Student Handbook: Making Sense of Human Subjects Research

2013

Office for the Protection of Research Subjects (OPRS)

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CODE OF ETHICS
OF THE UNIVERSITY OF SOUTHERN CALIFORNIA

At the University of Southern California, ethical behavior is predicated on two main pillars: a commitment to discharging our obligations to others in a fair and honest manner, and a commitment to respecting the rights and dignity of all persons. As faculty, staff, students, and trustees, we each bear responsibility not only for the ethics of our own behavior, but also for building USC’s stature as an ethical institution.

We recognize that the fundamental relationships upon which our university is based are those between individual students and individual professors; thus, such relationships are especially sacred and deserve special care that they not be prostituted or exploited for base motives or personal gain.

When we make promises as an institution, or as individuals who are authorized to speak on behalf of USC, we keep those promises, including especially the promises expressed and implied in our Role and Mission Statement. We try to do what is right even if no one is watching us or compelling us to do the right thing.

We promptly and openly identify and disclose conflicts of interest on the part of faculty, staff, students, trustees, and the institution as a whole, and we take appropriate steps to either eliminate such conflicts or insure that they do not compromise the integrity of the individuals involved or that of the university.

We nurture an environment of mutual respect and tolerance. As members of the USC community, we treat everyone with respect and dignity, even when the values, beliefs, behavior, or background of a person or group is repugnant to us. This last is one of the bedrocks of ethical behavior at USC and the basis of civil discourse within our academic community. Because we are responsible not only for ourselves but also for others, we speak out against hatred and bigotry whenever and wherever we find them.

We do not harass, mistreat, belittle, harm, or take unfair advantage of anyone. We do not tolerate plagiarism, lying, deliberate misrepresentation, theft, scientific fraud, cheating, invidious discrimination, or ill use of our fellow human beings—whether such persons be volunteer subjects of scientific research, peers, patients, superiors, subordinates, students, professors, trustees, parents, alumni, donors, or members of the public.

We do not misappropriate the university’s resources, or resources belonging to others which are entrusted to our care, nor do we permit any such misappropriation to go unchallenged.

We are careful to distinguish between legal behavior on the one hand and ethical behavior on the other, knowing that, while the two overlap in many areas, they are at bottom quite distinct from each other. While we follow legal requirements, we must never lose sight of ethical considerations.

Because of the special bonds that bind us together as members of the Trojan Family, we have a familial duty as well as a fiduciary duty to one another. Our faculty and staff are attentive to the well-being of students and others who are entrusted to our care or who are especially vulnerable, including patients, volunteer subjects of research, and the children in our daycare and community outreach programs.

By respecting the rights and dignity of others, and by striving for fairness and honesty in our dealings with others, we create an ethical university of which we can all be proud, and which will serve as a bright beacon for all peoples in our day and in the centuries to come.

*Adopted by the Board of Trustees of the University of Southern California, March 28, 2004*
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Introduction to Human Subjects Research Protection

Conducting research with human subjects is a privilege not a right.

Whether the research is social, behavioral, or biomedical, human subjects research must be conducted responsibly and it must protect the rights, welfare and safety of human subjects. The purpose of this book is to assist student investigators in meeting these obligations by providing guidance on USC human subjects research policies and Institutional Review Board (IRB) processes, as well as commonly cited ethical principles, and federal regulations.

Comments or questions about information in this guide may be addressed to the:
- Office for the Protection of Research Subjects at oprs@usc.edu
- University Park Campus IRB office at upirb@usc.edu
- Health Sciences Campus IRB office at irb@usc.edu
- IRB Student Mentor at irbgara@usc.edu

The Office for the Protection of Research Subjects (OPRS) website (https://oprs.usc.edu/) has additional information and educational materials.
I. Human Subjects Research; Basic Expectations

Research involving human subjects conducted at the University of Southern California must be reviewed and approved by one of four USC Institutional Review Boards (IRBs) prior to initiating research activities.

Investigators are required to follow federal and state regulations, university policies, and ethical principles when conducting human subjects research whether they are staff, students or faculty.

Student investigators must adhere to the study procedures approved by the IRB. If deviations, violations or unanticipated problems occur, these must be reported promptly to the IRB.

Changes to an IRB-approved research study must be reviewed and approved by the IRB prior to implementation, unless subjects are at immediate risk of harm. These changes are submitted as amendments in iStar, the online system.

Informed consent is central to the ethical treatment of human research subjects. Investigators must be forthright and realistic when describing the benefits and risks of research participation and when answering questions posed by subjects.

Adverse events and unanticipated problems involving risk to subjects or others must be reported in accordance with IRB policy using the iStar system for reportable events.

When the research study is complete, student investigators or other study staff are expected to notify the IRB of study completion and closure. This can be done by submitting a Continuing Review application or if your study is exempt, by checking on the “Close Study” button in iStar. For more information on the iStar system see Chapter IX.
II. Faculty and Student Responsibilities

This chapter will explain the duties and responsibilities of the faculty advisor and the student investigator. The IRB application requires both the faculty advisor and the student investigator/PI to sign an assurance that they understand and commit to fulfilling their research responsibilities and adhering to the regulations and policies at USC (see screenshot A for Faculty Advisor and B for student investigator/PI at the end of this chapter). The faculty advisor and student must also complete training in human subjects research. An online course in human subjects training is available at www.citiprogram.org. The CITI course will fulfill the human subjects training requirement.

