

Whom at USC do I contact for human subjects research info, or to voice a concern or complaint?

USC Complaints, Concerns, or Reports of Violations Website

This website provides info on how to report a complaint, concern, or violation (anonymously if you prefer). You can also contact the offices listed below.

<https://oprs.usc.edu/about/complaints/>

Office for the Protection of Research Subjects (OPRS)

Susan L. Rose, Ph.D., Executive Director
3720 South Flower Street 325
Los Angeles, CA 90089-0706
Tel: (213)-821-1154 Fax: (213)-740-9299
E-mail: oprs@usc.edu
<https://oprs.usc.edu/about/complaints/>

Health Sciences

Institutional Review Board

Darcy Spicer, M.D., Chair
Sandra Jean, CIP, IRB Director
General Hospital, Suite 4700
1200 North State Street
Los Angeles, CA 90033
Tel: (323)-223-2340 Fax: (323)-224-8389
E-mail: irb@usc.edu
<https://oprs.usc.edu/hsirb/>

University Park

Institutional Review Board

Richard John, Ph.D., Chair
Kristin J. Craun, MPH, CIP, Director
Credit Union Building (CUB), Suite 301
3720 S. Flower Street
Los Angeles, CA 90089
Tel: (213)-821-5272 Fax: (213)-821-5276
E-mail: upirb@usc.edu
<https://oprs.usc.edu/upirb/>

For copies of this brochure contact the oprs@usc.edu

Adapted from the Department of Veterans Affairs' Office of Research Compliance & Assurance "I'm a veteran. Should I participate in research?", and the University of Iowa Human Subjects Office "So you're thinking about being in a research study." <http://research.uiowa.edu/hso/docs/brochureforpublic.pdf>

Should I participate in research?



Some things you NEED to know before deciding to participate in research...



What is research?

Research is the collecting and analyzing of data that is done to answer a question. Some other words for research are clinical trial, protocol, survey, or experiment.

What is a human subject?

A subject is someone who volunteers to participate in research.

Who can be a subject in a research study?

Most research studies have certain requirements that must be met in order for a subject to participate. These requirements are designed to ensure the safety of the subjects and the usefulness of the research. Some studies have broad requirements such as being over 18. Other studies have a more focused requirement such as having a certain disease.

Do I have to participate?

NO! Participating in a research study is voluntary. A subject can drop out of a study at any time. Refusing to participate in a study will not result in a penalty or loss of any benefits to which you are entitled.



Are there risks to being in a research study?

Research may involve different types of risk. A study that asks you to fill out a survey has only minor risks, such as questions that may make you uneasy. For other studies, such as taking an experimental drug, the risks can be much greater (e.g. having a bad reaction to the drug). The research team is required to explain to you the foreseeable risks of being in the study before you decide whether or not to participate.

Are there benefits to being in a research study?

Not everyone who participates in a research study will benefit personally. Sometimes, your participation in the research study will be of benefit to society by helping researchers to learn more

about a certain disease or condition. In some studies, however, you may personally benefit from medication that aids in your recovery or from any needed counseling.



Who leads a research study?

The Principal Investigator (PI) leads the research study. The PI is responsible for the overall conduct of the research study. The PI is also responsible for assuring the safety of the subjects. PIs are often faculty, physicians, or students.

Who else is involved in research studies?

Principal Investigators often rely on a research team to assist them in their study. The research team can be made up of research

assistants, research nurses, data coordinators, statisticians, and other people with special skills needed for the study.

Who reviews a study?

At the University of Southern California, all studies that involve human subjects are reviewed by an Institutional Review Board (IRB) before they are allowed to begin.

What is an IRB?

An IRB is a committee of scientists and non-scientists who review projects submitted by researchers. The University of Southern California has four IRBs; one on the University Park Campus, and three on the Health Sciences Campus. The IRB's purpose is to protect the rights and welfare of the research subjects in a study.

Who will see my records?

Like your medical record, the information in your research record will be confidential. Information will be given only to the researchers who carry out the study or to those who make sure the study is safe and carried out the way it was planned.

Are there any special rules to help protect certain subjects?

Children, pregnant women, and prisoners can all be participants in research studies, but are considered potentially "vulnerable populations." There are special rules to protect participants who fall into



one of these groups.

What kinds of procedures are involved?

Research studies can involve a wide variety of procedures, ranging from filling out surveys and questionnaires to taking experimental medicines or using experimental devices.

Some research studies last only a few minutes, while others last for several years. The research team will describe to you all of the procedures that you will be asked to undergo before you agree to be in the study.



What is informed consent?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon a clear understanding of what will take place in the study and how it might affect you. The consent process begins when the research staff explains the facts about the research study to you. The research staff will assist you with the "informed consent form" that goes over these facts so you can decide whether or not you want to take part in the study. These facts include details about the study, tests, or procedures you may receive, the benefits and risks that could result, alternatives available should you decided not to participate, and your rights as a research volunteer.

What questions should I ask before I agree to take part in a research study?

Before you decide to volunteer for a research study, you need to know as much as possible about it. If there are any issues that concern you, be sure to ask questions. The following is a list of important questions. **Not every question applies to every study, but you have every right for answers to all you ask.**

- Will I benefit from this study?
- Who is doing this study and what question might it answer?
- Will this research help me to understand my condition? If so, how?
- Will I miss out on any "normal care" by participating in this study?
- What tests or procedures will be done?
- What alternatives are available if I decide not to participate in the study?
- Is it possible that I will receive only a placebo (inactive substance)?
- What could happen to me, good or bad, if I take part in the study?
- How long will the study last?
- What will happen to specimens I give?
- Who has reviewed/approved this study?
- If I have a condition, could it get worse during the study?
- Will I be charged anything or paid anything to be in this study?
- If I decide to participate in this study, how will it affect my daily life?
- What will happen to me at the end of the study?
- Will I be told the results of the study?
- Who will find out that I am taking part in this study?
- How do I end my participation in this study if I change my mind?
- Whom do I contact for questions and information about the study?
- What risks are involved in this study?



Where can I find reliable health and research information?

USC Human Subjects Information
Provides links to research and health info for subjects. <https://oprs.usc.edu/about/participating/>

American Heart Association
Features an online heart and stroke encyclopedia. www.americanheart.org

ClinicalTrials.Gov
Provides info about federally and privately supported clinical research. www.clinicaltrials.gov

Family Doctor
Health info from the American Academy of Family Physicians. www.familydoctor.org

Healthfinder
A health library available in English and Spanish. www.healthfinder.gov

Medem
A partnership among medical societies to foster doctor patient-communications; includes an online medical library. www.medem.com

Medline Plus
The National Library of Medicine's complete health info portal. <http://medlineplus.gov>

National Cancer Institute
Provides clinical details about every type of cancer and the latest treatments. www.cancer.gov