Guide to Human Subjects Research
For USC Medical Students

Office for the Protection of Research Subjects (OPRS)

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Introduction: Are you Conducting “Human Subjects Research”?

This booklet provides guidance for medical students who conduct biomedical, social and behavioral research or otherwise participate in research activities using human subjects, while at the Keck School of Medicine (KSOM). Research involving human subjects must comply with a formal and seemingly formidable set of regulatory rules and ethical principles, which include approval by the Institutional Review Board (IRB). The IRB, a committee of faculty, staff, and community members, review human subjects research projects to ensure the research meets regulatory standards. These requirements are easy to follow when there is good guidance and clear instruction; both of which this booklet intends to provide.

Not all research with humans is considered “Human Subjects Research” by federal definition. Thus, not all research needs IRB review and approval. Portions of this booklet explain categories that must receive IRB approval, as well as categories that meet the exception.

Medical Student Researchers:
Participation in research is an important part of the medical education experience, thus, KSOM encourages students to conduct and participate in research projects. In some instances, funding may be available for medical student projects through university grants, private funding (e.g. the Howard Hughes Medical Institute grants), or public sources (e.g. the National Institutes of Health) or as part of a funded study.

All medical students who conduct medical research projects must work under the guidance of a faculty mentor, university researcher, or industry sponsored investigator. Research activities are not limited to the USC campus. Activities may take place at other institutions, or in another country.
Research Opportunities for USC KSOM Students

This chapter provides information on research opportunities available to interested KSOM medical students (see [http://medweb.usc.edu](http://medweb.usc.edu)).

Among these opportunities are:

- **Dean’s Research Scholars Program**: This KSOM option is designed for medical students who have a strong interest in medical research. Applicants chosen to participate undertake a full year of research under the mentorship of a faculty member. [http://keck.usc.edu/en/Research/Office_of_Research_Advancement/~/media/Docs/Research/deans_research_scholars_program.pdf](http://keck.usc.edu/en/Research/Office_of_Research_Advancement/~/media/Docs/Research/deans_research_scholars_program.pdf)

- **Howard Hughes Medical Institute (HHMI)**: HHMI is a non-profit medical research organization that contributes to advancing biomedical research and science education in the U.S. Medical and dental students seeking domestic or international research training can apply for HHMI grants for support. These grants allow students to do independent research; a unique opportunity for students who exhibit originality and scientific merit in a proposed project. [http://www.hhmi.org/grants/individuals/](http://www.hhmi.org/grants/individuals/)

- **Keck School of Medicine**: The KSOM website provides information on the USC research portfolio and affiliated programs. The website contains information about USC research institutes, centers, programs and faculty projects, as well as multidisciplinary offerings. The website is a useful overview of KSOM areas of research. [http://www.usc.edu/schools/medicine/research/](http://www.usc.edu/schools/medicine/research/)


- **Summer Research Fellowship Application**: The KSOM funds summer research projects, primarily but not exclusively, for Year I students in good academic standing, who want to join an ongoing research project or develop one of their own. Additional information at: [http://medweb.usc.edu/research/Summer-Research-Application-March15th.pdf](http://medweb.usc.edu/research/Summer-Research-Application-March15th.pdf)

- **The Breman Student International Research Travel Grant**: The goal of this KSOM grant is to provide medical students and other health science students at USC an opportunity to increase their knowledge of the health problems in developing countries. A clinical, field, or laboratory research experience in a foreign country may encourage the student to consider a career in international health and public service.
• **National Institutes of Health (NIH):** The National Institutes of Health, within the U.S. Department of Health and Human Services, is the primary Federal agency funding and conducting biomedical research. Composed of 27 Institutes and Centers, the NIH provides leadership and financial support to researchers in every state and throughout the world. The NIH website describes nationwide research internships, workshops and programs to which medical and dental students may apply. [http://www.training.nih.gov/](http://www.training.nih.gov/)

• **Programs in Biomedical and Biological Sciences (PIBBS):** USC offers graduate Programs in Biomedical and Biological Sciences (PIBBS). The goal of PIBBS is to attract outstanding students and provide them with a rigorous, individually tailored educational experience to train them as internationally competitive research scientists. PIBBS serves as an entryway into fifteen Ph.D. programs in the biomedical and biological sciences at USC. Students accepted into the program carry out several laboratory rotations during their first year of study. Students may choose their laboratory rotations from among more than two hundred USC PIBBS faculty conducting internationally recognized research in a variety of biological disciplines. Students may use this website to find researchers by scientific discipline. [http://keck.usc.edu/Education/Degrees_and_Programs/PIBBS_Program.aspx](http://keck.usc.edu/Education/Degrees_and_Programs/PIBBS_Program.aspx)

• **PIBBS Seminar and Symposium Notices:** PIBBS offers a calendar of upcoming innovative seminars and symposiums that welcome medical and dental students, who want to learn about available research opportunities before committing to a discipline or faculty member. [http://pibbs.usc.edu/](http://pibbs.usc.edu/)

• **Required Scholarly Project (RSP):** The RSP requires that all USC medical students conduct a hypothesis driven research project under mentorship of a faculty member. Information regarding this project will be given to students during Year I. The research will take place during Year II, allowing students to continue work begun during the summer of Year I. More RSP information can be found at: [http://medweb.hsc.usc.edu/year1.html](http://medweb.hsc.usc.edu/year1.html). Key elements of the RSP are found at: [http://medweb.usc.edu/rsp/RSP-email-2-14-11-FINAL-SENT.pdf](http://medweb.usc.edu/rsp/RSP-email-2-14-11-FINAL-SENT.pdf).
How to Determine if a Project is Human Subjects Research

This chapter will help students determine if their project is Human Subjects Research or is “Not Human Subjects Research”.

Investigators and researchers working with human subjects must comply with applicable regulations and are obligated to follow ethical norms expected by the institutions and their advisory. Approval by a USC Institutional Review Board (IRB) confirms that the research fulfills these requirements. The research must be conducted according to the IRB approved protocol. (https://oprs.usc.edu/review/).

Typically, students will either initiate their own research project or join an existing study as research staff. For those students who plan to initiate their own Human Subjects Research project, IRB approval is needed. As mentioned before, some research projects appear to be Human Subjects Research but do not meet the federal definition of human subjects research, and thus do not require IRB approval (Part III, Section E, pg. 9). For OPRS guide to determination of Not Human Subjects Research click here: https://oprs.usc.edu/files/2013/03/NHSR_3.28.13.pdf. In all cases, IRB staff will help students determine whether a submission to the IRB is required or not.

Students who join an existing IRB approved research project must be added to the ongoing study as “key personnel” using an amendment application in iStar (https://istar.usc.edu). The student must also complete human subjects education using CITI (Collaborative IRB Training Initiative), the on-line system www.citiprogram.org

Human Subjects Research Policy at USC:

USC policies for the protection of human subjects apply to research being conducted at USC, with USC facilities, or by USC faculty, staff, or students.
The University of Southern California’s Office for the Protection of Research Subjects (OPRS) and Institutional Review Boards (IRB) are responsible for deciding what constitutes Human Subjects Research and how Human Subjects Research protections must be implemented. This is not the purview of individual researchers.