1. Faculty Advisor (FA)/Faculty Sponsor

USC faculty who advise students on research projects play an important role in human subjects protections. Faculty Advisors bear ultimate responsibility for their students and the ethical conduct of the research. FA efforts and commitment have a significant impact on the success of student projects, the quality of data, and the time elapsed from submission to IRB approval. A screenshot of the assurance is included at the end of this chapter (see item A).

To ensure student projects are successful – Faculty Advisors must:

- adopt an active role in mentoring
- accept responsibility for students’ research (both planning and conduct)
- approve study design and methodology
- allocate adequate time for each student
- assure scientific merit in student projects
- know if an informed consent or a waiver is needed
- help students determine the level of risk (less than or greater than minimal risk)
- know the levels of IRB review: Exempt, Expedited, Full Board, or Not Human Subjects Research (“NHSR”)
- anticipate time required for students to secure IRB approval and conduct the research
- fulfill the human subjects education requirement by taking the CITI online human subjects education training

2. Student Investigator/ Principal Investigator /Trainee

A screenshot of the student investigator/ PI assurance is included at the end of this chapter (see item B).

Under the direction of the Faculty Advisor, the Student Investigator is responsible for:

- ensuring the description of the proposal study in the IRB application is accurate and complete prior to IRB submission
- obtaining IRB approval before initiating any research activities
• informing the IRB of all proposed changes or additions to the previously approved study before implementing them unless there is immediate risk of harm to the subject
• submitting required continuing review (progress reports) to the IRB
• reporting unanticipated problems involving risks to subjects or others and adverse events to the IRB
• informing the IRB of study closure or termination
• fulfilling the human subjects education requirement by taking CITI, the online human subjects education training. More information about education requirements can be found at: https://oprs.usc.edu/education/citi/
• in addition to the Principal Investigator’s assurance, student investigators must also agree to meet with faculty sponsor on a regular basis in order to monitor study progress.
Faculty Advisor’s Assurance

The following screen shot was taken from iStar, the online system for submissions to the IRB. The Faculty Advisor must agree to accept the responsibilities associated with that role, as described in the faculty advisor’s assurance.

Submit Application to UP IRB

Use this form to submit your completed application for approval. Following is the Investigator’s Assurances:

Faculty Advisor’s Assurance:

By submitting this protocol for IRB review, I, as Faculty Advisor to a student or trainee Principal Investigator, accept responsibility to monitor and verify that the trainee/student PI complies with the following:

- 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 USC reporting guidelines.
- 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), PPRA regulations (34 CFR 98), HIPAA regulations (45 CFR 164.530), state/local laws, or IRB Policies and Procedures for the protection of human subjects.
- Per HIPAA Privacy Rule regulations (if applicable to the study), only the minimum necessary data to achieve the goals of the research described in this application is being sought.

In addition, I, as Faculty Advisor, will:

- If unable to supervise this research personally, as when on leave or vacation, I will arrange for another faculty member to accept responsibility in my absence.
- 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.
- I will meet with the trainee/student on a regular basis to monitor study progress.
- 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

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

* I agree: _

Name:
Date:

If you are not ready to approve this application, click Cancel.
A) Student Investigator/PI Assurance

The Student Investigator must agree to accept the responsibilities and roles of Principal Investigator and Trainee/Student Investigator. The two part assurance is pictured 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, 312), FERPA regulations (34 CFR 99), HIPAA regulations (45 CFR 164.530), state/local laws, or IRB Policies and Procedures for the protection of human subjects.
- For HIPAA Privacy Rule regulations, the minimum necessary data needed in order to achieve the goals of the research described in this application (if applicable to the study).
- If unable to direct the 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: ❑

Name: [Redacted]

Date: Fri Mar 29 18:00:00 2013

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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 assigned alternate faculty member who will assume these responsibilities.

* I Agree: ❑

Name: [Redacted]

Date: Fri Mar 29 18:00:00 2013

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OK Cancel
III. Ethical and Regulatory Framework

The current ethical and regulatory framework for the conduct of human subjects research dates from the 1940s Nuremberg Code. A brief summary of the major ethical and legal regulations that pertain to human subjects research is provided in this section.

Nuremberg Code

The Nuremberg Code was developed following the Nuremberg Military Tribunal convened to bring to trial Nazi doctors who conducted inhumane medical experiments on prisoners without their consent. The Code provided many of the basic principles that still govern the ethical conduct of human subjects research. For example, it asserts that “the voluntary consent of the human subject is absolutely essential” to conducting medical research.

