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Clinical Research: Benefits, Risks, and Safety

Español

If you're interested in volunteering for clinical research, you may wonder: What makes a study a good fit for me? How do I know it's safe? Clinical research involves studying health and illness in people through observational studies or clinical trials. Participating in a trial or study has many potential benefits and also some possible risks. Learn about the benefits and risks of participating in clinical research and how your safety is protected.

What are the potential benefits of participating in clinical research?

There are many possible benefits of being part of clinical research, including:

- You may have the chance to help scientists better understand your disease or condition and to advance treatments and ways to prevent it in the future.
- You may feel like you're playing a more active role in your health.
- You may learn more about your disease or condition.
- You may be able to get information about support groups and resources.

In addition, some people participate in clinical trials because they hope to gain access to a potential new treatment for a disease before it is widely available.

Read and share this infographic to learn more about how clinical research might be right for you.

What are the potential risks of participating in clinical research?

Clinical trials and studies do come with some possible risks, including:

- The research may involve tests that pose a risk to participants. For example, certain physical tests may increase the chance of falling, and X-rays may cause a small increase in the risk of developing cancer.
- Participating in a study could also be inconvenient for you. For example, you may be required to have additional or longer medical appointments, more procedures, complex medication instructions, or hospital stays.

Additional risks of participating in clinical trials may include:

- For those who receive the experimental treatment, it may be uncomfortable or cause side effects (which can range from mild to serious).
- The experimental treatment might not work, or it may not be better than the standard treatment.
- For trials testing a new treatment, such as a new medication or device, you may end up not being part of the group that gets the experimental treatment. Instead, you may be assigned to the control (or comparison) group. In some studies, the control group receives a placebo, which is given in the same way as the treatment but has no effect.

Participant confidentiality is a concern in any kind of research. People other than the researchers, such as the study sponsors or experts who monitor safety, may be able to access medical information related to the study. Safeguards are in place to ensure that researchers tell potential participants what information could be shared and how their privacy will be protected before they consent to participate in research.

The study coordinators will provide detailed information and answer questions about the risks and benefits of participating in a particular study. Having this information can help you make an informed decision about whether to participate.

Will I always get the experimental treatment in a clinical trial?

Clinical trial volunteers do not always get the treatment being tested. The gold standard for testing interventions in people is called a randomized controlled trial. Randomized means that volunteers are randomly assigned — chosen

by chance — to receive either the experimental intervention (the test group) or a placebo or the current standard care (the control or comparison group). Then, researchers compare the effects in each group to determine whether the new treatment works.

When you enroll in a clinical trial, you may be assigned to the test group or to the control group. While participants in the control group do not receive the experimental treatment, these volunteers are just as important as those in the test group. Without the control group, scientists cannot be sure whether an experimental treatment is better than the standard or no treatment.

In many cases, you won't know until the end of the trial whether you are in the test group or the control group. That's because knowing the group assignment might influence the results of the trial. Studies are often "blinded" (or "masked") to prevent this accidental bias. In a single-blind study, you are not told whether you are in the test group or the control group, but the research team knows. In a double-blind study, neither you nor the research team knows what group you are in until the trial is over. If medically necessary, however, it is always possible to find out which group you are in.

What is a placebo?

Whenever possible, clinical trials compare a new treatment for a specific condition to the standard treatment for that condition. When there is no standard treatment available, scientists may compare the new treatment to a placebo, which looks like the drug or treatment being tested but isn't meant to actually change anything in your body. A pill that doesn't contain any medicine is one example.

A trial that uses a placebo is described as a "placebo-controlled trial." In this type of study, the test group receives the experimental treatment, and the control group receives the placebo.

Placebos are not used if an effective treatment is already available or if you would be put at risk by not having effective therapy. You will be told if placebos are used in the study before entering a trial as part of the process of informed consent.

What happens if a clinical trial ends early?