USC adheres to the Federal Regulations for the Protection of Human Subjects (those of both HHS and FDA). The HHS regulations (at 45 CFR 46*) include the definitions of research and human subjects, both of which must be met in order to be considered Human Subjects Research.

Both these definitions* must be met:

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

**Human Subject**: 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 takes place 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 involving human subjects. However, the interaction or intervention itself may constitute human subjects research.

*http://ohsr.od.nih.gov/guidelines/45cfr46.html

The following brief examples illustrate types of human subjects research that require an application to the IRB before the study can be conducted

- Studies that test **devices, products, pharmaceuticals, biologics, or materials** that are not
yet commercialized; studies in support of an “off-label” use; or to evaluate the effects of environmental alterations on participants

- Studies that collect data through *intervention or interaction* with individuals. Intervention includes not only physical procedures (e.g., drawing blood) but also includes gathering information about the individual (e.g., surveys, questionnaires, interviews, and focus groups).

- Studies using or collecting *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 these materials weren’t collected for the study. Such research may be considered exempt or not requiring IRB review if materials are not personally identifiable. Only the IRB has the authority to make the exempt or coded specimen decision/determination.

- Studies that produce *generalizable knowledge* about categories or classes of subjects from individually identifiable information.
Institutional Review Board (IRB) ABCs for Student Investigators

This chapter provides a short overview of the IRB application process for student investigators and describes required training in human subjects protection. This section also explains what is expected from students when submitting research that requires IRB approval.

Going through the IRB review process can be intimidating and confusing. Student researchers often ask questions such as:

- Do I need to submit my project to the IRB?
- How do I submit to the IRB?
- Where do I start?
- What is iStar?
- How long does it take to get IRB approval?
- What training must I take?
- Will I be able to graduate on time?
- Who can help me with my application?

If these questions sound familiar, this section will help you. It provides answers to frequently asked questions regarding the IRB process.

- **IRB submission**
  “How To’s” for new study application, amending a study, and Summer Research fellowship projects:

  A. **New study application**
  
  If the student is the initiator of the research, then a New Study Application must be submitted via the IRB online application system. iStar is accessible 24/7, allows fast turnaround time for IRB review and approval, stores study documents on a secure server, collects quality control data, and tracks studies. If the student will be the Principal Investigator (PI), a faculty advisor must be named in the application.

  B. **Amending a study**
  
  Many students assist with research conducted by a faculty member/advisor that has already undergone the required Institutional Review Board (IRB) review. Prior to assisting with the research, the student must complete human subjects protection training and be added to the existing IRB approved application through an amendment application via the iStar system.
C. **Summer Research Fellowship Projects (often do not require an IRB submission)**

If the student is participating in the Summer Fellowship Program, a Summer Research Fellowship Application must be submitted to the KSOM project Director (No iStar application is required for initial summer program application), see the respective program website for details: [http://medweb.usc.edu/research/summer_research_application.pdf](http://medweb.usc.edu/research/summer_research_application.pdf)

“Traineeships”, “shadowing”, or “program evaluations” are not human subjects research. The summer program director, and OPRS or HSIRB determine if IRB review is required once the summer application is approved. If it is determined that the project is Human Subjects Research, an iStar application must be submitted.

- **Requesting an iStar Account**

Human Subjects Research IRB applications must be submitted through iStar, the online IRB application system at USC. To begin the IRB process, students must obtain an iStar account. To obtain an iStar account, send an email request to [istar@usc.edu](mailto:istar@usc.edu) with a name, email address, campus, and department/division. **Once you have an account, you can login in at:** [https://istar.usc.edu](https://istar.usc.edu)

- **What IRB Education Requirements Must I Complete?**

D. **CITI** (Collaborative IRB Training Initiative) is an online education program that offers various modules relevant to one’s role in human subjects research. CITI human subjects protection training is mandatory for all medical student researchers. Instructions on how to access the CITI program can be found at: [https://oprs.usc.edu/education/citi/](https://oprs.usc.edu/education/citi/).

**HIPAA** (Health Insurance Portability and Accountability Act) also known as “the privacy rule” (P.L.104-191) was enacted by the U.S. Congress to address the security and privacy of personal health data. It required the establishment of national standards to protect electronic health care transactions and records (medical charts). It established minimum Federal standards for safeguarding individual “protected health information” (PHI—any identifiable health information created or received by a health care provider) and set training and certification requirements for access and use of “protected health information.” HIPAA training is required for all USC key study personnel who have access to PHI through USC providers: [http://ooc.usc.edu/PrivacySecurity/HippaPrivacy/EduProgram.cfm](http://ooc.usc.edu/PrivacySecurity/HippaPrivacy/EduProgram.cfm)

a. **Medical student mandatory HIPAA Training** is required for all KSOM medical students to ensure that personal medical information that patients share with health care providers (including medical students, fellows, residents etc) remains private but is available to facilitate competent clinical care. HIPAA is important because it safeguards protected identifiable patient health information, provides patients with more control over what happens with their information, provides patients with informed choices about how their information is used, and balances the need to use information to treat patients, to teach, and to conduct research in accordance with the patient’s desire/need for privacy. The HIPAA education tutorial can be found at: [http://ooc.usc.edu/hipaa-online-education-program](http://ooc.usc.edu/hipaa-online-education-program)

b. **Student researchers conducting independent human subjects research**, are performing a different role from the one they inhabit as a learner, healthcare provider and medical
student (e.g. learning about patient care and healthcare operations). The medical student role only requires HIPAA training. As independent student researchers however, medical students do NOT have authorization to peruse medical record charts for research purposes. Students must go to the IRB for approval/permission for the study and for access to medical records. The IRB may either require HIPAA authorization from the patient-subjects or waive authorization (the latter being the most common in chart reviews). A copy of the USC HIPAA authorization form can be found here: http://oprs.usc.edu/files/2013/01/HIPAA_11.11.doc

E. **Good Clinical Practice (GCP)** is the international ethical and scientific standard for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. All “key personnel” participating in a clinical trial must complete GCP training. Principal Investigators (PIs), Co-Investigators, Faculty Advisors, Study Coordinators, recruitment staff, and anyone else performing study procedures or interventions are considered key personnel. Students may be required to take GCP training at the discretion of the IRB. Go here to access the GCP training site: http://oprs.usc.edu/education/citi/

- **What are the Levels of IRB Review?**
  
  Students submitting new study applications must select the level of IRB review. There are three levels of IRB review depending on the level of risk in the study. Risks can be physical, psychological, or have social impacts. The following is a description of the levels of review.

  - **Exempt** – 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 research. Investigators must submit proposed exempt research to the IRB for exempt determination. An example of an exempt research project is a “chart review” or an anonymous survey.

  - **Expedited Review** – The expedited category is used for certain kinds of research involving no more than minimal risk* and for minor changes in already approved research. An expedited review is performed by the IRB chair or a designated voting member rather than by the entire convened IRB. An example of expedited research is a study that interviews children about their experiences in a hospital after a medical procedure.