The Nuremberg Code further explains that this requirement for subjects includes:

- capacity of participants to consent
- voluntary participation
- freedom from coercion
- no penalty for withdrawal
- full knowledge of the risks and benefits of participation

The Nuremberg Code can be found at: https://history.nih.gov/research/downloads/nuremberg.pdf.
Declaration of Helsinki


The Declaration of Helsinki states:

- Research involving medical interventions with humans should be based on results from laboratory and animal experimentation
- Human research protocols should be reviewed by an independent committee prior to initiation
- Informed consent of research participants is necessary
- Research should be conducted by medically/scientifically qualified individuals
- Risks should not exceed benefits

The Declaration of Helsinki can be found at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the U.S. Congress in response to public outrage over the Tuskegee syphilis study conducted by the U.S. Public Health service in the 1940's, which used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available. The Commission produced “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.”

The Belmont Report sets forth three basic ethical principles for conducting research involving human subjects: respect for persons, beneficence, and justice. These terms have specific meaning when applied to human subjects research as noted below:

1) Respect for persons

Respect for persons requires that individuals be treated as autonomous, that is, as having the capacity to make their own choices and that persons with diminished autonomy be protected. In other words, a person must be capable of making an informed decision whether or not to participate in a human subjects research project and safeguards must be in place for those who cannot make an informed decision on their own. Informed consent of human research subjects is derived from the principle of respect for persons.
2) Beneficence

Beneficence is demonstrated when subjects are protected from harm, specifically, by maximizing possible benefits and minimizing possible harms from study participation. The “risk-to-benefit” ratio in a study must be acceptable to the IRB in order for the research to be approved.

3) Justice

Justice refers to equitable selection of subjects for a study without undue burden of risks or exclusion from likely benefits of a particular population. For example, exclusive enrollment of a subset of the population for a condition that is not unique to that subset is not just. Additionally, enrollment of a population unlikely to benefit from the results of the research is also unjust.

The Belmont report can be found at: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

Federal Policy for the Protection of Human Subjects (Common Rule)

In 1991, the U.S. Department of Health and Human Services codified into regulation the Policy for the Protection of Human Subjects (Title 45, Part 46). These regulations, called the “Common Rule” (Subpart A), provide the basic foundation for the human subjects protection program in use today. The Common Rule applies to research conducted, supported, or otherwise subject to regulation by any Federal department or agency, hence the title “Common Rule.” Institutions can choose to extend the Common Rule to all research, The Policy in Subparts B, C, D, provides additional protections to “vulnerable populations” such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects research.


FDA Regulations on Protection of Human Subjects (21 CFR 50) and Institutional Review Boards (21 CFR 56)

The U.S. Food and Drug Administration, under the Department of Health and Human Services, regulates clinical research seeking approval for drugs, devices, and biologics. Title 21, Part 50 contains the federal definition of human subjects, federal requirements for informed consent and the required safeguards for clinical investigations. Title 21, Part 56 contains specific regulations regarding the composition, organization, and functions of Institutional Review Boards.

The FDA regulates drugs, devices, and biologics through a series of regulations that must also be addressed by researchers and sponsors. They are: Biologics (21 CFR 600), Investigational New Drugs (21 CFR Part 312), and Investigational Device Exemptions (21 CFR 812).
The Code of Federal Regulations Title 21; Part 50 (Protection of Human Subjects) can be viewed [here](#).

The Code of Federal Regulations Title 21; Part 56 (Institutional Review Boards) can be viewed [here](#).

The U.S. Food and Drug Administration guidance for IRBs and Clinical Investigators can be viewed [here](#).

**Health Insurance Portability and Accountability Act (HIPAA) / (Privacy Rule)**

The Health Insurance Portability and Accountability Act (HIPAA) is a federal privacy law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities and clinics) from using or disclosing patients' “protected health information" (PHI) without written authorization.

When a student investigator intends to obtain or release PHI to others (e.g., sponsors, other investigators, collaborators) in connection with their research, he/she must indicate so in the IRB application.

Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the three following conditions:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

The Privacy Rule can be found at the HIPAA privacy website of the Office for Civil Rights (OCR): [http://www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa).

Additional references could be found at the USC OPRS HIPAA website: [https://oprs.usc.edu/education/hipaa/](https://oprs.usc.edu/education/hipaa/).

**International Conference on Harmonization/ Good Clinical Practice (GCP)**

The [International Conference on Harmonization](http://www.ich.org), an organization formed by the US, Canada and Japan to simplify drug approvals between these countries, has written guidelines for drug studies that have been adopted into law in many countries but are only used as guidance in the U.S.

Good Clinical Practice (GCP) is the international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Compliance with GCP provides regulators assurance that data are presented as reported,
results are credible and accurate, and the rights, safety, confidentiality, and well-being of trial subjects are protected. 

The Guidance for Good Clinical Practice (GCP) could be found here:

IV. What is/isn’t Human Subjects Research

The first question a researcher should consider with respect to IRB submission is whether the project fits the definition of human subjects research. In order to do so, the project must meet the federal regulatory definitions of both research and human subjects in order to require IRB approval.

Research

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102 (d)). "Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond that studied.

As described in the Belmont Report, “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

“Research” generally does not include operational activities such as routine outbreak investigations and disease monitoring and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services.

Human Subjects Research generally does not include journalism, political polls, or public health surveillance. However, some of these activities may include or constitute human subjects research in circumstances where there is a clear intent to contribute to generalizable knowledge – and the study collects data about the subjects themselves – then the entire project must receive IRB approval.

