# Research Participant FAQ

Choosing to participate in a clinical trial or research study is an important personal decision. The following frequently asked questions (FAQ) provide detailed information about clinical trials and were modified from the NIH Clinical Trials website and the UCLA Human Subjects Protection Program Website

**What is a clinical trial?**

A clinical trial is a research project conducted with men, women or children to determine if an investigational drug, device or procedure is safe and effective. A clinical trial is generally considered to be a biomedical or health-related research study in human beings that follows a pre-defined protocol. Some other words that describe clinical research are study, protocol, survey or experiment.
UCLA conducts both interventional and observational types of studies.

- Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. The information presented here will mainly pertain to interventional studies.
- Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

**What are the different types of clinical trials?**

- Treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.
- Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition.
- Screening trials test the best way to detect certain diseases or health conditions.
- Quality of Life trials (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

**Why should I enroll in a clinical trial?**

- When you participate in a clinical trial, you can play a more active role in your own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

**Who should enroll in a clinical trial?**

All clinical trials have guidelines about who can participate. Often, clinical trials will list medical or other conditions that must be met in order to participate in a particular study. In addition, UCLA encourages diversity in its clinical trial enrollments since the effects of diseases or conditions can vary with age, race, ethnicity, and gender.

**Is it safe to be in a clinical trial?**

Research is conducted in the laboratory, and often in animals, for many years before an investigational drug, device or procedure becomes available to clinical trial participants. Only the most promising new treatments make it to clinical trials, which are conducted to validate findings of this earlier research that indicated that the drug, device or procedure is safe in human participants. During the trial, physicians and medical staff will regularly and carefully monitor each participant to determine if the research is helpful and safe. However, there is always some level of risk, and side effects are possible. You will be fully informed of all risks before you start the study.

**Will the research help me personally?**

A clinical trial may or may not help you personally, but it will give researchers information about treating health conditions in the future. In most trials, you are randomly assigned to a control group or study group. The control group receives the currently approved medical treatment or a placebo. Cancer clinical trials are an exception since the best standard of care is always provided to the control group. The study group receives the investigational drug, device or procedure. If it becomes clear during a clinical trial that one treatment is better than another, the trial is stopped so that all participants receive the beneficial treatment

**How much will I know about the benefits and risks?**

Each clinical trial has a well-documented plan, or protocol, about what you will need to do and what is expected. You will be fully informed about the plan and everything that is known about the benefits and risks of the research. You can ask any questions at any time. If you decide to be in the trial, you will be asked to sign an "informed consent" form.

**How long does a clinical trial last?**

Clinical trials vary in length. Some are as short as a few hours or as long as a few years. You will be fully informed about how long you need to participate, and you may quit at any time.

**What can I expect to do in a clinical trial?**

Activities vary from one clinical trial to the next, but most require regular medical examinations. Some trials require taking either an approved or investigational drug, while others require a procedure. Sometimes you record information about how you are doing at home. You also may be asked to return for follow-up visits with the researcher so he or she can evaluate whether the research is working and is safe.

**How much does it cost?**

Clinical trial costs are either billed to the participant’s insurance or paid by the sponsor of the study. If you do not have

insurance, the costs are often paid by the sponsor. Cancer clinical trials are an exception. California law requires most health insurers to cover the routine costs of cancer clinical trials. Some trials, especially those that require several visits to the researcher, may compensate you for your time and transportation.

**What if I change my mind?**

If you agree to participate in a trial but later decide you want to drop out, you can do so with no change in your usual care.

**Will my information be confidential?**

The information participants provide for a clinical trial is confidential. However, UCLA may be required by law to share your information in certain situations. If the information from the trial is published or presented at scientific meetings, your name and other personal information will not be used. The clinical trial sponsor, as well as the U.S. Food and Drug Administration, also may review the research files and medical records.

**How do I learn more about clinical trials?**

For more information about UCLA clinical trials, explore ourWeb site. The National Institutes of Health also sponsors a clinical trials Web site, which lists many clinical trials being conducted across the country. A keyword search for Los Angeles or UCLA will allow you to view many of UCLA's clinical trials.

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