  - **Full Board (Convened) Review** – Research involving greater than minimal risk* must be reviewed at a fully convened IRB meeting at which a quorum of IRB members is present. Biomedical research and some social/behavioral research with vulnerable subjects, (e.g. pregnant women, prisoners, or children) may require Full Board review. For the research to be approved, it must receive the approval of a majority of IRB members. An example of a full board study is one that involves interviewing HIV positive subjects about risky, sexual behavior.

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* 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.
NHSR and Coded Data/Specimens: Special Types of Research

There are certain types of research that use humans or human data but do not “qualify” as Human Subjects Research. These studies do NOT need IRB approval and a short IRB application is used to receive confirmation that IRB review is unnecessary. This section explains those very specific categories.

- **Not Human Subjects Research**- At USC, projects that do not meet the federal definition of “human subjects” or “research” are called Not Human Subjects Research (NHSR). Investigators may submit a short (3 screen) application to the IRB for review and to verify the status. Once the NHSR determination is made, the study may proceed with no further IRB requirements and will receive a confirmation of the NHSR status.

  * The NSHR application button is located on the right hand side of the iStar homepage stating: Does my project qualify as Not Human Subjects Research? [https://istar.usc.edu](https://istar.usc.edu)

- **Coded Specimens and Data**- Research using coded private information or specimens that were not collected for the proposed project do not need IRB review, provided the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects, 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. This category also requires an IRB determination/confirmation.
### Types of IRB Application Submissions

This chapter provides student investigators with step by step instructions for submitting the appropriate IRB application.

<table>
<thead>
<tr>
<th>If Your Research Project is...</th>
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<tbody>
<tr>
<td><strong>Human Subjects Research</strong></td>
<td>Investigators must complete the “New Study Application” by logging into their iStar account AND CLICKING THE “New Study” button. (<a href="https://istar.usc.edu">https://istar.usc.edu</a>) More information can be found by going in the Training Resources section of the iStar website or through the Student Handbook: Making Sense of Human Subjects Research found on the OPRS/IRB website.</td>
</tr>
<tr>
<td><strong>believed to be NOT Human Subjects Research (NHSR)</strong></td>
<td>Investigators complete the “Not Human Subjects Research” (NHSR) application in iStar (<a href="https://istar.usc.edu">https://istar.usc.edu</a>). This will generate a shorter application. Investigators who are unsure if their proposed study qualifies as Human Subjects Research can find more information in the <em>Is Your Project Human Subjects Research?</em> booklet (or you call the IRB office)</td>
</tr>
<tr>
<td><strong>Obtaining and Analyzing Coded/Private Data (Secondary Data)</strong></td>
<td>Investigators must complete the “New Study Application” by logging into their iStar account AND CLICKING THE “New Study” button (<a href="https://istar.usc.edu">https://istar.usc.edu</a>). In Question 4 of the application, investigators will select “Coded Specimens/Data” from the drop down menu. This will generate a shorter application and an IRB confirmation of status.</td>
</tr>
<tr>
<td><strong>Obtaining and Analyzing Coded Biological Specimens</strong></td>
<td>Investigators must complete the “New Study Application” by logging into their iStar account AND CLICKING THE “New Study” button. (<a href="https://istar.usc.edu">https://istar.usc.edu</a>). In Question 4 of the application, investigators will select “Coded Specimens/Data” from the drop down menu. This will generate a shorter application and an IRB confirmation of status.</td>
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**Informed Consent, Information Sheets & Templates**

This chapter provides the student investigator with guidance about Informed Consent and the consenting process. An example of an information sheet is provided at the end of Part V.

A. **Informed Consent Basics**

   An essential element in conducting Human Subjects Research is the informed consent process. It is a key requirement of all HHS regulations and all international ethics guidelines. The goal of the informed consent process is to provide the information necessary for a participant to comfortingly determine whether or not they will enroll in a study. Additional consent issues/requirements arise when the human subjects in a study are recruited from a vulnerable population (e.g., prisoners, pregnant women, or children). For more information on doing research with vulnerable populations and the informed consent process, consult the USC IRB websites for the campus where the study will be reviewed:

   [http://oprs.usc.edu/hsirb/](http://oprs.usc.edu/hsirb/)
   [http://oprs.usc.edu/upirb/](http://oprs.usc.edu/upirb/)

**Informed Consent Documents Must Contain:**

A basic ethical tenet in conducting Human Subjects Research is that subjects participate voluntarily (not coerced). Voluntary participation means that subjects have enough information to give truly informed consent. Informed consent documents must address:

- **Purpose** of the research.
- **Benefits** of the research to society and/or possibly, to the individual human subject.
- **All research procedures** in which the subject will participate.
- **Alternatives**, if any 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.
- **Contact information of person to answer subjects’ questions**, or be notified 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 to which the person is otherwise entitled.
- Statement of subjects’ **right to confidentiality and right to withdraw** from the study at any time without any consequences.
Language of Consent Document

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 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. This language is called exculpatory language. Consent must be provided in the language of the subject, or alternatively, a translator and the short form process may be used.

Templates and model consent forms are available on the IRB websites:

Health Sciences IRB (HSIRB) Forms/Templates (including short forms)
http://oprs.usc.edu/hsirb/hsirb-forms/

University Park Campus (UPIRB) Forms/Templates
http://oprs.usc.edu/upirb/upirb-forms/

B. Information Sheet and Template

An information sheet may be used as a form of consent in certain circumstances where a signature could compromise the participant or in studies where signed consent is not required by regulations. Generally, Exempt research studies use information sheets instead of an Informed Consent form.

Below is a template for an information sheet and a sample information sheet from a summer trainee project.

USC INFORMATION SHEET TEMPLATE:

Study Title: ___________________________
PI: Tommy Trojan
Date: 1/23/08

You are invited to participate in a research study conducted by ___________ from the University of Southern California.

We are asking you to take part in this study because _________________________________.

Your participation is voluntary and would consist of _________________________________.

There are no anticipated risks to your participation and there are no direct benefits to you for taking part in this study (Or explain possible risks/benefits if applicable).

You will receive ___________________________ for your participation. You will be given a copy of this form.

If you have any questions about this research study, please contact: _____________________.

SAMPLE INFORMATION SHEET:

Study Title: Health Survey in Brillo Nuevo, Peru
PI: Tommy Trojan
Date: 1/23/08

We invite you to participate in a research study conducted by John Doe from the University of Southern California.

We are asking you to take part in this study because we are trying to learn more about the health practices in your community.

You were selected as a possible participant because you are a resident of Brillo Nuevo. We will ask you about 40 questions related to your family’s health, such as common illnesses and how you care for them. It will take about 20 minutes of your time.

Your participation is voluntary. There are no anticipated risks or benefits to your participation. You may decide to discuss your participation with your family or friends. You will be given a copy of this form.
Keck Student Summer Research Fellowship Projects May Not Be Human Subjects Research After All

This chapter provides student investigators with specific examples of how KSOM summer projects, clinical training, clerkships or assisting, differ from conducting one’s own Human Subjects Research (requiring IRB review).