Human Subjects

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102 (f)(1), (2)).

The following list contains brief explanations of the terms found in the definition of human subjects.

- The term living individual refers to the state of the subject. The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from non-living subjects are not subject to the human subject protection regulations.
- “About whom” indicates that the data received from the living individual is about the person. A human subject research project requires that the data received from the living individual is about the person.
• **Intervention** includes physical procedures, manipulations of the subject, or manipulations of the subject’s environment for research purposes.

• **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

• **Identifiable private information**\(^1\) includes 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) (45 CFR 46.102(f)(2)) and information about behavior that occurs in a context in which an individual can reasonably expect that no recorded observation is taking place (such as a locker room or public restroom).

• **Identifiable** means the information contains one or more data elements that can be used alone or combined with other reasonably available information to identify an individual (e.g. Social Security number).

• **Observational studies** of public behavior (including television and internet chat rooms) are not human subjects research if they do not involve intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

In light of the potential regulatory consequences of not obtaining IRB review and approval, the investigator should err on the side of caution and consult the IRB when he/she is uncertain if a project is human subjects research.

**Identifying Studies that *Are* Human Subjects Research**

Certain studies may have the characteristics of research but do not meet the regulatory definition of human subjects research. Federal Regulations state that the definition of human subjects and research must both be met in order for a study to be considered human subjects research.

\(^1\)Disclosure of private information may place subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation. Researchers must use caution with collections of identifiable data of a sensitive nature.
Examples of activities that are Human Subjects Research:

1. Utilizing test subjects for new devices, products, drugs, or materials.
2. Collecting data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.
3. Using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
4. Using bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the key. Click here for guidance on research involving coded private information or biological specimens.
5. Producing generalizable knowledge about categories or classes of subjects from individually identifiable information.
6. Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living, working space or test chamber.

Identifying Studies that Are Not Human Subjects Research (Do Not Need IRB Review):

Examples of activities that are Not Human Subjects Research (NHSR):

1. **Data collection** for internal departmental, school, or other university administrative purposes. Examples: teaching evaluations, customer service surveys.
2. **Service surveys** issued or completed by university personnel for the intent and purposes of improving services and programs of the university or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This would include surveys by professional societies or university consortia.

**Note:** If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.
3. **Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.

4. **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. Example: instruction on research methods and techniques.

   **Note:** The IRB is only required to review studies that meet the Federal definitions of research and human subject, or “engaged in research”.

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

6. **Independent contract for procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.

7. **Research involving cadavers**, autopsy material or bio-specimens 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.

8. **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 particular individuals.)

9. **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.

   **Note:** Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

10. **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.


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**Note:** Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available”.

12. **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 data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects’ names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator.

**Note:** Investigators are not allowed to make this determination. These projects require verification from the IRB.

See the [OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](https://www.hhs.gov/ohrp) for more information.

### Determining if a Study is Human Subjects Research

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](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 “Request for Human Subjects Determination” is submitted online through iStar, an email notification will be sent to the investigator. If a study does not qualify as Human Subjects Research, the IRB will issue a letter stating that the project does not require IRB review or approval.

**NOTE:** Grant offices, faculty advisors, publications, and/or dissertation committee members may require a determination letter from the IRB to verify that the decision was not made by the researchers. Students who apply to iStar using Not Human Subjects button, will receive a letter to confirm the decision was made by the IRB.
V. Institutional Review Board (IRB)

What is the Institutional Review Board?

The Institutional Review Board is an independent committee established at institutions or organizations where human subjects research is conducted or supported.

The IRB is charged with reviewing research projects involving human subjects for compliance with institutional policies and state, local, and federal laws. The IRB will also assess whether the risks posed to subjects are proportional to the benefits.

The IRB is comprised of at least five members from relevant academic disciplines including at least one non-affiliated member. The members include faculty, staff, students, and members from the local community. The IRB functions as a surrogate “human subject advocate” whose role is to protect subjects participating in research by reviewing research projects before research is allowed to begin.

IRB members must have the necessary experience and expertise to evaluate proposed research projects. IRBs must be diverse in terms of race, gender, and cultural backgrounds.

The IRB is part of a comprehensive system, the Human Subjects Protection Program (HSPP), responsible for the protection of research subjects. The HSPP at USC includes the Office for the Protection of Research Subjects, the Office of Compliance, the IRBs, and the Institutional Official.

IRB functions and duties are described in the 1991 Federal Policy for the Protection of Human Subjects (Common Rule - Title 45 CFR 46).

What does the IRB do?

The IRB is responsible for reviewing and approving proposed or continuing human subjects research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, obtaining fully informed consent, minimizing risks, maximizing possible benefits and assuring the maintenance of privacy and confidentiality of persons and data. Human subjects research projects cannot be conducted without the approval of the IRB.

The committee has the authority to approve, require changes to study procedures, or disapprove proposed research projects. Institutional officials can disapprove an IRB approved project but cannot approve a project that has been disapproved, suspended, or terminated by the IRB.