Most clinical trials run as planned from beginning to end. However, sometimes researchers end trials early. Clinical trials may be paused or stopped for a number of reasons:

- There is clear evidence that one intervention is more effective than another. When this happens, the trial may be stopped so that

> the new treatment can be made available to other people as soon as possible.
> - The trial shows that the treatment doesn't work or causes unexpected and serious side effects.
> - The researchers can't enroll enough people in the trial to provide meaningful results.
>
> Even when a clinical trial ends early, it can still provide researchers with valuable information. For example, scientists may gain insights about how to best design and conduct clinical trials in a specific research area. In some cases, health information collected during a trial can lead to new potential therapies that researchers can test in the future.

How is the safety of clinical research participants protected?

Based on many years of experience and learning from past mistakes, strict rules are in place to keep participants safe. Today, *every* clinical investigator in the United States is required to monitor and make sure that *every* participant is safe. These safeguards are an essential part of the research.

Each clinical study follows a careful study plan, called a protocol, which describes what the researchers will do. The principal investigator, or head researcher, is responsible for ensuring the protocol is followed.

Safeguards to protect clinical research volunteers include Institutional Review Boards, informed consent, Data and Safety Monitoring Boards, and Observational Study Monitoring Boards.

- Most clinical studies in the U.S. must be approved by an **Institutional Review Board (IRB)**. The IRB is made up of doctors, scientists, and members of the general public who ensure that the study participants are not exposed to unnecessary risks. The people on the IRB regularly review the study and its results. They make sure that risks (or potential harm) to participants do not outweigh the potential benefits of the study.
- **Informed consent** also helps protect participants. Informed consent is the process by which you learn the key facts about a study before deciding whether to participate. Members of the research team explain the research before you start and throughout the study. They provide an informed consent document, which includes details about the study, such as its purpose, how long it will last, required procedures, and who to contact. The informed consent document also explains risks and potential benefits. You are free to ask questions, request more information, or withdraw from the study at any time.

Clinical trials and studies also have committees that monitor the safety of the research as it occurs.

- Clinical trials that test an intervention are closely supervised by a **Data and Safety Monitoring Board**. The board is made up of experts who review the results of the study as it progresses. If they determine that the experimental treatment is not working or is harming participants, they can stop the trial early.
- **Observational Study Monitoring Boards** monitor the safety of observational studies with large or vulnerable populations, or risks associated with tests or standard of care.

Several historical incidents have caused mistrust in clinical research. These events also led to the creation of laws that provide clinical research participants with multiple levels of protection.

One example is the U.S. Public Health Service Syphilis Study at Tuskegee, which was conducted between 1932 and 1972. In this study, researchers wanted to determine the effects of untreated syphilis. They did not explain the study's risks or obtain informed consent from the participants, all of whom were Black men. They also did not offer the study participants penicillin when it became widely available in the mid-1940s, causing preventable illness and suffering. After news of the study leaked in 1972, it led to sweeping changes in standard research practices and guidelines to protect human research participants. Today, IRBs are responsible for reviewing all studies involving humans to ensure they meet these guidelines and for reporting any study plan that breaks the rules.

After obtaining all the information, you can make an informed decision about whether or not to participate in a clinical trial or study. If you decide to volunteer for clinical research, you will be given an informed consent form to sign. By signing the form, you show that you understand the details and want to be part of the research. However, the informed consent form is not a contract. You may leave the study at any time and for any reason.

Where can I find a clinical trial or study?

Looking for clinical research related to aging and age-related health conditions? There are many ways to find a trial or study. Talk to your health care provider and use online resources to:

- **Search for a clinical trial or study**.
- **Look for clinical trials on Alzheimer's disease, other dementias, and caregiving**.
- **Find a registry for a particular diagnosis or condition**.
- **Explore clinical trials and studies funded by NIA**.

To learn more about a particular trial or study, you or your doctor can contact the research staff and ask questions. You can usually find contact information in the study description.

You may also be interested in

- Getting more information about clinical trials and studies
- Downloading and sharing an infographic with the benefits of participating in clinical research
- Learning about participating in Alzheimer's disease research

For more information about clinical research

Clinical Research Trials and You
National Institutes of Health
www.nih.gov/health-information/nih-clinical-research-trials-you

ClinicalTrials.gov
www.clinicaltrials.gov

U.S. Food and Drug Administration
888-463-6332
druginfo@fda.hhs.gov
www.fda.gov

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