it verifies you understand the study and describes what your participation will include and how your data will be used. Your consent in a clinical trial is ongoing and your participation is voluntary. You may stop participating at any time.

Institutional Review Board Review

Institutional review boards (IRBs) review and monitor most clinical trials in the United States. An IRB works to protect the rights, welfare, and privacy of human subjects. An IRB usually includes a team of independent doctors, scientists, and community members. The IRB's job is to review potential studies, weigh the risks and benefits of studies, and ensure that studies are safe and ethical.

If you're thinking about volunteering for a clinical trial, ask if an IRB reviewed the trial.





What kinds of questions should I ask the study team before deciding if I want to take part in a clinical trial?



It can be helpful to write down any questions or concerns you have. When you speak with the study team, you may want to take notes or ask to record the conversation. Bringing a supportive friend or family member may also be helpful.

The following topics may give you some ideas for questions to ask:

- The study's purpose and duration
- The possible risks and benefits
- Your participation and care
- Personal and cost concerns

For a list of specific questions, check out Questions to Ask About Volunteering for a Research Study from the U.S. Department of Health and Human Services' Office for Human Research Protections at www.hhs.gov/about-research-participation.

What happens when a clinical trial ends?



When a clinical trial ends, researchers will analyze the data to help them determine the results. After reviewing the findings, researchers often submit them to scientific journals for others to review and build on.

Before your participation ends, the study team should tell you if and how you'll receive the results. If this process is unclear, be sure to ask about it.

Where can I find more information?



This fact sheet covers the basics of clinical trials. You can find more details and resources at www.nimh.nih.gov/clinicaltrials.



National Institute
of Mental Health