Even studies that qualify for the “Exempt” category in the regulations must receive an exempt determination by the IRB or a designee of the IRB.

IRB project approval is valid for up to one year. If the research continues for more than a year, a continuing review application must be submitted to the IRB to extend approval for a year.
VI. Types of IRB Review

Federal regulations provide for three types of IRB review: exempt, expedited, and full-board\(^4\). The following chapter provides an explanation of each category of review and examples of studies that meet those categories. The IRB conducts reviews using the criteria contained in the Federal Policy for the Protection of Human Subjects (CFR 45; Part 46, Section 46.111).

**Exempt Review**

Exempt research is research with human subjects that is “exempt” from the provisions of the Code of Federal Regulations (45 CFR 46). An exempt research project does not require annual continuing review unless the project is amended in such a way that it no longer meets the criteria under which it was determined to be exempt. Exempt projects involve less than minimal risk.

The IRB staff – not the researcher – must determine when a research project falls under one of the six exempt categories. There are six exempt categories listed in the federal regulations (45 CFR 46.101(b)).

**Exempt Review Categories:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or comparison of instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **AND** (b) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.\(^5\)

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g, or for the National

---

\(^4\) A unique category, **Not Human Subjects Research**, is used when the research does not meet the federal definition of **human subjects** and/or **research** and thus will not require IRB review. This term may also be used for **coded data/specimens** when use of such collections meets certain conditions.

\(^5\) Studies involving children can be exempt if the PI only plans to observe and not interact with the children. Student investigators are advised to contact the IRB for further information regarding subjects under the age of 18 and other categories of vulnerable subjects.
Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.

4. Research involving the collection or study of existing data, documents, records, pathological 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.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level found to be safe, an agricultural chemical or environmental contaminant at or below the level found safe by the Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Expedited review applies to those research projects that do not fit an exempt category but do not present more than minimal risk. These projects must meet one of the nine categories for expedited review. Expedited review requires the same approval criteria as a full board study but because these studies entail less risk they are reviewed by the IRB Chair or a Designated Reviewer, rather than the convened committee. During this process, IRB reviewers exercise all of the authorities of the IRB except that they may not disapprove the research. There are nine expedited review categories in the federal regulations (45 CFR 46.110).

Expedited Review Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3

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6 Publicly available refers to record sets that are readily available to the broad public, such as census data, federal health, labor, or educational statistics. An investigator should not assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.
ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

   Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

   Note: Some research in this category may be exempt from the Department of Health and Human Services regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

The following expedited categories apply solely to projects initially reviewed and approved by a convened IRB that now require continuing review:

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Board (Convened) Review

Studies that involve more than minimal risk require full board review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members.
While federal regulations do not specifically list categories that require full board review, studies such as those listed below are normally sent to full board for review when part of the study design involves greater than minimal risk procedures:

- studies involving clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures
- studies taking place internationally (particularly countries with little or no provisions for protection of human subjects) where subjects may be at physical, psychological or legal risk
- studies in which disclosed information could require mandatory legal reporting (e.g., child/elder abuse, etc.)
- studies involving deception which raise the risk to subjects or others
- studies in which the IRB staff, chair, member, or designee determines risk to subjects or others to be greater than minimal risk
- studies using “vulnerable” populations and thus requiring extra protections

A Reminder…

Student investigators should consult with IRB staff, faculty advisor, and/or the student mentor if they are unsure which level of review is required for their research.

All human subjects research whether conducted by student researchers, faculty or staff must obtain IRB approval prior to initiation of any research activity/study (presuming the study fits the federal definition of human subjects and research and is not solely a classroom exercise).

Retroactive approval for data previously collected for an unapproved study is not allowed, however, in some cases previously collected data, not originally intended for a current study, may qualify for use as existing data. The student researcher can contact the IRB for clarification. Failure to seek IRB approval for research may invalidate a study and/or result in delayed graduation. Many journals will not accept a human subjects research paper without proof of IRB approval.

IRB Review Exceptions

Not Human Subjects Research (NHSR)

Not Human Subjects Research (NHSR) is research that does not meet the federal definition(s) of human subjects and/or research. NHSR studies are not defined in the federal regulations. USC policy requires that investigators submit a short (3 screen) application for IRB review so that the IRB can determine if the study is NHSR.

For more information on NHSR, see Chapter IV of this book.

Coded Data/Specimens

Studies using coded private information or coded biological specimens not collected by the current investigator, nor collected for the currently proposed project, do not require IRB review provided that the current investigator is not able to link the coded data/specimens to individual subjects. Further, if the data/specimen provider has access to the identity of the subject, the
investigator must enter into an agreement with the provider stating that under no circumstances will the identity of the subjects be released to the investigator.

VII. Tips for Expedited and Exempt Research

This chapter provides information to assist students in determining the type of IRB review (exempt or expedited) required for their research.