Students as research assistants (or study personnel)

Students participating in “research” fulfill a variety of roles, many of which do not require IRB approval. For example, some in the Medical Student Summer Fellowship Program, although working on a research project and performing a variety of tasks, often work under the direction of a faculty member who already has IRB approval for that project. In this instance, the student would be the research assistant or research personnel, and must be added to the project through an amendment in the iStar system.

In a few cases, KSOM students will initiate their own human subjects research projects and propose their own hypotheses and methods. Examples include: interviewing people about their behaviors or health, performing minor medical procedures under someone’s supervision (if the procedures are not required for the individual’s healthcare), making systematic observations of individual behavior or reactions, testing a new or unproven technique or intervention on a population.

If these studies are systematic, provide information that may be useful in other settings, contribute to the advancement of medical knowledge, and are “about” the individual participants, these studies are considered Human Subjects Research and IRB review is required.

These research related activities on their own do not need IRB review: “shadowing”, clinical training, research assisting (data collection, chart reviews, statistical analysis, data organization/management), and/or some epidemiology studies. To determine whether the activity constitutes Human Subjects Research, a fellowship application is required.

- KSOM Summer Fellowship Application
  The application submitted to KSOM must clearly delineate what “research” activities will be done by that student, not a full description of the project for which the faculty member is the PI. If the project is “Human Subjects Research,” students must also submit an application to the IRB through the iStar system.

- KSOM Summer Research Fellowships that do NOT require IRB review
  If a project is a training assistantship and involves working with or “shadowing” a faculty member to gain new clinical skills, an IRB application is NOT required.

- *Collaborative IRB Training Initiative (CITI) Requirements for all Summer Research Fellowship Students. All students are expected to complete CITI training. See: [http://www.citiprogram.org](http://www.citiprogram.org)
Undertaking International Research

This chapter provides student investigators with an overview of cultural and regulatory considerations for conducting international research.

Some projects offer the opportunity to conduct or join an ongoing study in another country, where customs and culture differ from those in the United States. The information below is important to consider when conducting research in a foreign setting. Students are expected to have knowledge of and sensitivity for the culture in which the research will take place. This cultural awareness must be documented in the research application. Ideally, language proficiency is desirable or a local translator should be available to the student investigator.

What is “community” in foreign context? Researchers must be knowledgeable about the community in question. What constitutes a community and who is the community leader? Do community leaders always serve community interests? What are the roles of the individuals or women in this context?

Tips for International Student Research

- Learn basic conversational language to be used at the site
- Be aware of cultural norms of acceptable behavior.
- Cultural Sensitivity: Learn about the local customs, and demographics before departing for study site.
- Healthcare availability: Be aware of local health care systems and availability, and implications for the research.
- Community vs. Individual Implications for Consent: Not all societies practice “autonomy” or self direction in the same way as Western cultures. Often, tribal elders or community leaders must agree (consent) to allow research to be conducted and to give consent for individual participation. U.S. requirements for individual consent are still required.

Socio-cultural Attitudes to Note

- Values about illness, health, and autonomy
- Sense of self - collective vs. individual
- Individual vs. collective decision making
- Spirit/Religion – cultural differences in belief systems
- Sense of body/spirituality—e.g. Navajo, sacred
- Meaning/Sense of illness – illnesses caused by punishment, spirits
- Natural course of disease vs. intervention
- Aging—embrace, celebrate, avoid
- Care giving vs. curing
**Medical Education Research**

This chapter provides student investigators with an overview of what is meant by medical education research, when this undertaking qualifies as Human Subjects Research, and when it does not.

**What is Medical Education Research?**

Medical education research uses the scientific method to design and evaluate educational innovations, examine educational relationships, and conduct investigative surveys. Innovation research involves measuring the impact of a new or changed curriculum (course, workshop, and training program), comparing teaching methods, designing new evaluation instruments, or implementing improved educational processes. These projects measure outcomes such as learner skills, behavior, attitude, practice, or impact on patient care, or health system. Evaluation of an educational innovation may qualify as either Human Subjects Research or curriculum program improvement. Depending on the scope and design of the study and the intended use of the acquired data, the study may or may not require IRB approval. For example, curriculum improvement studies may be intended to increase the effectiveness of specific programs in medical school curricula, but may also acquire enough private information about subjects to make IRB review and approval necessary. Ongoing evaluations of students and curriculum, and required medical school operations are not research and are not Human Subjects Research.

As a result of their educational experiences, medical students may have ideas about how to improve KSOM education programs for future students. These ideas can be turned into rigorous research projects that may improve the medical education that USC Keck students receive. A student research opportunity to work with Keck medical education faculty to improve curricula will benefit students who intend to become educators. The KSOM medical education faculty should be contacted for guidance and opportunities to work with them.

Examples to help determine whether projects will require IRB review are provided below:

**Projects Which Do Not Require IRB Review (Not Human Subjects Research):**
• A study comparing the effectiveness of three teaching tools: power points only, overhead transparencies only, and a combination of both will be studied. Learning outcomes data will be collected from students using an anonymous attitude survey.

• A study investigating the amount of interaction between students and professors in online classes as compared to in-person courses. The study will compare numbers of student discussants in class versus numbers of active participants in online listserv discussions.

**Projects Which DO require IRB Review (Human Subjects Research):**

• A study to evaluate the scores of those who take the medical board exam preparation class with those individuals who do not take the class. Scores will be compared by ethnicity, gender, SES, GPA, and expectations from psychometric questionnaires.

• A survey is given to students asking which particular personal behaviors helped them prepare for real world medicine and those behaviors that had a negative impact. Student names and telephone numbers will be collected for a phone interview with half the students being surveyed at graduation and the others after an internship. Failing students will also be followed.

“Well, is my medical education research project human subjects research or not?”

For help with projects that may be hard to categorize, students should talk to their Faculty Advisor, the medical education department, or the IRB to determine whether their project is or is Not Human Subjects Research (NHSR).

If still unsure, students should submit a description of their proposed study to the IRB to determine status. IRB applications are submitted through iStar (http://istar.usc.edu). To use iStar, login to iStar, click the "NHSR?" button, and complete the short application. The IRB will provide a written determination in the form of a letter confirming the determination or requesting a full IRB application.

**Tips for Student IRB Submissions**

This chapter provides guidance to avoid submission problems that may delay research approval. Although student research varies greatly and some of these issues may not apply, these are the most commonly identified IRB concerns. Use of these tips to avoid common problems will speed IRB approval and strengthen the research.

A. **Elements to Consider Before Submitting to the IRB:**

Answer the following items fully in the IRB application when applicable to your study:

- Will vulnerable subjects (prisoners, pregnant women, children or neonates) be included in your study?
  - Are you collecting identifiable data (person’s name attached to data)?
  - How will you protect confidentiality of data (i.e. passwords, codes, encryption)?
  - Do you need informed consent? What type? (i.e. parent consent, child assent)
  - Have you minimized risk to subjects and maximized benefits?
  - How have you determined the correct level of review? (by risk level and/or study design?)
  - Research outside the USA?
  - Are there cultural or language issues in study design or subject pool? (in international or domestic studies)?
  - Are you collecting data you don’t need? **Stop, only collect elements that can be justified by the hypothesis**

B. **Study Design Tips:**
When designing a project, investigators should only use those procedures below, justified by the hypothesis. Removing unnecessary procedures or collecting unnecessary data can save investigators considerable amounts of time in gaining IRB approval. The following procedures should be used only when needed/justified to answer the hypothesis or fulfill scientific goals:

- Audio-taping of interviews
- Collecting identifiers when recording data
- Retaining identifiable material once the study is completed
- Quoting subjects by name in reports
- Interviewing or intervening with vulnerable populations (children, pregnant women, prisoners)
- Collecting sensitive information/data (Justify all data fields that will be collected)
- Video-taping or photographing human subjects in field observations
- Using experimental techniques or deception

It is acceptable to include any of the above procedures when needed to support the hypothesis or aims.

C. **Avoidable Difficulties in IRB Submissions:**

These errors/issues are seen on both USC campuses in student IRB applications. If any of these apply to you, fixing them before submitting your study will make the IRB process smoother.

- Not allowing enough time for IRB review and approval (do not wait for deadlines in your program, plan ahead)
- Inconsistent information between the Star application, protocol, and informed consent documents
- The principal investigator or faculty advisor did not complete CITI
- Obtain IRB Authorization Agreement and/or or permission letter when conducting research at non-USC sites
- Identify requested revisions made to the protocol or consent documents using Track Changes
- Understand the difference between research and patient care / program delivery
- Delineate research procedures (not needed for care) from medical care (need for care) in iStar application and in informed consent
- Study logistics, Medicare/insurance payments and credentialing must be adequately addressed and documented when research uses medical procedures. Location of
services and procedures evidence of hospital privileges, physician referrals, and budgets must be documented by a knowledgeable research coordinator.

- If you are using protected health information for research, you must have HIPAA authorization or HIPAA waiver.
- If you are confused about HIPAA when conducting research with protected health information, find out from IRB if HIPAA is required or HIPAA waiver may be obtained.

iStar Application Questions that Cause Delays: (Check yours)

- Item 2.4: PI or co-investigators not provided; no one is identified as person(s) to obtain informed consent
- Item 9.3: Failure to check the box “Prospective collection of data” when applicable
- Item 10: Inclusion/exclusion criteria not well defined
- Item 11.1: Study summary incomplete, does not contain all elements requested in the question
- Item 18: Regulatory status of medical devices unclear, experimental or commercial? Significant or insignificant risk device?
- Item 26: Data gathering, recording, and sharing unclear; data collection form (i.e. survey template) not uploaded into iStar
- Item 28.1: Risk/benefit ratio is not assessed (Is R/B favorable? Do benefits outweigh risks? Are risks minimized?)
- Item 36.1: Researcher review of medical records requires waiver to copy and remove patient contact information, however a waiver not requested.

Common Informed Consent Issues:

- Language too complex for participants
- Consent does not match IRB template
- Risks for all procedures are not fully described

Advertisement/Recruitment Material Issues:

- Publishing participation compensation amounts is not allowed by HSC IRB
• The word “Free!” may be considered coercive
• Potential benefits are overstated (medical care is not a benefit)
• Emphasize research, nature of study; it is not treatment, it is not a cure

D. Acceptable IRB Submissions:

• Use complete answers to avoid returned submissions
• Use correct IRB forms and upload all required study documents
• Submit to the correct IRB (UPC or HSC)
• Use clear language and well described concepts
• Do NOT use jargon
• Student projects must be reviewed and approved by the Faculty Advisor for correctness and merit before submission

E. Who Can Help?

• Faculty Advisors
  • USC Health Sciences Institutional Review Board
  Tel: (323) 223.2340
  E-mail: irb@usc.edu
  http://oprs.usc.edu/hsirb/
  • Researchers/departments within the student’s school/program
  • The IRB Student Mentor. (An IRB Student Mentor is available to assist student investigators with the IRB process). For help, send an email to irbgara@usc.edu
  • USC Office for the Protection of Research Subjects
  Tel: (213) 821.1154
  E-mail: oprs@usc.edu
  http://oprs.usc.edu/
Appendix A: Human Subjects Research (HSR) and Responsible Conduct of Research (RCR) Booklets

Human Subjects Research (HSR) Booklets

USC HSR brochures are available to guide investigators, students, participants, and others through the Human Subjects Research process. These booklets can be found on the Office for the Protection of Research Subjects (OPRS) website to view or print at: http://oprs.usc.edu/education/booklets/. Call OPRS for hard copies (213) 821-1154.

Booklets include:

Are You the Holder of an IND or IDE?
Describes the responsibilities of IND/IDE holders. A reference for investigators holding an IND or IDE and/or IRB staff who will be reviewing IND/IDE studies.

Student Handbook: Making Sense of Human Subjects Research
This comprehensive manual aids student with the IRB process. Provides information about the intricacies of human subjects research.

Informed Consent in Human Subjects Research
An overview of informed consent: its importance, required elements of consent, the consenting process, and documenting consent. USC resources for informed consent information are included.

You Want to be an IRB Community Member...Now What?
Guides IRB community members through the human subjects research process and helps them transition into a valuable members of the IRB committee. It can also serve as a great introduction for anybody new to human subjects research and the IRB.

Should I Participate in Research?
Aimed at assisting potential research participants in their decision to participate in research. Also available en Español: ¿Debería participar en una investigación?

Designed to guide Principal Investigators through the IRB process. Includes information on defining human subjects, the levels of IRB review, and informed consent requirements.

A guide to help investigators determine if their project is human subjects research. Offers definitions and examples of human subjects research.
Are You a Faculty Advisor? The ABCs of Human Subjects Responsibilities
For Faculty Advisors (FA) serving on student IRB projects. Provides a brief overview of the FA role and tips for navigating the IRB process from the FA perspective.

Responsible Conduct of Research (RCR) Booklets

OPRS has also developed a series of nine booklets on the RCR (based on CITI RCR online). The booklets are available at: http://oprs.usc.edu/education/rcr/. (Students supported by the National Science Foundation (NSF) and by certain NIH programs are required to complete RCR training.)

Booklets include:

Using Animal Subjects in Research
Describes the ethical and regulatory requirements associated with the use of animal subjects in research. Case studies and reference lists are provided.

Collaborative Research
Guidance on preparing, managing and terminating collaborative research relationships. Readers will have a better understanding of the responsibilities involved in sharing work and credit in a joint research venture. Case studies and reference lists are provided.

Conflicts of Interest and Commitment
This booklet presents an overview of conflicts of interest, as well as case studies and reference lists.

Data Management and Acquisition
Discusses how circumstances in which data must be protected to secure the intellectual property inherent in new inventions and protect the confidentiality of human research subjects. Explains legal/ethical issues related to ownership of data collected in an academic environment. Case studies and references are provided.

Human Subjects Research
Information about the responsible conduct of human subjects research. Key human subjects research definitions are provided as well as a concise historical overview of how the federal regulations came about. The Informed Consent process and Institutional Review Boards are also discussed. Case studies and reference lists are provided.

Mentoring USC Students and Postdoc Researchers
A resource for USC faculty, students, postdoc researchers and staff involved in mentoring relationships. Mentor/mentee expectations and responsibilities are discussed. Case studies and reference lists are provided.

Peer Review
A look at some of the issues authors and reviewers face as they prepare grant proposals and literature for publication.

**Responsible Authorship and Publication**
An overview of the issues involving publication and authorship as well as a model academic policy on authorship. Case studies and references are provided.

**Avoiding Being Penalized: Research/Scientific Misconduct**
An overview of research misconduct including historical and contemporary examples, guidelines on reporting misconduct, and a description of the investigatory process. The booklet includes case studies on research misconduct and reference lists.
Appendix B: Useful Websites for the Medical Student Researcher

USC

- USC Student Researchers
  http://oprs.usc.edu/students-3/

- iStar (IRB Submission Tracking And Review system)
  https://istar.usc.edu

- Health Sciences Institutional Review Board (HPIRB)
  http://oprs.usc.edu/hsirb/

- CITI (Collaborative IRB Training Initiative)
  http://oprs.usc.edu/education/citi/

- Office for the Protection of Research Subjects (OPRS)
  http://oprs.usc.edu/

- USC Office of Compliance
  http://ooc.usc.edu

- USC Human Subjects Protection Program (HSPP) Complaints
  http://oprs.usc.edu/about/complaints/

- USC Human Subjects Newsletter
  http://oprs.usc.edu/about/listserv-2/

- Human Subjects Research Policy at USC
  http://oprs.usc.edu/rules/

Federal

- U.S. Food and Drug Administration
  www.fda.gov/

- U.S. Department of Health and Human Services / Office for Human Research Protections
  http://www.hhs.gov/ohrp/

- Health Insurance Portability and Accountability Act (HIPAA)
  www.hhs.gov/ocr/privacy
Appendix C: “Not Human Subjects Research” – Two Unique Categories

A. “Not Human Subjects Research (NHSR)”-Projects that do Not Meet Federal Definition

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. See chapter 2 for definitions of “research” and “human subject”.

Examples of NHSR Projects:

- **Data collection** for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.

- **University Services and Program Evaluation Surveys** issued or completed by University personnel/students with the intent of improving services and programs of the University or for developing new services or programs, as long as the privacy of the subjects is protected, and the confidentiality of individual responses are maintained.

- **Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thoughts regarding themselves.

- **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are not intended for use outside of the classroom.

- **Biography or oral history** research involving a living individual that is not generalizable beyond that individual.

- **Fee-for-service contract** for procedures or services by a laboratory or other entity that is not engaged in the research.
- **Research involving cadavers**, autopsy material or biospecimens from deceased individuals. *Note: some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the IRB for further information.*

- **Innovative therapies** except when they involve "research" as defined by the federal definition. (An innovative clinical practice is an intervention designed solely to enhance the well being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to a particular class of patients.)

- **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge and use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice.

- **Case histories** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.

- **Research use of publicly available data** does **not** require IRB review. Examples: Use of census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available”.*

B. **Coded Private Information or Biological Specimens Research**

Guidance from the Office for Human Research Protections (OHRP) allows coded private information or biological specimens to be considered not human subjects research. This provision enables researchers who receive such data or specimens (but do not receive the key to identifying the source from which the data/specimens come) to fall outside the category of Human Subjects Research ([http://www.hhs.gov/ohrp/policy/cdebiol.html](http://www.hhs.gov/ohrp/policy/cdebiol.html)). This allows the IRB to approve this research with a shortened application. In your application, select coded data/specimens in iStar question 4. This elicits the minimal information required to evaluate if the information is coded, and was collected for another purpose. [https://istar.usc.edu/](https://istar.usc.edu/)

OHRP does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:
(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;

(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example: (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement); (b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or (c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Note: the original researcher who first obtained the data/specimens is subject to IRB oversight.

Useful Excerpts from the guidance are:

**Coded** (as provided by OHRP guidance) means that:
(1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

**Coded private information or biological specimens** that were not collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects.

In general, OHRP considers private information or specimens to be individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Obtaining Private Identifiable Information/Specimens

Conversely, obtaining identifiable private information or identifiable specimens for research purposes does constitute human subjects research. Obtaining identifiable private information or identifiable specimens includes, but is not limited to:
(1) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source; and

(2) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in the possession of the investigator.

**Who Should Determine Whether Human Subjects are Involved in Research**

OHRP recommends that institutions have policies in place that designate the individual or entity authorized to determine whether research involving coded private information or specimens constitutes human subjects research. Thus, at USC, the IRB is responsible for this determination. OHRP recommends that investigators not be given the authority to make an independent determination that research involving coded private information or specimens do not involve human subjects.
Appendix D: Exempt Research vs. “Not Human Subjects Research”

Exempt Research vs. “Not Human Subjects Research (NHSR)”

Questions often are raised regarding the distinction between research involving private information or specimens that does not involve human subjects and Human Subjects Research that is exempt from the requirements of HHS regulations 45 CFR part 46. This distinction can be made easier by always using the following sequential assessment when evaluating a particular activity.

(1) Does the activity involve research? **If yes**, proceed to question (2). **If no**, 45 CFR part 46 does not apply to the activity.

(2) Does the activity involve human subjects? **If yes**, proceed to question (3). **If no**, 45 CFR part 46 does not apply to the activity.
In analyzing a particular activity under the second question, it is important to focus on what is being obtained by the investigators. If the investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information, then the research activity does not involve human subjects. Therefore, no assessment of the research activity using the third question below regarding exemptions is required because the exemptions provided for under 45 CFR 46.101(b) apply only to research involving human subjects.

(3) Is the activity exempt under HHS regulations at 45 CFR 46.101(b)? If yes, 45 CFR part 46 does not apply. If no, 45 CFR part 46 does apply.

**Determination of exempt category 4**

With respect to research involving private information and specimens, the exemption that is most frequently relevant is the exemption under HHS regulations at 45 CFR 46.101(b)(4):

*Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.*
Having determined under the second question above that a research activity involves human subjects because the investigators are obtaining identifiable private information or specimens, assessment under the exemption at 45 CFR 46.101(b)(4) focuses, in part, on: (1) whether the data or specimens are **existing** at the time the research is proposed to an institutional official or IRB for a determination of whether the research is exempt, and (2) how the data or information is **recorded** by the investigators. This exemption would not apply if the investigators, having obtained identifiable private information or specimens from existing records or specimens, record the data or information in a coded manner, since the code would enable subjects to be identified through identifiers linked to the subjects.

**Examples:**

To demonstrate how the determination of whether a research study is human subjects research differs from the determination of whether a human subjects research study is exempt under 45 CFR 46.101(b)(4), consider the following examples, in which an investigator obtains health information of living patients who were treated for arthritis with either Drug A or Drug B. The investigator obtains this information in order to evaluate and compare the treatment outcomes associated with these two drugs:

1. **An investigator obtains only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients’ treating physician.** The only involvement of the treating physician is to provide coded information to the investigator. The investigator and the treating physician enter into an agreement prohibiting the release of the key from the treating physician. In this example, the investigator is not conducting Human Subjects Research because the investigator cannot readily ascertain the patients’ identity.

