Los Alamitos
CARDIOVASCULAR

Volunteering for a Clinical Trial at Los Alamitos Cardiovascular

Serving patients in Los Angeles and Orange Counties for over 30 years

Frequently Asked Questions

Q: What is a Clinical Trial?

A: A clinical trial (or clinical research project) is a research study used to test new medical treatments and therapies such as a drug or device. Clinical trials involve people, reflect the most promising laboratory research and are done in stages or phases. In Clinical Phase I through Phase III volunteers are under the supervision of a physician and other research professionals. Some clinical research occurs after a drug or treatment is launched, and has been on the market—that type of research falls under the scope of Phase IV studies. Generally speaking our primary focus has been Clinical Phases II, III and IV.

Most of our clinical research is developed by leading academic institutions, pharmaceutical and biotechnology companies (sponsors), who select qualified physicians (investigators) to help. Before being presented to Los Alamitos Cardiovascular each proposed study has met FDA protocols, and has been approved and is under the supervision of an Institutional Review Board (IRB). Because of the nature of our practice and its large patient base, our practice is frequently invited to participate in cardiovascular-related research.

Q: How Does a Clinical Trial Work?

A: A clinical trial is led by a principal investigator, who is often a doctor. In many cases your Los Alamitos Cardiovascular physician will be one of the principal investigators. The principal investigator and members of the research team regularly monitor each volunteer's health to determine the study's safety and effectiveness.

In a clinical trial a volunteer is normally assigned to a specific study group. Typically, clinical trials compare a new product or therapy with another that already exists to determine if the new one is as successful as, or better than, the existing one. In some studies participants may be assigned to receive a placebo (an inactive product that resembles the test product, but without its treatment value).

Comparing a new product with a placebo can be the fastest and most reliable way to demonstrate the new product's therapeutic effectiveness. Placebos are not used if a patient would be put at risk—particularly in the study of treatments for serious illnesses—by not having effective therapy.

Potential participants are told if placebos will be used in the study before they enter a trial, but are not told if they are in the "placebo" group. Important trial details are reviewed with each volunteer during the Informed Consent process.

Q: What is Informed Consent?

A: Informed Consent is the process of providing potential participants and enrollees with the key facts about a clinical trial. Informed Consent is an on-going process, and continues throughout the study.

Initially, interested volunteers receive a document called "Consent to Participate in a Clinical Research Study" that explains the study in straightforward language. A member of the research team will review the protocol, and answer each volunteer's questions. Reading and understanding the protocol is every volunteer's responsibility. Volunteers will not be hurried into making a decision, and will be asked to sign the document, and enroll only after they feel comfortable with the information and commitment.

Even after enrolling in the trial, volunteers are free to withdraw from the study completely, or to refuse particular treatments or tests at any time. Sometimes, however, this will make them ineligible to continue the study.

Q: Does My Information Remain Confidential and Private?

A: Controls are in place so that no volunteer's personal information is ever released outside our system. Information linking your name to your medical information is replaced by other identifiers—like numbers. Your information remains completely confidential and private.

Who Can Participate in a Trial?

Clinical research is conducted according to a plan known as a protocol. The protocol is carefully designed to safeguard the volunteer's health and answer specific research questions. A protocol describes the following:

- Who is eligible to participate in the trial — which is also referred to as "inclusion and exclusion criteria"
- Details about tests, procedures, medications and dosages
- The length of the study and what information will be gathered

If You Qualify

Patients who qualify for a clinical trial decide with the advice of their physician, whether to participate in the study. How a treatment will work for a patient in a trial cannot be known ahead of time. Therefore, the patient should be aware of both the risks and benefits of clinical trials before making a decision. If you qualify we encourage you to discuss participation not only with you physician, but your family as well.

What Happens After the Trial?

After a clinical trial is completed, researchers carefully examine information collected during the study before making decisions about the meaning of the findings and about further testing. Study results can become important building blocks to new and better treatments, further research and other types of medical advances.

Volunteering for a Clinical Trial

Los Alamitos Cardiovascular has been conducting clinical research for several years.

Our patients often ask us questions about what it means to participate in clinical research.

This pamphlet offers an overview of how a clinical trial works and answers questions potential volunteers frequently have about what it means to participate in a medical research study.

Are You Interested in Volunteering?

If you are interested in joining a clinical trial, then please contact your Los Alamitos Cardiovascular physician or call our general telephone number (562) 430-7533, and ask to speak with our Research Coordinator.

For more details about our research, please visit our website:

www.losalcardio.com

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