Before You Begin:

- Obtain an iStar account (See Chapter IX for instructions).
- Complete the Human Subjects Protection Training (CITI) (required of all study personnel: student PI, Faculty Advisor, research staff).
- Determine appropriate level of IRB review (NHSR, coded data, exempt, expedited). A study may fall under more than one category within that review level (exempt, expedited).
  - Note: Expedited Review is a type of IRB review. It does not mean a faster review.
- Allot enough time for the IRB submission and review process. An initial IRB review takes approximately 5-10 business days.
- Applications are reviewed by the IRB in the order received.
- Answer each question on the iStar application. Do not leave questions blank. Use the iStar guidance available on the right side of each question.
- Request site permission before submitting an IRB application. Some sites/schools require permission to conduct research even if the research is exempt from IRB review.
- If accessing LAUSD resources to conduct research studies, obtain approval from the LAUSD Committee for External Research Review (CERR).
- Adhere to FERPA (Family Educational Rights and Privacy Act) and PPRA (Protection of Pupil Rights Amendment) requirements, as applicable.

How to Decide if a Project is Expedited or Exempt

The federal regulations allow for six exempt and nine expedited review categories (See Chapter VI). Designation of a study in either the expedited or exempt research categories is often a judgment call rather than a hard line regulatory decision. These decisions become clearer with experience and dialogue with others. The following section has been designed to help investigators reflect on the distinction between expedited and exempt studies.

First, look at the abstract and methodology and determine if it meets the federal definition of both human subject and research. If the project does not meet both, then it is Not Human Subjects Research (NHSR). An NHSR application should be submitted in iStar and the IRB will confirm the determination.

OR

If the project will use data or specimens that are “coded” and the investigator does not have access to the key to decipher the code, then the project is Not Human Subjects Research
according to DHHS “Coded Specimen Guidance”. To submit a project using coded data or specimens, the New Study Application (Expedited/Full Board) must be submitted via iStar. The study application will allow you to choose Coded Specimen/Data (at Question 4.1) and direct you to an abbreviated application.

If neither of the two descriptions above fit the project, look at the six exemption categories in Chapter VI and reflect on which category the project fits.

If an exemption category seems to fit the project, consider the following questions:

- Will vulnerable subjects be used, such as children or prisoners?
- Will the investigator collect sensitive/private information and keep identifiers for them?
- Is there a risk to participants from the information being collected?

If the answer to any of these questions is “yes”, then the project may not be exempt and may require Expedited or Full Board IRB review.

If the project does not appear to fit any exempt category, or there are “yes” answers to the questions above, forward the project as expedited or full board for further determination.

**Side By Side Guide to Determine Expedited vs. Exempt Review Categories**

(Note: these are general guidelines, there may be exceptions)

<table>
<thead>
<tr>
<th>Points to Consider</th>
<th>Expedited</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is it human subjects research?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Involves human subjects</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>must meet federal definition of human subject</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is research</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>must meet federal definition of research</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Research categories**

- Project meets one or more of the expedited research categories X
- Project meets one or more of the exempt research categories X
- If there’s no perfect Exempt fit, project must be Expedited X

**Number of interactions/interventions with subject**

- Interactions once (e.g. one time anonymous survey) X
  no retention of personal / contact information
- Interaction more than once (i.e. design requires repeated interactions) X
  Retains personal / contact information for additional interaction or follow-up

**Analyzing data only (no interaction with human subjects)**

- Anonymous data / de-identified / no identifiers maintained X
  may qualify as “Not Human Subjects Research” or Coded Specimen Research
<table>
<thead>
<tr>
<th>Data linked to personal information</th>
<th>X</th>
</tr>
</thead>
</table>

**Level of risk**

<table>
<thead>
<tr>
<th>Minimal</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>risks not greater than those encountered in daily life, or routine physical / psychological exams / tests</td>
<td></td>
</tr>
<tr>
<td>(e.g. interviews about levels of anxiety or depression, surveying children, blood draws)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>None or less than minimal</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>risk that is less than minimal as defined above (e.g. questionnaire asks for favorite food, # of vacations in past year, etc.).</td>
<td></td>
</tr>
</tbody>
</table>

**Points to Consider**

<table>
<thead>
<tr>
<th>Expedited</th>
<th>Exempt</th>
</tr>
</thead>
</table>

**Annual IRB review (continuing review)**

<table>
<thead>
<tr>
<th>Continuing review is required</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing review is NOT required</td>
<td>X</td>
</tr>
</tbody>
</table>

**Are the data (questions) collected (asked) sensitive in nature, or identifiable private information?**

<table>
<thead>
<tr>
<th>Sensitive</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>data could put the subject at risk (e.g. job loss, marriage, reputation, etc)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not sensitive</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>includes innocuous data/questions only (e.g. food preferences, cell phone usage)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Identifiable private information</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>includes information about behavior occurring in a private context, information gathered for specific purposes where the individual expects the information to be kept private (e.g. medical records), and data/info is identifiable (e.g. name/address).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOTE: identifiable information can qualify as exempt if the information is innocuous</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Intent or use of information gathered**

<table>
<thead>
<tr>
<th>Generalizable</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>intend to share information to benefit society</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not intended to contribute to generalizable knowledge</th>
<th>NA</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>submit a &quot;Human Subjects Research Determination Request&quot;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Who are the subjects?**