2. **An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients’ existing individually identifiable medical records at the clinics where the patients were treated.**
treated. The investigator records the patients’ treatment outcomes in a coded manner that could permit the identification of the patients. In this example, the investigator is conducting Human Subjects Research because the investigator is obtaining identifiable private information from patients’ (and now subjects’) medical records. The study would not be exempt under 45 CFR 46.101(b)(4) since the investigator is recording the information in a coded manner, thus allowing the subjects to be identified indirectly through identifiers linked to the subjects.

(3) An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients’ existing individually identifiable medical records at the clinics where the patients were treated. The investigator records only patient age, sex, diagnosis, treatment, and health status at the end of 6 months of treatment so that the investigator cannot link the recorded information back to the patients. In this example, the investigator is conducting Human Subjects Research because the investigator is obtaining identifiable private information from patients’ (and now subjects’) medical records. However, the study would be exempt under 45 CFR 46.101(b)(4) since the investigator records the information in such a manner that subjects cannot be identified either directly or indirectly through identifiers linked to the subjects.
Appendix E: The HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA), also known as the “Privacy Rule”, was designed to establish minimum federal standards for safeguarding the privacy of individually identifiable health information. The HIPAA Privacy Rule went into effect April 14, 2003. [www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa). The law generally prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from using or disclosing protected health information (PHI) without written authorization from the individual (HIPAA Authorization).

Any identifiable health information relating to the individual's past, present or future physical or mental health condition or payment for health care is considered protected health information (PHI). If you are using or obtaining PHI, please review the HIPAA Template and Instructions section of the HSIRB website at: [http://oprs.usc.edu/hsirb/hsirb-forms/](http://oprs.usc.edu/hsirb/hsirb-forms/)
Appendix F: Investigator Reporting Responsibilities after IRB Approval

After IRB approval is obtained, investigators must continue to submit various reports and applications to the IRB when certain events, circumstances or regulations require reporting. These requirements are described/outlined below.

A. Changes to an IRB approved study (Requires iStar Amendment Application)

Any proposed changes to an IRB approved full board or expedited study must be submitted for IRB review and approval before the changes can be implemented (except when necessary to eliminate apparent immediate hazards to the subjects).

Proposed changes to a study determined to be “exempt” by the IRB, require IRB review only when the changes alter the risk/benefit ratio. Administrative changes that do not alter the risk/benefit ratio do not require IRB review. If unsure about whether the change requires IRB review, contact the IRB office for assistance.

B. Renewal and Completion Applications (Requires iStar Continuing Review Application)

Renewing the Study’s Approval Period (Continuing Review)
When the IRB approves a research project, the approval period is typically for one year. If the study continues beyond that first year, the investigator must submit a continuing review application at least 30 days prior to the study expiration date. Once this renewal application is reviewed by the IRB, the study can continue for an additional year.

Study Expiration
Once the approval period for a given study has expired, it is considered a lapsed study and all research-related procedures must halt, except where doing so would jeopardize the welfare of the human subjects. When a study expires and IRB renewal has not been received, no subjects may be enrolled in the research, no data may be collected, and data analysis must stop. Once a continuing review application is submitted and approved by the IRB, the new approval period (i.e. one year) is established and the study activities may resume.

Study Completion
By submitting a notice of study completion (iStar continuing review application), the researcher confirms that the study is finished and no further interactions with subjects or their data will occur. Once the continuing review application is reviewed by the IRB, the
researcher is no longer required to submit annual continuing review applications. If the investigator wishes to enroll new subjects for the study, or otherwise engage human subjects in research, he/she must reactivate the study with the IRB.

C. Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others

(Requires iStar Reportable Event Application)

In case of a Serious Adverse Event or an Unanticipated Problem Involving Risks to Subjects or Others, the investigator is required to submit a written report to the IRB, within a set time frame depending on the type of event. The investigator’s report should contain enough information for the IRB to determine whether the event raises new questions about risks to participants or requires a change to the research design.

Definitions

Adverse event (AE) is an undesirable and unintended, though not necessarily unanticipated, injury, physical, or emotional occurrence in a human subject that may or may not be related to study.

Serious Adverse Event (SAE) are adverse events that are fatal or life threatening; that result in significant or persistent disability; that require or prolong hospitalization; that result in a congenital anomaly/birth defect; or that, in the opinion of the investigators, represent other significant hazards or potentially serious harm to research subjects or others.

Unanticipated Problems Involving Risks to Subjects or Others (UPX) includes any incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unexpected or unanticipated refers to any adverse event occurring in one or more research subjects where the nature, severity, or frequency of the event(s) is not consistent with the known/foreseeable risk associated with the study procedures described in the IRB approved study, any related study documents, and the IRB approved informed consent document.
**Appendix G: iStar Screenshots**

The screenshots that follow are examples of iStar application questions, along with guidance as to how to answer them.

To access question-by-question iStar screenshots and guidance, visit OPRS’s [iStar page](#).

Please be advised that iStar applications are subject to change.

**Home Page for PI & Staff Role**
Study Home Page
The Student Investigator must agree to accept the responsibilities and roles of both the Principal Investigator and Trainee/Student Investigator when submitting his/her application in iStar. The two part assurance is shown below.

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**Principal Investigator’s Assurance:**

By submitting this protocol for IRB review, I, as Principal Investigator, accept responsibility for the following:

- I have reviewed the conflict of interest portion of my application and the information disclosed is correct.
- The information provided in this application represents an accurate description of the study.
- All project personnel will conduct the study in compliance with all applicable federal, state, and local regulations and IRB and institutional requirements and policies. All project personnel will be properly trained in their respective responsibilities, licensed as required, and have requisite hospital privileges.
- Only the currently approved, IRB stamped informed consent documents and recruitment scripts will be used.
- No changes will be made to the protocol without prior IRB approval except when necessary to eliminate immediate hazards to the subject, in which case the IRB will be notified as soon as possible.
- Valid informed consent/assent will be obtained and documented from all research subjects or their legally authorized representatives unless these requirements have been waived by the IRB.
- Timely written reports of unanticipated problems involving risks to subjects or others and adverse events will be submitted to the IRB according to its reporting guidelines.
- I will keep myself informed of current developments that may impact the research, and I will immediately notify the IRB if I become aware of any information that may materially alter the risk/benefit ratio.
- All required research records will be maintained and will be made available in accordance with applicable regulations and IRB policy.
- The IRB will be immediately informed of any violations of HHS regulations (45 CFR 46), FDA regulations (21 CFR 50, 56), FERPA regulations (34 CFR 99), HIPAA regulations (45 CFR 164), state/local laws, or IRB Policies and Procedures for the protection of human subjects.
- Per HIPAA Privacy Rule regulations, the minimum necessary data needed is being requested to achieve the goals of the research described in this application (if applicable to the study).
- If unable to direct this research personally, as when on leave or vacation, I will arrange for a co-investigator to accept responsibility in my absence.
- I certify that I have read and agreed to the foregoing statements and that my submission of this application has the same force and effect as my written signature.

