

Protecting Human Research Subjects



-A Guide for Student Investigators

The requirements to protect human subjects apply to a much broader range of research studies than many student investigators realize.

If you are conducting research using human subjects for a class project with the intent to publish your results, or for a doctoral dissertation or Master's thesis, you must seek IRB (Institutional Review Board) approval or exemption *prior* to data collection.

IRB approval must precede initiation of any work involving human subjects. There is no retroactive approval for previously collected data. Failure to seek approval for your thesis or dissertation research may invalidate your study, or result in your inability to graduate.

What Constitutes Human Subject Research?

- Studies that use people to test *devices, products, or materials* that have been developed through research; or to evaluate environmental alterations, for example, weatherization options or habitat modifications.
- Studies that collect data through *intervention or interaction* with individuals. Intervention includes not only physical procedures (e.g., drawing blood) but also manipulation of a subject's environment (e.g., surveys, questionnaires, interviews, and focus groups). Examples of this type of research include: the evaluation of teaching methods and programs; internet surveys about alcohol consumption; deception research; research involving risky behaviors or attitudes; and open-ended interviews with minors about family values in a foreign country. Data collection using non-individually identifiable information may be **exempt**.¹ (Only the IRB has the authority to determine exemptions).
- Studies using *private information* that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- Studies that use *bodily materials* such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if you did not collect these materials for the

study. However, such research may be considered *exempt* if materials are not personally identifiable. Only the IRB has the authority to make the exempt determination.

- Studies that produce *generalizable knowledge* about categories or classes of subjects from individually identifiable information.

If your research belongs to any of the above categories, you must comply with the Federal Regulations and the University of Southern California's policies for the protection of human subjects.

These requirements apply if the research is conducted using USC facilities or property, supported with USC funds, or performed by USC faculty, staff, or students.



Human Subjects Research

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

USC adheres to the Federal Regulation 45 CFR 46 Protection of Human Subjects² which states:

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 (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

USC Institutional Review Boards

An IRB is a committee of scientists and non-scientists who review projects submitted by researchers.

The IRBs at the University of Southern California must review and approve research if it involves human subjects.

This process is designed to ensure the protection of the rights and welfare of human subjects by minimizing risks, selecting subject equitably, obtaining informed consent, and ensuring privacy and confidentiality.

IRB approval is valid for one year. If the research continues, the IRB must review and approve the study at least once a year.

The investigator is required to notify the IRB if subjects experience: physical injury, unexpected or adverse events, improper disclosure of private information, economic loss, and other harmful or potentially harmful occurrences.



Informed Consent

Informed consent is the process of informing potential volunteers about the key facts of a research study.

The human subjects in your study must participate willingly, after having been adequately informed about the research.

If the human subjects in your study are part of a vulnerable population, such as prisoners or children, special protections are required. For more information on vulnerable populations, please consult the USC Institutional Review Boards' websites.

Voluntary participation means that subjects have enough information to give true informed consent. Such information includes:

- *Purpose* of the research.
- *Benefits* of the research to society and, possibly, to the individual human subject.
- *Procedures* involved in the research.
- *Alternatives* available should a subject decide not to participate in the research.
- *All foreseeable risks or discomforts* to the subject. Note that these include not only physical injury, but also possible 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.
- Subjects' *right to confidentiality and right to withdraw* from the study at any time without any consequences.



Consent documents must be clearly written and understandable to subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be plainly defined. It is often recommended that the informed consent be written at the 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 offices or the IRB website at...

<http://www.usc.edu/admin/provost/irb/uc.html>.

Types of IRB Review

Full Board (Convened) Review – Some studies involve more than minimal risk³ and merit Full Board Review. These studies require a review of the proposed research at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present.

Expedited Review – Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Expedited review is performed by the IRB chair, a designated voting member, or group of voting members rather than by the entire convened IRB.

Exemption – When it is determined that the study does not involve human subjects (as defined in 45 CFR 46) or the involvement of human subjects is in one of the six exempt categories listed in the Regulation (45 CFR 46.101(b))⁴, it is exempt. The exempt categories include certain educational practices and tests, study of existing data, public service programs and food evaluations.

Any research study involving human subjects thought to be exempt must be submitted to the IRB for a determination.

Recommendation

To avoid possible delays in approving your project and large amounts of paperwork, it is recommended that you design your project so that it will fall in the “exempt” category. To help ensure that projects can satisfy the requirements for exemption **AVOID** the following:

- Audio-taping of interviews;
- Collection of identifiers in recording data;
- Quotation by name in reports.
- Interviews or interventions with vulnerable populations;
- Video-taping or photography of human subjects in field observations;
- Use of experimental techniques or deception.

Any research study involving human subjects thought to be exempt must be submitted to the IRB for a determination.

¹ See “Types of IRB Review: Exemption” in this brochure for more information.

² See Federal Policy for the Protection of Human Subjects (45 CFR 46) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) for more information.

³ Minimal risk – 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.

⁴ See Federal Policy for the Protection of Human Subjects (45 CFR 46.101(b)) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) for a detailed description of exemption categories.

To Learn More:

USC Institutional Review Boards:

<http://www.usc.edu/admin/provost/irb>

Office for the Protection of Research Subjects

<http://usc.edu/admin/provost/opr>

U.S. Department of Health and Human Services (DHHS):

Office for Human Research Protections (OHRP) <http://hhs.gov/ohrp/>

U.S. Food and Drug Administration (FDA) <http://www.fda.gov/>

U.S. Department of Education:

<http://www.ed.gov>



If you have questions or concerns, the staff at the following offices will assist you.

Health Sciences Institutional Review Board

Darcy Spicer, M.D., Chair
Sandra Jean, CIP, IRB Director
IRD Building
2020 Zonal Ave, Room 425
Los Angeles, CA 90033
Tel: (323) 223.2340
Fax: (323) 224.8389
E-mail: irb@usc.edu
<http://ccnt.hsc.usc.edu/irb/irb.html>

University Park Campus Institutional Review Board

Richard John, Ph.D., Chair
Kristin J. Craun, CIP, IRB Director
837 Downey Way
Stonier Hall, Room 224a
Los Angeles, CA 90089-1146
Tel: (213) 821.5272
Fax: (213) 821.5276
E-mail: upirb@usc.edu
<http://www.usc.edu/admin/provost/irb/upc.html>

Office for the Protection of Research Subjects (OPRS)

Susan Rose, Ph.D., Executive Director
3720 South Flower Street
Credit Union Building 325
Los Angeles, CA 90089-0706
Tel: (213) 821.1154
Fax: (213) 740.9299
E-mail: opr@usc.edu
<http://www.usc.edu/admin/provost/opr>

Office of Compliance

Laura La Corte, J. D.
Senior Associate Vice President
University Gardens Building, Room 105
3500 Figueroa St.
Los Angeles, CA 90007
Tel: (213) 740.8258
Fax: (213) 740.9657
E-mail: complan@usc.edu
<http://www.usc.edu/admin/compliance>

The Student Mentor (irbgara@usc.edu) at the USC Office for the Protection of Research Subjects is available to help student investigators with questions regarding human subjects and the application for IRB approval.