WHO TO CONTACT

Office for the Protection of Research Subjects (OPRS)
3720 South Flower Street, Third Floor
Los Angeles, CA 90089-0706
Tel: (213) 821. 1154 E-mail: oprs@usc.edu
Web: oprs.usc.edu

IRB Student Mentor
Phone: (213) 821. 4219 E-mail: irbgara@usc.edu
Web: oprs.usc.edu/about/#studentmentor

Health Sciences Institutional Review Board
General Hospital, Suite 4700
1200 North State Street
Los Angeles, CA 90033
Tel: (323) 223.2340 E-mail: irb@usc.edu
Web: oprs.usc.edu/hsirb

University Park Campus Institutional Review Board
Credit Union Building (CUB), Suite 301
3720 S. Flower Street
Los Angeles, CA 90089
Tel: (213) 821. 5272 E-mail: upirb@usc.edu
Web: oprs.usc.edu/upirb

iStar Technical Help
Phone: (323) 276. 2238 E-mail: istar@usc.edu
Web: https://istar.usc.edu

CITI Helpdesk
Phone: (213) 821. 5272 E-mail: citi@usc.edu
Web: http://oprs.usc.edu/education/citi/

CONDUCTING HUMAN SUBJECTS RESEARCH?

A Guide for Principal Investigators

Office for the Protection of Research Subjects (OPRS)

Office of Research

Human Subjects Research Policy at USC:

USC policies for the protection of human subjects in research govern research being conducted at USC, with USC facilities, or by USC faculty, staff, or students (oprs.usc.edu/policies-and-procedures/)

USC adheres to the Federal Regulations for the Protection of Human Subjects (HHS OHRP*/FDA). The HHS OHRP regulations at 45 CFR 46 state:

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject is a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual or
2. identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable in order for the information to constitute research

*OHRP / FDA Policies:

http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

- HSIRB: oprs.usc.edu/hsirb/forms/

If the subjects in a study are prisoners, pregnant women, children, or other vulnerable populations, additional protections are required. For more information on vulnerable populations, please consult the Federal Regulations (45 CFR 46) website:

www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

iStar (IRB Submission, Tracking, and Review)

Investigators must submit new IRB applications through the online iStar system. Continuing reviews, amendments, and reportable events must also be submitted through iStar. An iStar account is needed to utilize this system.

iStar can be accessed at: istar.usc.edu

Obtaining an iStar Account

To obtain an iStar account visit istar.usc.edu and select "Obtaining an iStar Account" from the left-side menu.

If you need technical help with the system call (323) 276-2238 or email istar@usc.edu

CITI (Human Subjects Training)

CITI is the online education program required of all USC investigators and key personnel conducting human subjects research including student researchers and faculty advisors. IRB applications are not approved until this education requirement is met.

Information/access on CITI: oprs.usc.edu/education/citi/

- That the study is research.
- *Purpose* of the research.
- *Benefits* of the research to society and possibly to the individual human subject.
- *Procedures* involved in research participation.
- *Alternatives* available should a subject decide not to participate in the research.
- Any foreseeable risks or discomforts to the subject.

  *Note: these include not only physical injury but also psychological, social, or economic harm, discomfort, or inconvenience.
- *Length of time* the subject is expected to participate.
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency.
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive.

- Statement of subjects' *right to confidentiality and right to withdraw* from the study at any time without consequence.

Consent documents must be clearly written and understandable to subjects. The language must be non-technical (comparable to the language in a newspaper or popular magazine). Scientific, technical, and medical terms must be clearly defined. It is often recommended that the informed consent be written at the sixth to eighth grade reading level. The same recommendation applies to the assent forms for minors and study recruitment materials.

Informed consent may not include language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability or negligence. Templates and model consent forms are available from the IRB websites at:

- UPIRB: oprs.usc.edu/upirb/forms/

involving human subjects. However, the interaction or intervention itself may constitute research involving human subjects.

