The Basics

The NIH Clinical Trials and You website is a resource for people who want to learn more about clinical trials. By expanding the below questions, you can read answers to common questions about taking part in a clinical trial.

What are clinical trials and why do people participate?

Clinical research is medical research that involves people like you. When you volunteer to take part in clinical research, you help doctors and researchers learn more about disease and improve health care for people in the future. Clinical research includes all research that involves people. Types of clinical research include:

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- Epidemiology, which improves the understanding of a disease by studying patterns, causes, and effects of health and disease in specific groups.
- Behavioral, which improves the understanding of human behavior and how it relates to health and disease.
- Health services, which looks at how people access health care providers and health care services, how much care costs, and what happens to patients as a result of this care.
- Clinical trials, which evaluate the effects of an intervention on health outcomes.

What are clinical trials and why would I want to take part?

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 disease. Clinical trials can study:

- New drugs or new combinations of drugs
- New ways of doing surgery
- New medical devices
- New ways to use existing treatments
- New ways to change behaviors to improve health
- New ways to improve the quality of life for people with acute or chronic illnesses.

The goal of clinical trials is to determine if these treatment, prevention, and behavior approaches are safe and effective. People take part in clinical trials for many reasons. Healthy volunteers say they take part to help others and to contribute to moving science forward. People with an illness or disease also take part to help others, but also to possibly receive the newest treatment and to have added (or extra) care and attention from the clinical trial staff. Clinical trials offer hope for many people and a chance to help researchers find better treatments for others in the future

How does the research process work?

What are clinical trial protocols?

Clinical trials follow a plan known as a protocol. The protocol is carefully designed to balance the potential benefits and risks to participants, and answer specific research questions. A protocol describes the following:

- The goal of the study
- Who is eligible to take part in the trial
- Protections against risks to participants
- Details about tests, procedures, and treatments
- How long the trial is expected to last
- What information will be gathered

A clinical trial is led by a principal investigator (PI). Members of the research team regularly monitor the participants' health to determine the study's safety and effectiveness.

What is an Institutional Review Board?

What is a clinical trial sponsor?

What is informed consent?

Informed consent is the process of providing you with key information about a research study before you decide whether to accept the offer to take part. The process of informed consent continues throughout the study. To help you decide whether to take part, members of the research team explain the details of the study. If you do not understand English, a translator or interpreter may be provided. The research team provides an informed consent document that includes details about the study, such as its purpose, how long it's expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits. You can then decide whether to sign the document. Taking part in a clinical trial is voluntary and you can leave the study at any time.

What are the types of clinical trials?

What are the phases of clinical trials?

What do the terms placebo, randomization, and blinded mean in clinical trials?

Who takes part in clinical trials?

What do I need to know if I am thinking about taking part in a clinical trial?

What questions should I ask if offered a clinical trial?

How is my safety protected?

What happens after a clinical trial is completed?

How does clinical research make a difference to me and my family?

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