Participating in a Clinical Research Study

What is a clinical research study?

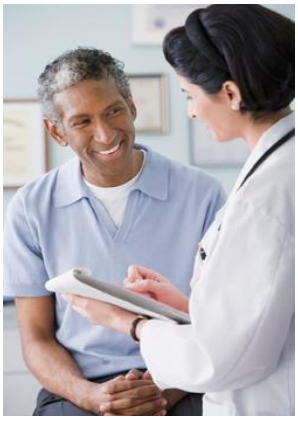
A clinical research study is an essential step in making new medical treatments available to the general population. These medical treatments may be new drugs, new combinations of drugs, new surgical procedures, or new medical devices.

When a pharmaceutical company creates a new medical product, an extensive and carefully planned study on patient volunteers must be conducted to determine its safety and efficacy. The Food and Drug Administration (FDA) work closely with the pharmaceutical company to ensure the study is meeting high medical, scientific, and ethical standards.

The overall goal of a clinical research study is to discover better ways to effectively prevent, diagnose, or treat disease. With the participation of patient volunteers, clinical research is the best way to advance medical knowledge and improve patient care.

Why do people participate in a clinical research study?

People participate in clinical research for a variety of reasons. Participants in a clinical research study gain access to new research treatments before they are widely available. In addition, patients regularly receive careful medical attention from doctors and other health professionals on the research team. These benefits are available at no cost to the patient and without the need for health insurance. Oftentimes, participants are compensated for their time and travel.



Not only does participation in a clinical research study allow people to play an active role in their own health care, but it also helps others by contributing to medical research. The results of these studies make a difference in the care of future patients by providing information about the benefits and risks of medical treatments.

How are participants protected in clinical research?

In general, the ethical and legal codes that govern medical practice also apply to clinical research. Other ethical guidelines for clinical researchers include the ICH Guidelines for Good Clinical Practice and the World Medical Association's Declaration of Helsinki.

In addition to industry guidelines, an independent ethics committee, known as an Institutional Review Board (IRB), must review clinical research studies before they begin. The goal of the IRB is to protect the rights and safety of patient volunteers.

Another protection for participants is the Informed Consent process. Informed Consent is the process of learning the key facts about a clinical research study before deciding whether to participate. Participants will discuss their involvement in the study with the research staff and understand the purpose, duration, required procedures, risks, and potential benefits of the study. If the participant decides to enroll in the study, the Informed Consent document will be signed. However, Informed Consent is not a contract; participants are free to withdraw from the study at any time.

How can I participate in a clinical research study?

To learn more about participating in a clinical study, simply call us at **(814) 940-1212** or visit www.clinicalresearchassoc.com and fill out your contact information. One of our study coordinators will tell you about our enrolling studies and discuss qualification criteria with you.

Clinical Research Associates *is an experienced clinical research site located in Central Pennsylvania. CRA's research professionals work with local physicians to build a multidisciplinary team focused on providing high quality clinical data. At Clinical Research Associates, our mission is to advance patient care through quality research and good clinical practice.*

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