By endorsing the "I agree" box below, I accept these conditions.

* I Agree: [ ]

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**Trainee/Student Investigator’s Assurance (if applicable):**

By endorsing the "I agree" box below, I certify the above assurances and that I will meet with my faculty sponsor on a regular basis to monitor study progress. If my sponsor is away, I will meet with the arranged alternate faculty member who will assume these responsibilities.

* I Agree: [ ]
**Question 1: Project Identification Information**

1. **Project Identification and Abstract**

1.1. *Type of Submission:*

- Research Protocol or Study on Human Subjects
- Grant/Contract Only
- Facilitated Review (NCI CRB
- USC/CHLA Collaborative Review
- Clear

1.2. *Full Title of Research Protocol:

   Test

1.3. *Short Title:

   Test

1.4. **Abstract:** Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.

   Test

1.5. *Select which IRB you are requesting review from:

- USC - Health Sciences IRB (HSIRB)
- USC - University Park IRB (UPIRB)
- CHLA - Committee on Clinical Investigations (CCI)
- Clear
Project Identification Information

1.1 Indicate the type of submission and title.

Research Protocol/Study/Class Project should be chosen for any research involving human subjects (both funded and unfunded).

Grant/Contract Only should only be checked for projects seeking administrative review only according to 45CFR46.118 “Applications and Proposals Lacking definite Plans for Involvement of Human Subjects.”

Facilitated Review (CIRB) is only allowed for studies previously approved by the CIRB. This option should only be used for phase II/III multi-center cancer trials. If you are unsure whether your study qualifies for facilitated review, please consult your IRB before continuing with these forms.

Type the full title of your study.

USC/CHLA Collaborative Review is used for studies utilizing USC and Children’s Hospital Los Angeles resources.

Except for research exempted or waived under 46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB.

1.2 Full Title of Research Protocol

1.3 Type an abbreviated title of your study. Try to limit your short title to 10-15 words.

1.4 Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.

1.5 Choose the IRB you are requesting a review from: Health Sciences, University Park, or Children’s Hospital.
Question 2: Study Personnel

2. Study Personnel

2.1  List any study personnel, including yourself and your faculty advisor. You may add any other personnel in this section as a guest to review your application.

Using the “Add” button, identify the Principal Investigator who is the single individual responsible for the conduct of the research study. This would be the student investigator.

Using the “Add” button, identify the individual who will serve as the “study contact” with the IRB regarding the study. This person will send and receive IRB correspondence such as study-related documents, revisions, informed consents, etc. This is the person the IRB will contact, if needed, to answer application-related questions.

Using the “Add” button to identify all co-investigators who will be involved with the conduct of this study (you may select more than one at a time). Please note that HSC
applications will be routed for electronic signatures to all of the listed co-investigators and their Department Chairs and Division Chiefs. **Most student investigators will not need to list a co-investigator.**

**Student investigators must choose a faculty advisor from the list provided**
The faculty advisor assumes responsibility for the student investigator’s conduct of this research protocol. Please note that this application will be routed for the electronic signature of the faculty advisor.

If the faculty advisor’s name is not listed, please contact the iStar help desk at istar@usc.edu.

2.2 **Student investigators, resident, fellow or visiting scholar must choose “YES.”**

2.5 Specify the group/organization who has reviewed this study for scientific merit. For example, this may include your department chair.
Not Human Subjects Research (NHSR)

Certain studies may have the characteristics of human subjects research but may not meet the regulatory definition of “human subject” and/or “research”. Studies which do not meet the definition of human subjects research do not require IRB review.

Any investigator who is unsure of whether his/her proposal constitutes “human subjects research” should contact the IRB office or submit an online “Request for Human Subjects Research Determination” through iStar (http://istar.usc.edu/). The IRB staff, Chair and/or designee will determine if the study is human subjects research. Federal regulations do not allow investigators to make this determination themselves.

If a study does not qualify as human subjects research, the IRB can issue a letter stating that the project has been evaluated but does not require IRB review or approval. When a “Request for Human Subjects Determination” is submitted through iStar, a decision letter will be sent to the investigator via email. NOTE: Grant offices, faculty advisors, or publications may require a copy of the determination letter from the IRB.

The online iStar IRB application for Not Human Subjects Research studies consists of the following 3 sections.

**Section I: Project Information**

![iStar IRB Application](image-url)
II. Does Project Meet Regulatory Definitions

"Human Subjects"

1. ° Does the study involve interaction or intervention with live human subjects?  
   (Though interaction or intervention may have occurred previously, specimen(s)/data/information were collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects).

2. ° Is the information/data/specimen(s) obtained about the subjects?  
   (i.e. does the research data sought pertain to the individual subject, or is the data sought merely provided by the subject. For example, a quality improvement project for an education program may ask teachers to provide information on how to improve the program. This information is not "about" the teacher but information provided by the teacher about the education program.)

3. ° Is the collected information/data/specimen(s) private information?  
   (Private information is that which allows identity of individual to be associated with the information/specimen/data)

"Research"

1. ° Is your study designed to produce generalizable knowledge?  
   (Generalizable knowledge is when the intended use of the research findings can be applied to populations or situations beyond the studied unit.)

2. ° Is the study systematic?  
   (Follows step by step procedures organized according to interrelated ideas or principles evidenced by a research plan and objectives.)
Section III: Study Description

III. Study Description

Additional information to determine whether or not your project qualifies as human subjects research:

1. Provide a brief (1 to 2 paragraphs) description of the study in **LAT LANGUAGE**. This should not be a scientific abstract.

   ![Description Field]

2. Describe the subject population being studied.

   ![Population Description Field]

3. Provide a brief description of the design and methodology of the study.

   ![Methodology Description Field]

4. Submit the survey or questions that the subjects will be asked (if applicable).

   ![Survey Questions]

**Available Submission Activities**

If you are ready to submit, you can submit this application directly from this page with the link below.

![Submit Request]
Human Subjects Research (HSR) Contacts

Office for the Protection of Research Subjects (OPRS)
3720 South Flower Street
Credit Union Building #325
Los Angeles, CA 90089-0706
Tel: (213) 821.1154
Fax: (213) 740.9299
E-mail: oprs@usc.edu
http://oprs.usc.edu/

IRB Student Mentor
3720 South Flower Street
Credit Union Building #325
Los Angeles, CA 90089-0706
Tel: (213) 821.4219
Fax: (213) 740.9299
E-mail: irbgara@usc.edu
http://oprs.usc.edu/education/mentor/

Health Sciences Institutional Review Board
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
http://oprs.usc.edu/hsirb/

Office of Compliance
University Gardens Building, Room 105
3500 Figueroa St.
Los Angeles, CA 90089-8007
Tel: (213) 740.8258
Fax: (213) 740.9657
E-mail: complian@usc.edu
http://ooc.usc.edu