

VOLUNTEERING FOR A CLINICAL TRIAL

This section has been developed to provide information about clinical trials and what it means to volunteer to participate in a clinical trial.

Should I join a clinical trial?

Volunteers in a clinical trial help to develop new medical therapies for life-threatening and chronic diseases.

Patients volunteer to participate in a clinical trial for many reasons. You may want to take an active role in your medical care. You may get involved in a trial because you want to help others by contributing to the advancement of science. You can gain access to new treatments and expert medical care that are not available to the general public.

No matter what reason you choose you may still have questions about clinical trials and research. This section will help answer some of these questions. Be sure to ask your doctor and the research staff any questions you may have before becoming involved in a clinical trial.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a carefully designed study that is done with people like you who volunteer to receive investigational or experimental treatment under close supervision of a physician and other research professionals.

A clinical trial may also involve studying more closely the treatments that are currently being used are not investigational. This information is being collected to further evaluate these treatments.

The clinical testing of a new drug or product is a step-by-step process that ensures you receive carefully guided medical attention. All clinical trials of investigational drugs or products are carried out with a approval of the United States government's Food and Drug Administration (FDA) and are overseen by UCSD Human Research Protections Program (HRPP)

The HRPP is an independent committee. Their mission is to assure your rights as a research subject is fully protected and that you are not exposed to any unnecessary risks. The HRPP is also responsible to see that the informed consent form you sign clearly explains the design of the study, its purpose, any risks or benefits, alternative treatments available and possible reimbursement for time and travel. The consent

will also explain any costs that the study will pay for if you participate in the study. The consent also describes the compensation for injury if you become ill or are injured as a direct result of the study drug or properly performed procedures required by the protocol

Clinical trials that involve an investigational drug or product are usually conducted in three phases. A volunteer is usually assigned to a specific study group. Sometimes volunteers in one study group will receive a new treatment and sometimes they will receive a placebo or a treatment already available.

A placebo is a harmless, inactive drug or product used to compare to the study drug or product. You, the research staff and your physician will not know who is receiving a placebo and who is receiving the experimental treatment. This allows volunteers to be observed by the physician and the research team more fairly. Whether you receive the placebo or the investigational treatment, the level of medical attention and care that you receive is the same.

WHAT CAN I EXPECT FROM VOLUNTEERING?

If you are being considered for a clinical trial, a member of the research team will review the Informed Consent form with you and discuss the details of the study. If you decide to participate in the research trial, you will be asked to sign the Informed Consent form and you will be given a copy. You will be asked to sign a HIPAA form and you will be given a copy. The HIPAA form gives permission to release your personal health information to the research team for research, to others at UC that are required by law to review the research and to others that are required by law to review the quality and safety of the research. Your medical records will be kept confidential and in a secure location You will also receive a copy of the Experimental Subjects Bill of Rights outlining your rights as a volunteer in a clinical trial.

Your physician and members of the research team will monitor your care for the duration of the study. You are encouraged to discuss your medical treatment with your doctor or a member of the research team at any time during or after your participation in the trial.

Your safety is the number one priority in a clinical trial. Therefore, it is important that you follow all the instructions you have been given. It is important that you answer your doctor's questions regarding how you feel and notify your doctor of any changes as soon as possible..

There may be some risks in participating in a clinical trial such as: side effects or adverse reactions to the study drug/treatment, the study treatment may be ineffective, the study may require many trips to the study site or require hospital stays or dosage requirements. There may or may not be any direct benefit to you from participating

in this study. In addition to the risks listed above, there may be others that cannot be foreseen at this time.

WHAT HAPPENS AFTER THE CLINICAL TRIAL ENDS?

After the study is complete, all of the information is collected and analyzed. A research report will be created based on the information; however your personal information e.g. name, address, telephone or social security number will not be included. If the study involves a new drug or products, this information determines whether the treatment is working, whether it is safe and whether it has any side effects. In these types of studies, FDA medical advisors and specialists closely review this data before approving any new treatment.

Every volunteer in a clinical trial is extremely valuable and important. Your participation in a clinical trial may or may not benefit you directly. By participating in a clinical trial, you may be helping yourself and others like you to improve the quality of medical care for everyone.

If you have any questions the study or any research related questions you can contact HRPP at 858-455-5050 from 8:00am to 4:30pm Monday thru Friday. You can also mail your questions to HRPP UCSD 9500 Gilman Drive Mail Code 0052 La Jolla, CA 92093-0052.