The University of Southern California's Institutional Review Boards (IRBs) and the Office for the Protection of Research Subjects (OPRS) are responsible for making final decisions as to what constitutes human subjects research and how human subjects research protections must be implemented.

What Constitutes Human Subjects Research?

If your research belongs to any of the following categories, you must comply with Federal Regulations for human subjects research as well as USC policies for the protection of human subjects.

- Studies that use people to test *drugs, devices, products, or materials* that have been developed through research; to evaluate physical or social reactions to environmental alterations.
- Studies that collect data through *interaction* or *intervention* with individuals. Interaction may include surveys, interviews, questionnaires, and focus groups. Intervention may include physical procedures (e.g., drawing blood), or manipulation of a subject's environment (e.g. hot/cold stressors).
- Studies using *private information* that can be readily identified with individuals, even if the information was not collected specifically for the study.
- Studies that use *bodily materials* such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if you did not collect these materials. However, such research may be *exempt* if materials are not personally identifiable. (**Only the IRB has the authority to determine exemptions.**)
- Studies that produce *generalizable knowledge* about categories or classes of subjects from individually identifiable information.

USC Institutional Review Boards (IRB)

An IRB is an ethics committee that reviews and approves human subjects research. USC has four IRBs. The IRB process is designed to ensure that the research protects the rights and welfare of human subjects by minimizing risks, selecting subjects equitably, obtaining informed consent, ensuring privacy and confidentiality, and other conditions specified by the IRB.

IRB approval is valid for no more than one year. If the research continues, the IRB must review and approve the study again prior to the approval expiration date.

Note: The IRB requires investigators to notify the IRB if subjects experience*:* physical injury, unexpected or adverse events, improper disclosure of private information, economic loss, and/or potentially harmful occurrences.

Types of IRB Review

There are three levels of IRB review depending on the risk to the participant. Risks can be physical, psychological, or have social impacts. Minimal risk is the regulatory threshold for level of review.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Greater than minimal risk research exceeds the limits stated above. The following is a description of the types of review:

Exempt Review – Certain kinds of research involving minimal risk, or less than minimal risk, may be "exempt" from continuing IRB review when the activities fall into one or more of the exempt categories of 45 CFR 46.101. Proposed exempt research must be submitted to the IRB for determination. Data collection using non-individually identifiable

information may fit the exempt category. (**Only the IRB has the authority to determine exemptions**).

Expedited Review – The expedited category is used for certain kinds of research involving no more than minimal risk and for minor changes in approved research. An expedited review is performed by the IRB chair or a designated voting member, rather than the convened IRB.

Full Board (Convened) Review – Research involving greater than minimal risk must be reviewed at a fully convened committee meeting. Often, this research involves vulnerable subjects such as pregnant women, prisoners, or children. For the research to be approved, it must receive the approval of a majority of members present.

Special Categories: NHSR and Coded Data/Specimens

At USC, projects that do not meet the federal definition of either human subjects or research are called Not Human Subjects Research (NHSR), a category not defined in the federal regulations. USC policy requires the IRB to make this determination after investigators submit a short (3 screen) application for IRB review on iStar (https://istar.usc.edu).

Research using coded private information or coded specimens that were not collected by the current investigator, nor collected for the currently proposed project, do not need IRB review. To meet this exception, the current investigator must not be able to link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subject, the investigator must enter into an agreement with the provider that states under no circumstances will the identity of the subjects be released to the investigator.

Guidance on Coded Data http://www.hhs.gov/ohrp/policy/cdebiol.html

The Informed Consent Process

Informed consent is a process of providing potential volunteers with key facts about the research study. Consent is obtained after a verbal discussion with written documentation of consent.

A basic tenet is that subjects in research must be willing participants, after having been adequately informed about the research.

Voluntary participation means that subjects have sufficient information to give truly informed consent. Such information must include: