

Guide to Human Subjects Research For USC Medical Students



Office for the Protection of Research Subjects (OPRS)

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Guide to Human Subjects Research For USC Medical Students

Are you Conducting “Human Subjects Research”?

Introduction:

This booklet provides guidance for medical students who conduct biomedical, social and behavioral research or otherwise participate in research activities 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 includes approval by the Institutional Review Board (IRB). The IRB is a committee of faculty, staff, and community members who review human subjects research projects to ensure the research meets both 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 definitions. Thus, not all research needs IRB review and approval. Portions of this booklet explain categories that meet this exception, as well as categories that must receive IRB approval.

Medical Student Researchers:

Participation in research is an important part of the medical education experience, thus, KSOM encourages students to participate in the conduct of research projects. Funding may be available for projects through university grants, private funding (e.g. the Howard Hughes Medical Institute grants), or public sources (e.g. the National Institute of Health).

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



Part I

Research Opportunities for USC KSOM Students

Part I provides information on research opportunities available to interested KSOM medical students (see <http://medweb.usc.edu>).

These opportunities are:

- **Fifth Year Option:** 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://medweb.usc.edu/research/5th_year_research_option.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/>
- **Health Research Association (HRA) Roster of Funded Investigators:** The USC Health Research Association (HRA) provides clinical trial support services to USC researchers. The HRA listing of USC Investigators with funding from outside sponsors can be used by students to search for projects or researchers in fields of interest and pursue contacts:
http://medweb.usc.edu/research/pi_listing_feb06.pdf
- **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. The website is a useful overview of KSOM research.
<http://www.usc.edu/schools/medicine/research/>
- **KSOM Contracts and Grants Awards:** The KSOM Contracts and Grant Awards database includes all funded investigators name, project title, sponsor, project length, and dollar amount awarded. Students may contact researchers for possible research and training opportunities.
http://medweb.usc.edu/research/ksom_current_awards_1_20_06.pdf

- **National Institutes of Health (NIH):** The National Institutes of Health (NIH), 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/>
- **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 15 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 200 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://www.usc.edu/programs/pibbs/site/research_topics.html
- **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 research opportunities before committing to a discipline or faculty member.
<http://www.usc.edu/programs/pibbs/site/seminars.html>
- **Summer Research Fellowship Application:** The KSOM funds summer research projects, primarily but not exclusively, for 1st year students in good academic standing who want to join an ongoing research project or develop one of their own. Advice regarding these fellowships can be clarified by Dr. Joel Schechter, KSOM faculty advisor for the summer program, with additional information at:
http://medweb.usc.edu/research/summer_research_application.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.
http://www.usc.edu/schools/medicine/school/offices/educational_affairs/global_health/assets/Breman_Student_Application.pdf



Part II

How to Determine if a Project is Human Subjects Research

Part II will help students determine if their project is human subjects research or not. Investigators and researchers working with human subjects must comply with regulations and are obligated to follow ethical norms. Approval by a USC Institutional Review Board (IRB) confirms that the research application fulfills these requirements. The research must be conducted according to the IRB approved protocol.

(<http://www.usc.edu/admin/provost/oprs/citi>).

Typically, students will either initiate their own research project or join an existing study. 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 (more details on this follows). In all cases, IRB staff will help students with their proposed projects to 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 (<http://istar-chla.usc.edu/>). The student must also complete human subjects education using CITI (Collaborative IRB Training Initiative), the on-line system.



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 (See policies in appendix).

The University of Southern California's Institutional Review Boards (IRB) and the Office for the Protection of Research Subjects (OPRS) are responsible for deciding what constitutes human subjects research and how human subjects research protections must be implemented. These are 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*](#)) provide the definitions for research that must adhere to human subjects regulations and USC policies.

*<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

These definitions* are:

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 occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable in order for the information to constitute research involving human subjects. However, the interaction or intervention itself may constitute research involving human subjects.

The following brief examples illustrate types of human subjects research that requires 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 or 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 can also include 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 you did not collect these materials for the study. However, 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.



Part III

Institutional Review Board (IRB) ABCs for Student Investigators

Part III provides a short overview of the IRB application process for student investigators including required training in human subjects protection. This section also explains what is expected from students when submitting research requiring 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.

A. IRB submission “How Tos” for --- new studies, amending a study, and Summer Research fellowship projects:

- **New study**
If the student is the initiator of the research, then submit a New Study Application through iStar 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 records. If the student will be the Principal Investigator (PI), a faculty advisor must be named in the application.
- **Amending an ongoing IRB approved study**
If the student is joining an existing IRB approved study, then an Amendment Application must be submitted. Many students assist with research conducted by a faculty member/advisor that has already undergone the required Institutional Review Board (IRB) approval. Prior to assisting with the research, the student must be added to the existing IRB approved application through an amendment application via the iStar system.
- **Summer Research Fellowship Application**
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
“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.

B. 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 with a name, email address, campus, and department/division. **iStar:** <http://istar-chla.usc.edu>

C. What IRB Education Requirements Must I Complete?

- **CITI** (Collaborative IRB Training Initiative) is an online human subjects education program that offers various modules relevant to one's role in human subjects research. CITI training is mandatory for all medical student researchers. Instructions on how to access the CITI program can be found at: <http://www.usc.edu/admin/provost/ops/citi>
- **HIPAA Training** (Health Insurance Portability and Accountability Act) also known as “the privacy rule” established minimum Federal standards for safeguarding individual “protected health information” (PHI—any identifiable health information created or received by a health care provider) as well as training and certification requirements for access and use of “protected health information.” HIPAA training is required for all key study personnel who have access to PHI through USC providers. The HIPAA education tutorial can be found at: <http://ooc.usc.edu/PrivacySecurity/HippaPrivacy/EduProgram.cfm>



D. What are the Levels of IRB Review?

Students submitting new study applications must choose 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.

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.

- **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.
- **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 with children may require Full Board review. For the research to be approved, it must receive the approval of a majority of IRB members.

E. 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 available 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.
* The NSHR application button is located on the right hand side of your iStar homepage stating: **Does my project qualify as Not Human Subjects Research?** <http://istar-chla.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 subject, the investigator must enter into an agreement with the provider that states under no circumstances will the identity of the subjects be released to the investigator.

Part IV

Types of IRB Application Submissions

Part IV provides student investigator with step by step instructions for submitting the appropriate IRB application.

If Your Research Project ↓	
<p>Is Human Subjects Research</p> <p>Then →</p>	<p>Investigators must complete the “<u>New Study Application</u>” by logging into their iStar account AND CLICKING THE “New Study” button. (https://istar-chla.usc.edu) More information about each question can be found by going into the Study Application Guidance in the Training Resources section of the iStar website or through the <i>Student Investigator’s Guide to the IRB Process and Human Subjects Research</i> handbook found in the OPRS/IRB website.</p>
<p>Is believed to be <u>NOT</u> Human Subjects Research (NHSR)</p> <p>Then →</p>	<p>Investigators complete the “<u>Not Human Subjects Research</u>” (NHSR) application in iStar (https://istar-chla.usc.edu). Investigators who are unsure if their proposed study qualifies as Human Subjects Research can find more information in the <i>Is Your Project Human Subjects Research?</i> booklet. http://www.usc.edu/admin/provost/oprs/private/docs/oprs/NHSR_3_6_06_WEB.pdf</p>
<p>Obtains and Analyzes Coded/Private Data (Secondary Data) Only</p> <p>Then →</p>	<p>Investigators complete the “<u>Not Human Subjects Research</u>” (NHSR) application in iStar (https://istar-chla.usc.edu). Investigators who are unsure if their proposed study qualifies as Coded Data can find more information in the <i>Is Your Project Human Subjects Research?</i> booklet. You can also find information on the Office for Human Research Protections website: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm</p>
<p>Obtains and Analyzes Coded Biological Specimens Only</p> <p>Then →</p>	<p>Investigators complete the “<u>Not Human Subjects Research</u>” (NHSR) application in iStar (https://istar-chla.usc.edu). Investigators who are unsure if their proposed study qualifies as Coded Biological Specimens can find more information in the <i>Is Your Project Human Subjects Research?</i> booklet. You can also find information on the Office for Human Research Protections website: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm</p>

Part V

Informed Consent, Information Sheets & Templates

Part V provides the student investigator with guidelines about the Informed Consent process and what the document must contain. Examples of individualized consent forms are provided at the end.

A. Informed Consent Basics

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

<http://www.usc.edu/admin/provost/oprs/hsirb/>
<http://www.usc.edu/admin/provost/oprs/upirb/>



Informed Consents Must Contain:

A basic ethical tenet in conducting human subjects is that subjects participate voluntarily of their own choice. 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 procedures* involved in the research to which subject will participate.
- *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.
- *Contact information of person* to answers 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 that the person is otherwise entitled to receive.
- Statement of subjects' *right to confidentiality and right to withdraw* from the study at any time without 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 so called short form may be used.

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

Health Sciences IRB (HSIRB) Forms/Templates
<http://www.usc.edu/admin/provost/opr/hsirb/forms/>

University Park Campus (UPIRB) Forms/Templates
<http://www.usc.edu/admin/provost/opr/upirb/forms/>

Short forms can be found at the following website:
<http://www.usc.edu/admin/provost/opr/hsirb/forms/#other>

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 IRB. 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:

SAMPLE INFORMATION SHEET:

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

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

We are asking you to take part in this study because (Purpose/brief description of study).

Your participation is voluntary and would consist of (Provide procedures & length of time it will take).

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 (provide description of payment-if applicable) for your participation. You will be given a copy of this form.

If you have any questions about this research study, please contact: (Provide contact information).

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.

Part VI

Keck Student Summer Research Fellowship Projects May Not Be Human Subjects Research After All

Part VI 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 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 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 individuals participants, these studies are considered human subjects research and IRB review is required.

The following activities do not necessarily 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 **thoroughly filled out fellowship application is required.**

KSOM Summer Fellowship Application

The application submitted KSOM **must clearly delineate what "research" activities will be done.** 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>

Part VII

Undertaking International Research

Part VII 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 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 translator should be available.

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 customs, and demographics before you go
- **Healthcare availability:** Be aware of local health care systems and availability, and the implications for his or her 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 consent for the research to be conducted and give consent for individual participants. U.S. requirements for consent are expected (although modifications may be justified).

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?

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



Part VIII

Medical Education Research

Part VIII provides student investigators with an overview of what is meant by medical education research and when this undertaking qualifies as human subjects research, and when it does not.

What is Medical Education Research?

Medical education research uses 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, or 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.



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 working with Keck medical education faculty to improve curricula will benefit students who intend to become educators.

To help determine whether projects will require IRB review, some examples are provided below:

Which Projects Do Not Require IRB Review (Not Human Subjects Research)?

- A study tracking the use of three teaching tools: power points only, overhead transparencies only, and a combination of both. Data on learning outcomes 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.

Which Projects DO require IRB Review (Human Subjects Research)?

- This study will evaluate the effects of a medical board exam preparation class with those who do not take the class. Scores will be compared by ethnicity, gender, SES, GPA, and student expectations.
- A survey is given to students, asking which particular courses helped them prepare for real world medicine and those courses that did not. 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.

“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.

Or if still unsure, students may submit a description of their proposed study to the IRB through the iStar system (<http://:istar-chla.usc.edu>). To do this, login to the iStar system, 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.

A booklet from OPRS, [“Is Your Project Human Subjects Research? A Guide for Investigators”](#) may also provide useful insight.

Part IX

Tips for Student IRB Submissions

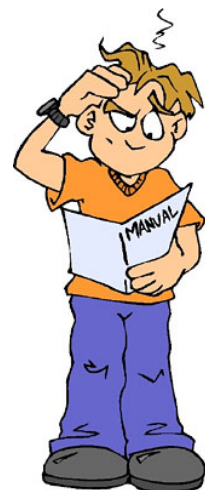
Part IX provides an overview of general issues that arise among student IRB submissions. Although student research varies greatly and some of these issues may not apply to your study, these are the most commonly identified IRB concerns. Using these tips and avoiding common problems will speed IRB approval and strengthen the research.



A. Elements to Consider Before Submitting to the IRB:

Describe these items fully in the IRB application if applicable to your study:

- Are you using vulnerable subjects?
- Are you collecting identifiable data?
- How will you protect confidentiality of data?
- Do you need informed consent? What type?
- Have you minimized risk to subjects and maximized benefits?
- How have you determined the level of review?
- Are you doing international research?
- Are there cultural or language issues?
- Are you collecting data you don't need?



B. Study Design Tips:

When designing a project, investigators should only use those procedures necessary for answering the hypothesis. Removing unnecessary procedures can save investigators considerable amounts of time in gaining IRB approval. The following procedures should be used only when needed 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. Avoid These Common Student Errors:

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

General Difficulties in IRB Submissions:

- Not allowing enough time for IRB review and approval
- Inconsistent information in 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
- Failure to identify revisions made to protocol or consent documents (not using Track Changes)
- Understand the difference between research and patient care / program delivery

- Failure to delineate research procedures from medical 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. Locations of services and procedures evidence of hospital privileges, physician referrals, budgets for procedures should be documented.
- Confusion about HIPAA for research with protected health information (Does HIPAA apply? Do I need to request a HIPAA waiver?)

Common iStar Application Questions that Cause Delays:

- Item 2.4: PI or co-investigators not added; no one identified 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
- Item 26: Data gathering, recording, and sharing unclear; no data collection form submitted for exempt studies
- Item 28.1: Risk/benefit ratio not assessed (Is R/B favorable? Do benefits outweigh risks?)
- Item 36.1: Failure to request a partial waiver of HIPAA to review medical records to identify potential subjects

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 compensation amounts is not allowed at HSC
- Using the word “Free!” (may be coercive)
- Potential benefits overstated (medical care is not a benefit)



- Emphasize research, not medical treatment

D. Acceptable IRB Submissions:

- Use complete answers to avoid returned submissions
- Use correct IRB forms and upload required study documents
- Submit to the correct IRB
- Use clear language and well described concepts
- Do NOT use jargon
- Are reviewed by the Faculty advisor for correctness and merit



E. Who Can Help?

- Faculty advisors
- USC Health Sciences Institutional Review Board
Tel: (323) 223.2340
E-mail: irb@usc.edu
<http://www.usc.edu/admin/provost/oprs/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
- Student Investigator's Guide to the IRB Process and Human Subjects Research:
[http://www.usc.edu/admin/provost/oprs/private/docs/oprs/Student Investigators Gui de.pdf](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/Student%20Investigators%20Gui%20de.pdf)
- USC Office for the Protection of Research Subjects
Tel: (213) 821.1154
E-mail: oprs@usc.edu
<http://www.usc.edu/admin/provost/oprs>



Appendix A

Human Subjects Researchers Brochures

Appendix A provides Human Subjects Research Brochures

USC HSR brochures are available to guide investigators, students, participants, and others through the human subjects research process. Contact the IRB or the OPRS to obtain these brochures or visit the OPRS website to view or print them online at:

<http://www.usc.edu/admin/provost/oprs/training/brochures.html>



[Are You a Faculty Advisor? The ABCs of Human Subjects Responsibilities](#)

This brochure is for Faculty Advisors (FA) serving on student IRB projects. It provides expectations of the FA role and also includes tips for navigating the IRB process.



[Should I Participate in Research? Before deciding to participate in research, here are some things you NEED to know...](#)

This brochure is for potential research participants to assist them in their decision to participate.

It is also available en Español:

[¿Debería participar en una investigación?](#)



[Are You Conducting Research Using Human Subjects? A Guide for Investigators](#)

This brochure is designed to guide Principal Investigators through the IRB process. It includes information on defining human subjects, the levels of IRB review, and informed consent.



[Making Sense of Human Subjects Research: A Student Guide](#)

This guidance is a comprehensive manual aimed at assisting student with the IRB process. It provides information needed to understand the intricacies of human subjects research, a question-by-question explanation of the IRB application, and examples of IRB applications.



[Is Your Project Human Subjects Research? A Guide for Investigators](#)

This brochure is a guide for investigators to help them determine if their project is human subjects research. It offers not only definitions of human subjects research, but examples as well.



[You Want to be an IRB Community Member...Now What?](#)

This booklet guides IRB community members through the human subjects research process. It is a great introduction for anybody new to human subjects research and the IRB.

Appendix B

Useful Websites for the Medical Student Researcher

USC

- USC Student Researchers Webpage
<http://www.usc.edu/admin/provost/oprs/research/student.html>
- iStar (IRB Submission Tracking And Review system)
<http://istar-chla.usc.edu>
- Health Sciences Institutional Review Board (HPIRB)
<http://www.usc.edu/admin/provost/oprs/hsirb/>
- CITI (Collaborative IRB Training Initiative)
<http://www.usc.edu/admin/provost/oprs/citi>
- Office for the Protection of Research Subjects (OPRS)
<http://www.usc.edu/admin/provost/oprs>
- USC Office of Compliance
<http://www.usc.edu/admin/compliance>
- USC Human Subjects Protection Program (HSPP) Complaints
<http://www.usc.edu/admin/provost/oprs/contact/complaints>
- USC Human Subjects Newsletter
<http://www.usc.edu/admin/provost/oprs/news/listserv.html>
- Human Subjects Research Policy at USC
<http://www.usc.edu/admin/provost/oprs/policies/hssp.html>

Federal

- U.S. Food and Drug Administration
<http://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)
<http://www.hhs.gov/ocr/privacy/index.html>
- Guideline for Good Clinical Practice
<http://www.ich.org/LOB/media/MEDIA482.pdf>

Appendix C

“Not Human Subjects Research”: Two Unique Categories

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

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.

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 for the intent and purposes 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, the confidentiality of individual responses are maintained, and survey participation is voluntary.
- **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 now 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 above criteria. (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. Research Involving Coded Private Information or Biological Specimens

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>

Federal regulations have been modified by guidance from the Office for Human Research Protections (OHRP) to allow coded private information or biological specimens to be considered Not Human Subjects Research (NHSR). 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.

Excerpts from the guidance are as follows:

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.

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; and (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.

Obtaining Private Identifiable Information/Specimens

Conversely, *obtaining* identifiable private information or identifiable specimens for research purposes constitutes 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.

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.

At USC, the IRB must make this determination. The investigator must submit a short “Not Human Subjects Research” application for IRB determination. This elicits the minimal information required to evaluate if the information is coded, and was collected for another purpose. <http://istar-chla.usc.edu/>

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. The person(s) authorized to make the determination should be knowledgeable about the human subject protection regulations. In addition, the institution should ensure the appropriate communication of such a policy to all investigators. 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.

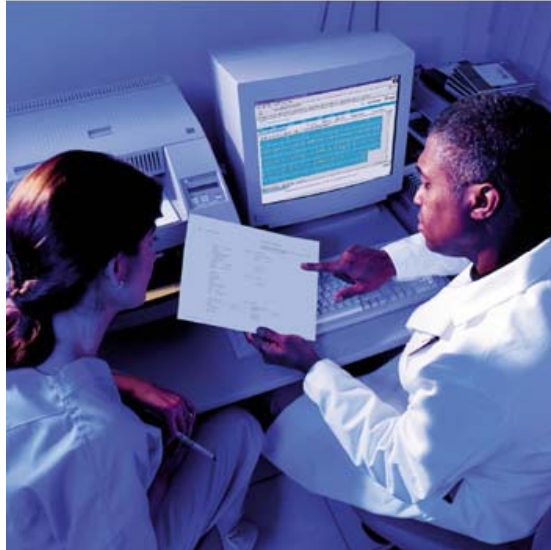


HSIRB Health Sciences
Institutional Review Board



Appendix D

Exempt Research vs. “Not Human Subjects Research”



Exempt Research vs. “Not Human Subjects Research”

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.

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.

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 to decipher the code to the investigator under any circumstances, until the individuals are deceased. 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. 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 an individual’s identifiable health information. HIPAA’s Privacy Rule went into effect April 14, 2003 <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://www.usc.edu/admin/provost/ops/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 IRB when certain events or circumstances 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 when the changes are more than minor (i.e. 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

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 (via 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 yearly 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.

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.

Institutional Review Board (IRB) 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://www.usc.edu/admin/provost/oprs>

IRB Student Mentor

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

Health Sciences Institutional Review Board

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://www.usc.edu/admin/provost/oprs/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: compliance@usc.edu
<http://www.usc.edu/admin/compliance>