Volunteers for Clinical Research at UCSF

What you need to know if you are considering participating in research….

Information for Prospective Volunteers

WHAT IS CLINICAL RESEARCH?

Clinical research is the way doctors and scientists learn about new ways to prevent and treat illness in people. Clinical research is the fastest way to find answers to the many questions about health and disease. It is sometimes called “human research” or a “clinical trial.”

At UCSF most research that needs human volunteers happens in hospitals and clinics. Other types of research studies take place in a doctor’s office, a treatment center, a nursing home, or a community clinic. Some studies involve asking questions in an office, by telephone, or even on the street or in a home.

There are different ways volunteers participate in clinical research. For example,

- Volunteers participate by filling out questionnaires about their health, or they may answer questions about their health in an interview with researchers.
- Volunteers may be asked to donate specimens such as a tube of blood or a tissue sample for a clinical research study.
- Volunteers may participate in clinical research to find out if new treatments, or new ways of using known treatments, are safe and effective to use in people.

The faculty, staff and doctors at UCSF are dedicated to research and are deeply committed to finding new ways to prevent and treat illness and improve the health of patients who come to the University Medical Center for healthcare.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a strictly controlled research study conducted in people. Each study is carefully designed to answer specific questions about a new treatment like a drug or a medical device to make sure it is safe and effective to use in people.

The details of the clinical trial, including all the tests and procedures used in the study, are outlined in a research plan, also called a protocol. The doctors, nurses, and scientists who run the clinical trial must follow the protocol and run the tests according to the strict rules set by the Food and Drug Administration (FDA) and other government agencies. The rules ensure that people who participate in the clinical trial are treated as safely as possible.

Researchers at UCSF are testing new treatments for many different types of diseases.

- To find clinical trials at UCSF follow the links below:
  - UCSF Clinical Trials
  - UCSF Clinical Trials Seeking Volunteers
- To find a clinical trial somewhere else in the United States, follow the link below:
  - ClinicalTrials.gov (http://clinicaltrials.gov)

WHAT IS AN INSTITUTIONAL REVIEW BOARD?

An Institutional Review Board, also called an IRB, is a committee of doctors, scientists, and people from the community where the clinical research is taking place. An IRB reviews the clinical research plan to make sure people in the research study will be treated fairly and that any risks will be explained to them.

Before a clinical research study can begin, the research plan must be approved by an Institutional Review Board. The IRB at UCSF is called the Committee on Human Research (CHR). The telephone number for the CHR is (415) 476-1814. You can always call the IRB if you have questions, concerns, or complaints.

WHO PAYS FOR RESEARCH?

A clinical research study is paid for by the organization that sponsors the research. If the research is sponsored by the government, it may be paid for through a grant awarded to the doctors and scientist who conduct the research.

Some research studies are sponsored and paid for by drug and medical device companies. Other studies are paid for by private foundations for specific diseases, by gifts to the University or scientist, or by the researcher's department at the medical center.

HOW LONG DOES A RESEARCH STUDY TAKE?

Each study is different. The amount of time a study takes depends on the research questions the study is designed to answer. A study may take a few hours, a few months, or even years to finish.

WHO VOLUNTEERS FOR RESEARCH?

People who volunteer for research come from all walks of life. Volunteers may be healthy and participate in clinical research, or they may be patients or other people with health problems.

People with a specific type of medical condition or disease may be asked to volunteer for a research study because doctors want to learn more about their condition or there may be a promising new treatment being studied.

Because disease and life-threatening conditions affect everyone regardless of race, gender, age, and national origin, volunteers are needed for many types of research studies.

CAN CHILDREN PARTICIPATE IN CLINICAL RESEARCH?

Yes. Children can participate in research studies. Just like for studies with adults, there are guidelines explaining who can take part. The child's parent or guardian needs to give permission for their child to participate. If the child is an adolescent or old enough to understand what the study is about, the child will also be asked to give their assent to take part in the study.

WHAT ARE THE POTENTIAL BENEFITS OF BEING IN CLINICAL RESEARCH?

Participation in a clinical research study has several potential benefits:

- A chance to take part in clinical research that will help you and the researchers learn more about your condition or disease.
- The chance to receive a new and potentially promising treatment that is not available to the general public.
- The chance to receive care for you condition at the nation's leading teaching hospitals and research institutes.
- A chance to take part in clinical research that will hopefully find better ways to prevent and treat diseases in the future.

WHAT ARE THE POTENTIAL RISKS OF BEING IN A CLINICAL RESEARCH?

Along with benefits, there are potential risks and drawbacks of participating in a clinical research study:

- Your disease or condition may not get better with the experimental treatment.
- You may experience side effects or have a bad reaction to the study treatment you receive.
- You may be in the group that gets a placebo (a sham or inactive treatment). A placebo is like taking a sugar pill and will not cure a disease.
- You may be in the group that gets standard treatment instead of the experimental treatment being studied.
- You may have to visit the doctor more often than you would for regular, standard care. The visits might involve having lab tests and procedures done.

WHAT HAPPENS IF I THINK I WANT TO VOLUNTEER FOR CLINICAL RESEARCH?

If you think you might want to volunteer for a clinical research study, tell the researchers you are interested in learning more. Someone from the research team, usually the principal investigator (the physician in charge of the study) or a trained staff member will explain the details of the study to you. The information must include the following:

- The purpose or goals of the study
- A description of the study design, such as the use of placebos, controls, and whether the study is conducted in a blind or double-blind manner
- Why the study is being conducted
- Information about the treatment being studied and how the treatment will be administered
- Exactly what your participation involves – the exact tests and procedures will you be required to undergo and the amount of time the study will take

- The known risks and benefits of participation
- Alternative treatments that are currently available
- Contact information for the investigators
- Contact information for the Committee on Human Research
- A statement that your participation is voluntary and that you may stop or withdraw from the study without any penalty.

During this discussion you should ask as many questions as you want in order to fully understand the details of the study. Take as much time as you need to make your decision. You may want to ask family members or friends to read the consent form.

If you decide to participate in the research study, you will be asked to sign the consent form.

If you agree to participate, and after you sign the consent form, you may be asked to take part in screening tests to make sure you qualify for the research study. Researchers use a set of guidelines to help them select volunteers for the clinical research study. They want to make sure it is okay for volunteers to participate.

WHAT TYPES OF QUESTIONS SHOULD I ASK THE RESEARCHER?

Volunteering to be in a clinical research study is an important decision. For a list of some general questions about taking part in clinical research, follow this link. Not all the questions on the list will apply to the clinical study you are thinking about.

CAN I CHANGE MY MIND?

YES! If you decide to be in a study now and you change your mind later, that is okay. You just have to tell the study doctor or the study staff as soon as you change your mind. They may ask you to come back for a final visit to check your health.

DO I HAVE OTHER CHOICES BESIDES BEING IN A RESEARCH STUDY?

It is always your choice to participate, or not to participate in a research study. It doesn't matter if you are a healthy volunteer or if you have an illness, you will want to find out all the details of the study before deciding to participate or not.

If you have an illness, you should ask your doctor or healthcare provider about all the ways you can be treated. It is your decision whether or not to take part in a clinical research study.

DO I HAVE TO PAY TO BE IN A RESEARCH STUDY?

Financial arrangements are different for different research studies. Research costs, such as the cost of hiring personnel and managing data, are covered by the organization paying for the clinical study. Some research studies will pay you for joining the trial, but many will not pay you for participating. Some studies will reimburse some of your expenses, such as transportation, parking fees and childcare costs.

Costs for some studies, like clinical trials for drugs and implantable medical devices, may be charged to patients or their medical insurance. You should seek more information about the financial arrangements from the clinical research team and from your insurance provider.

WILL OTHER PEOPLE KNOW ABOUT MY PARTICIPATION IN A RESEARCH STUDY?

Information about you and your participation in a research study will be kept as confidential as possible. Information will be given only to those who have permission to see your records. This may include the group sponsoring the study and those who make sure the study is safe and carried out according to the research plan. Some studies are reviewed by the Food and Drug Administration (FDA).

It is a good idea to tell your primary healthcare provider about the clinical research study. If you decide to participate, your primary healthcare provider will want to know.

WHAT HAPPENS TO THE CLINICAL RESEARCH DATA?

Researchers review and analyze data collected during the research study. Results of clinical studies are sometimes published in medical journals, but your identity will not be published.

A single research study may take place at many different medical centers at the same time. After the study has been completed, all the information is sent to one central place to be analyzed. If the study was sponsored by a government agency, such as the National Institute of Health, officials from the agency will review the study information.

If the clinical study was conducted to get FDA approval for a new drug or medical device, the completed data will be submitted to the FDA for review. If the FDA finds the treatment to be safe and effective the agency may approve the treatment for use in the general public.