Should I Participate in a Clinical Study?

A Guide to Clinical Research Basics

LOMA LINDA UNIVERSITY

Clinical Research Basics

What is research?

Research is the process of developing and/or testing and evaluating products and services, which will contribute toward improved medical care in the future. Medical research begins in a lab, after which the product or procedure is tested in animals. Once it is proven safe in animals, new medicines or devices are tested in humans. Much of this research is started by companies that make drugs or devices or by academic institutions funded by industry or governmental agencies.

What is a clinical study?

A clinical study is the process of testing the safety, effectiveness, and unwanted side effects in a new medicine or medical device, or new uses for existing medicines or devices in humans. Clinical studies are conducted at medical centers and are overseen by a study doctor.

Who participates in clinical studies?

Anyone who qualifies for the study may participate. Allowing someone to enter a clinical study who does not qualify may put that person at risk and cause the study to provide inaccurate results.

How do I know if I can participate?

Each clinical study has a list of specific criteria used to decide who may participate, such as a requirement for all subjects to be within a certain age range, or to have a particular medical condition. Every study has inclusion criteria and exclusion criteria. "Inclusion" criteria are conditions or factors that must be met by every participant. "Exclusion" criteria are conditions or factors that participants must not have. You must meet ALL the inclusion and exclusion criteria in order to be in the study. These criteria are developed to make sure that the study provides a high level of safety for all participants and to assure the study can provide accurate results. If you are interested in a specific clinical study and are not sure whether you qualify, please talk to the study doctor or to a member of the research staff conducting the clinical study.

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Who provides me with details about the study?

You will meet with the study doctor or members of his/her research staff. They will provide you with more details about the study and will answer any questions you may have. In addition, you will be provided with contact information for a third-party representative—someone who is not directly connected with the study and can assist you with any concerns you might have about joining the study. If, as a participant, you have questions, concerns, or complaints, you can contact the research staff or third-party representative during the study and even after the study is completed. You will also receive a written description of your rights and options as a study participant. If you are qualified to participate, you will receive more details at the informed consent meeting.

What is informed consent?

Informed consent is the process that will give you the information you need to reach a decision about participating in the clinical study. The study doctor and the research staff will review all parts of the clinical study with you. Among other topics, this discussion will cover the purpose of the study, how long it will last, what you will have to do, the risks and benefits of participating, and your rights as a participant. Providing this information will help you make a fully informed decision about whether to participate in the clinical study. You are free to take the information you receive during the informed consent meeting home and to talk it over with your family, friends, or other people, including your personal physician, before making a decision. The consent form will tell you how to contact the third-party representative with whom you can discuss concerns or questions. You will be asked to sign the consent form only after you have received adequate answers to all your questions, after you understand all parts of the clinical study to the best of your ability, and have willingly agreed, **without any undue influence**, to participate in the clinical study. You will receive a copy of the signed consent form, which you should keep for reference.

Consent is an on-going process. During the clinical study, you will continue to be provided with any new or additional information that may affect your decision to keep participating. You can ask questions throughout the study and expect to receive answers.

You may decide to stop participating at any time and for any reason. This will not affect your right to receive medical care at this institution. However, if you decide to quit, you should tell the research staff as soon as you reach that decision so your withdrawal can be done safely.

Is It Right for Me?

Why do people participate?

Clinical studies are very important in determining if new medicines and devices are safe, and if they help patients. These studies can also show if medicines and devices approved for one condition are useful in treating a different condition. The quality of medical care people receive in the future depends on knowledge gained from today's research.

Who decides this study is safe?

A group of trained people, called the Institutional Review Board (IRB), reviews the plans for all clinical studies. The IRB is a diverse group of qualified individuals (community members, ethicists, scientists, professors, physicians, research administrators, etc.) who examine each study in detail before it is allowed to start. The review process is thorough and detailed. The IRB makes certain that the rights and well-being of participants are given first priority. In addition, there are many laws and regulations the study must follow. A study may begin only after it is approved by the IRB.

Is It Right for Me?

Are there any risks involved?
In research, risks are to be expected. They will be explained by the research staff during the consent process. Some risks may be unknown and cannot be planned for in advance. On rare occasions, they may be serious or life-threatening. During the study, you will be closely monitored by the research staff for all side effects, for your safety, and for the accuracy of the study. It is very important to report any side effects you might experience to the research staff.

How long will I be in the study?
The length of time varies depending upon the study design. You should ask the research staff how long you will be expected to participate. Remember, you may decide to stop at any time. Please check the consent form for withdrawal procedures. There may be certain safety considerations involved.

Where can I find a clinical study in which I might participate?
There are several ways to find out about current clinical studies, including:

- Asking your physician
- Contacting hospitals that conduct research
- Looking online (i.e. – www.clinicaltrials.gov)

What Is My Role?

What are my responsibilities as a participant?

- **Be honest.** In order for the researchers to obtain useful results about the value of a medication or device being tested, it is important for you to be completely honest about everything, beginning with evaluating your eligibility for participation and throughout the entire course of the study.

- **Return unused medication and all medical devices.** The medications or devices used in clinical studies are strictly regulated and must be returned to the research staff at the end of your participation. Discuss with your study doctor if you have questions about what access you will have to medication or devices after the study has ended.

- **Report.** In order for the researchers to effectively treat you and obtain accurate results, you must report all side effects to the research staff.

- **Show up.** Attend all of your scheduled visits. If you are unable to make an appointment, please reschedule your visit in advance.

- **Communicate.** Take every opportunity to ask questions and to communicate your concerns to the appropriate people. If you decide to withdraw from the study at any time, be sure to tell the research staff.

Questions to Enhance Your Knowledge

Before making a decision about being in a clinical study, be sure all your questions are answered and concerns are addressed. Write down a list of questions you wish to review with the research staff. Some commonly asked questions are listed below:

- What is the purpose of the clinical study?
- Has this treatment/intervention been tested before?
- What tests/treatments are required while in the study?
- Why should I participate in the study instead of continuing my current treatment?
- How is the care and treatment I will receive in the study different than the care and treatment I would have outside of the study?
- Can I participate even if I do not expect to benefit from the study?
- What risks or side effects might occur?
- Are these risks different than risks I would face as a patient who does not participate in the study?
- Are there any costs to me if I participate?
- How long will my participation last?
- Will participating in the study require any changes to my current lifestyle?
- Is there any financial benefit or reimbursement to me?
- Will follow-up care be provided or required?
- Does everybody in the study get the same treatments?
- How do I know if the treatment will work?
- What happens if I have side effects or am injured by the drugs, devices, or procedures while I'm in the study?
- What should I do if I experience any side effects after the end of the study?
- Will I be able to learn the results at the end of the study?
- If I withdraw, will I be entitled to treatment for side effects or health problems caused by the drugs or treatments used in the study?
- Is it OK to discuss the study with my personal physician?
- Will I receive the medication/device being tested, or will some participants be assigned a different treatment, or no treatment?

It's Up to You…

New drugs and devices can only be tested adequately with the help of research participants, and sometimes new scientific knowledge for the medical field can only be proven by clinical studies. These results are important for society as a whole. However, being in research means risk-taking on your part. Even those studies with a possibility for your direct personal benefit will also involve risks. Therefore, the decision whether or not to be a participant in a clinical study is an important one. Even with the advice of your personal physician, family, friends, or others, it is a decision that ultimately only you can make. Each person's situation is unique. The purpose of this brochure is to inform you, so that you can more effectively think about whether participating in research is right for you. Thank you for considering research.

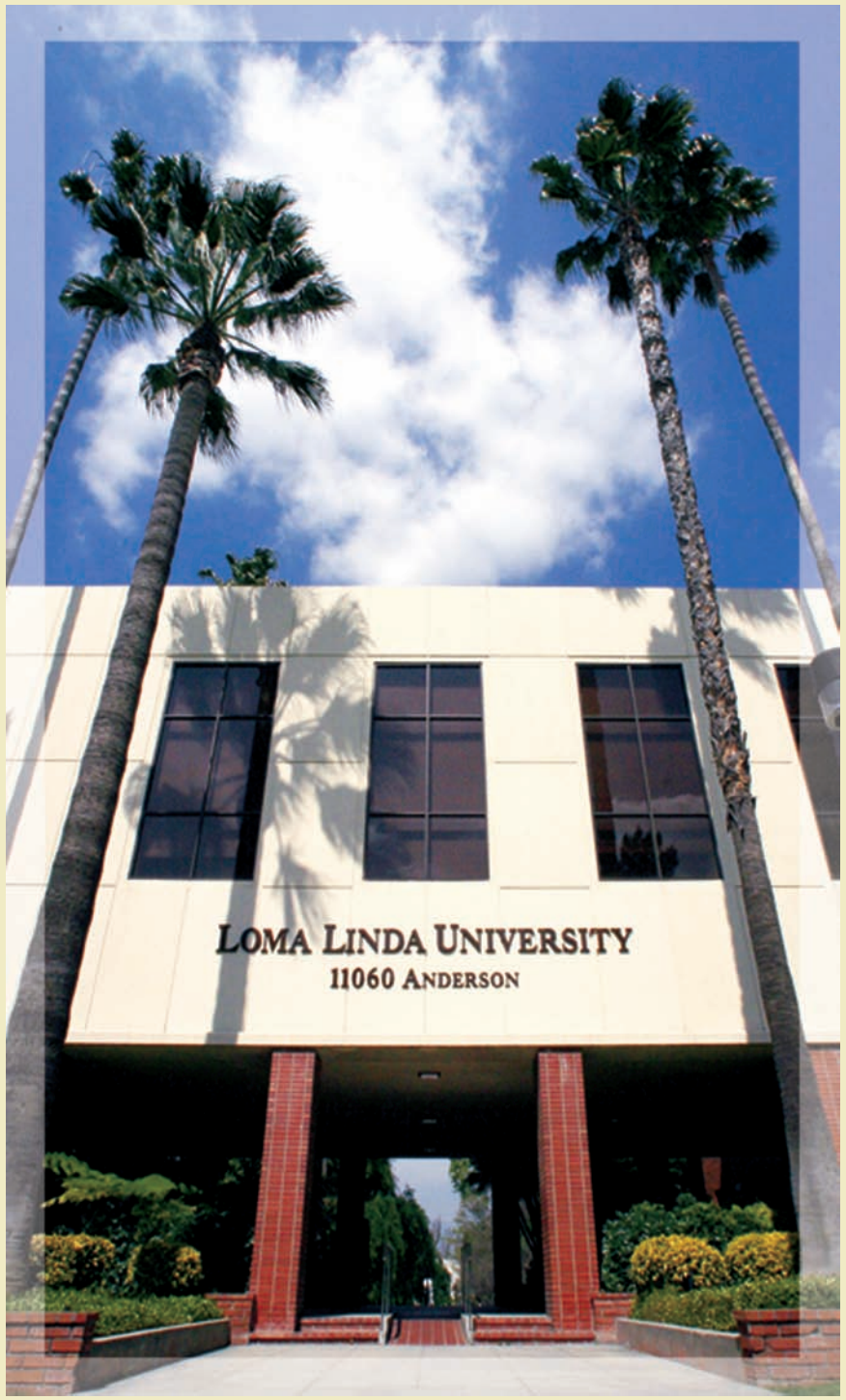
Resources

Office of Human Research Protection
Provides information to individuals interested in research on the protections they receive as a research participant, through regulations, and the ethical concerns related to research.
http://www.hhs.gov/ohrp

Food and Drug Administration
Provides information on regulations developed to protect research participants.
http://www.fda.gov

National Institutes of Health
Provides information on diseases, clinical research background, and different clinical research studies.
http://www.nih.gov

ClinicalTrials.gov
Allows individuals to look for information on available clinical trials.
http://clinicaltrials.gov/



For patient concerns or comments,
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