<table>
<thead>
<tr>
<th>Children</th>
<th>X</th>
<th>*X</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Exempt category 2 is allowable in studies with children, only when there is passive observation and no interaction with the children. Exempt categories 1 and 3 - 6 (45CFR46) can apply to research with children or adults.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pregnant Women (45CFR46 Subpart B)</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt research is allowable with pregnant women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expedited research with pregnant women requires extra considerations (45CFR46.204)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prisoners</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>research with prisoners cannot be exempt (45CFR46 Subpart A)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Normals</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>generally healthy adults without physical / mental impairments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Points to Consider</td>
<td>Expedited</td>
<td>Exempt</td>
</tr>
<tr>
<td>--------------------</td>
<td>-----------</td>
<td>--------</td>
</tr>
<tr>
<td>Consent and Waivers of Consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Informed Consent</strong></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Waiver of Consent, if applicable</strong></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Waiver of Written Consent, if applicable</strong></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Information Sheet (alternative / shortened consent )</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Who Can Approve the Study for the IRB?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IRB Designee</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>IRB Staff</strong></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Research Methods</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Focus groups / Interviews</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Voice / Video / Photograph / Recordings</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Involves Deception</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Uses HIPAA identifiers</strong></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
VIII. Student Projects and the IRB Review Process

Preparation for iStar Submission

Once a student, his/her advisor and dissertation/thesis committee have approved the research topic, design, and methods, the project is ready for IRB submission through the iStar application. The student and the faculty advisor can work together to determine whether the project requires exempt, expedited, or full board review. However, the final determination of the review category is made by the IRB.

Students should seek study-related assistance from their advisors before submitting to the IRB to assure study risks are minimized and that advisors monitor the ethical conduct of the project. Students can seek guidance from the IRB staff or the student mentor for help pertaining to the IRB submission process.

Please note that student investigators and their faculty advisors must fulfill the University’s CITI Human Subjects Education requirement before IRB approval for the study can be obtained. Students whose projects are determined to not qualify as human subjects research do not need to complete CITI.

CITI information can be found at https://oprs.usc.edu/education/citi/.

Faculty Review and Approval

Once the application is submitted electronically via iStar, the faculty advisor must review and sign-off on the application before the IRB will review the study. Through this process, the advisor attests to the scientific merit of the submission, the availability of needed resources, and the department acceptance of the study.

Application Submitted to IRB for Review

After the faculty advisor sign-off, the application is routed to the IRB staff, or IRB designee for review. The IRB grants the final approval. If a study is exempt or does not qualify as human subjects research, as determined by IRB staff, no further IRB approval is required. However, any study changes that affect this determination must be submitted and approved by the IRB staff prior to initiation of changes.

The chart below provides an outline of the IRB review process, starting with online IRB submission by the researcher and ending with the IRB granting approval of the research.
Schematic of IRB Approval Process

Key:

(1.) **Principal Investigator (Faculty/Staff/Student) Designs and Submits Study via iStar:**
Investigators design their protocol and submit it via the iStar application system. Investigators must indicate if the application requires exempt, expedited, or full board review. The final determination of the review category is made by the IRB.

**NOTE:** Investigators, key personnel and faculty advisors must fulfill the University’s CITI Human Subjects Education requirement before the IRB will give final approval.

(2.) **Faculty Advisor and Department Sign-off:**
Once the application is submitted (via the online iStar application system) the faculty advisor must review and sign off on the application. In some cases, a departmental representative must also sign the application. The faculty advisor signs first. This sign-off represents consideration of scientific merit, availability of resources, or other issues at the department level.

(3.) **IRB Office:**
After department or faculty advisor approval is obtained, an initial review of the application is conducted by the IRB staff or IRB designee. At USC, the IRB staff conducts a thorough pre-review of the application to verify the correct level of review, and to evaluate the protocol and supporting documents (e.g., consent form, recruitment materials, etc.). If a study is approved as **exempt** or determined to be “**not human subjects research**,” no further IRB action is required. Any significant changes to the approved study must be submitted and reviewed by the IRB prior to implementation of changes.

For studies designated as **expedited** or **full board**, IRB review is required by a designated reviewer or the full board, respectively. (For more information on the IRB Review categories see Chapter VI: Types of IRB Review).

The possible determinations/outcomes that can be made on a study are as follows:
• **Approved** – the application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted.

• **Approved with Contingencies** – the application is complete but there are issues/changes that must be addressed before the project can begin. Once a satisfactory response to these contingencies is received the IRB will grant final approval and the research may then be initiated.

• **Deferred** – applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The researcher’s response is reviewed by the IRB and will be approved or deferred until all issues are addressed satisfactorily.

• **Disapproved** – Applications that are found to have risks that outweigh the potential benefits to subjects and/or society will receive a non-approval and the research will not be allowed. This determination can only be made by the full board at a convened meeting. Institutional administrative officials may not override this decision.

(4.) **Study Approved and PI Notified:**

The researcher will be notified through an iStar generated email when the study has been approved.

See Appendix A for an overview of the IRB Submission Process.

**Amendments and Reportable Events**

Once the application is approved, the researcher may begin recruiting subjects and conducting the study. The researcher must let the IRB know if any of the following subsequently occur:

• Changes to the original study must be reviewed and approved by the IRB through an amendment to the study via iStar before they are implemented, unless the subject is at immediate risk.

• Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (harm to subjects or others resulting from the study must be reported to the IRB promptly).

• Complaints regarding human subjects research (any complaints from the subjects or the study staff must be reported to the IRB promptly).

• Breach of Confidentiality (Confidential data that has been disclosed by any member of the study staff must be reported to the IRB immediately, for example, the theft of a laptop containing research data with names and addresses of participants).

**Continuing Review: Progress Report/Study Close Out**

All active expedited or full board (non-exempt) studies must be reviewed at least once a year. Investigators must submit a continuing review application at least one month prior to the study expiration date. The investigator must provide a progress report indicating the status of the study.
since the start of study (e.g. enrolling new subjects, enrollment closed/data analysis only, closed/final report). If the study is complete, a final report must also be submitted to the IRB in the form of a continuing review application. The requirement for continuing review does not apply to research determined to be exempt from IRB review.

For additional iStar Guidance, see Appendix B. For tips for IRB submissions, see Appendix C.
IX. iStar: The IRB Submission Tracking And Review System

1. What is iStar?

The iStar system is the USC web-based system for IRB applications. All IRB applications must be submitted through iStar, as well as continuing reviews, reportable events and changes to approved research.

2. How do I obtain an iStar account?

You must send a request by email. Below are three simple steps to obtain an iStar account:

Put “iStar Account Request” in the subject line of an email.

In the body of the email type your:

- Name
- Campus (HSC or UPC)
- School
- Division or department
- Email address

Send the email to istar@usc.edu. Within one business day, you will receive an email with your user name and temporary password. Use this information to login to your iStar account.

3. How do I request accounts for my research team?

If you are part of a research team, one person in your team can request iStar accounts for more than one person in the same email. If you wish to request an account, in the body of the email include the following information for each team member requiring an account:

- Name
- Campus (HSC or UPC)
- School or Division and Department,
- Email address

4. I forgot my password or username, how do I reset them?

Go to the iStar website (http://istar.usc.edu) and click “forgot password” or “forgot username”. Follow the instructions as prompted, and your password information will be reset. An email containing your new password and/or username will be emailed to you.

You can also call the iStar help desk at 323-276-2238, or send an email to istar@usc.edu to have your password reset.
5. My faculty advisor’s name does not appear on the list when I try to designate a faculty advisor in iStar. What should I do?

Your faculty advisor must have an iStar account AND have the faculty advisor user role in iStar. If your faculty advisor does not have an iStar account, they can send an email request to istar@usc.edu, or you can request an account on their behalf. In the email, indicate that the faculty advisor role is required.

If your advisor does have an iStar account, but is not listed in the faculty advisor question/window, they need the “faculty advisor” user role added to their account. Call the help desk at (323) 276-2238 to have it added or send a request by email.

6. How do I attach a new version of the consent form (or other document) to the study and keep the older versions?

When the application is in an editable mode (Pre-submission, Changes Requested, etc.), click the ADD button to upload newer revised versions of the same documents in Section 24.7 of iStar.

Do not delete previously uploaded documents! These must be kept in the iStar application.

Note: If the study has been approved and a revision to the approved consent is needed, an amendment to the study must be submitted to iStar before the consent is uploaded. See question 18.

7. Why do we have to submit everything with tracked changes?

Using “strikethrough” and “clean copy” documents allows the IRB to make a side by side comparison of changes so they can review and note changes more quickly. “Track Changes” copies of the informed consents are essential to keep record of changes made.

8. How do I turn on track changes?

“Track Changes” is a feature in Microsoft Word that will allow you to create edits in a document while maintaining a record of what has been removed, added, or replaced. Using this tool will allow you and the IRB to exchange documents that clearly reflect when updates and corrections have been made to an application.

To turn on the track changes feature, please do the following:

**STEP 1:** In Microsoft Word, open the document you want to revise.

**STEP 2:** In Word (2007), click the Review tab, then Track Changes.

**NOTE:** If you are using an older version of Microsoft Word: Go to Tools, click Track Changes --> Highlight Changes. Check all three boxes and click OK.
STEP 3: Make the changes you want by inserting, deleting, or moving text or graphics. You can also change any formatting. Microsoft Word uses revision marks to show the tracked changes. The two methods for track changes are as follows:

“Inline” tracked changes do not remove deleted text from a document. Instead, the text is shown with a line drawn through it, as seen below. The underlined text reflects additions to the document.

Example:

Before you decide to take part in this study, you should talk to your doctor. Your doctor will explain about the benefits and risks of the treatments available to you.

“Balloon” tracked changes will record text in balloons along the margin when it has been removed from a document.

Example:

Before you decide to take part in this study, you should talk to your doctor. Your doctor will explain about the benefits and risks of the treatments available to you.

STEP 4: After you have made your edits, save the document with the tracked changes.

Example of the file name:

parent permssn strikethru 080709.doc

STEP 5: After saving, close the file.

STEP 6: Lastly, create a “clean” version of the document with tracked changes you just saved. Re-open the tracked changes file you just created, and save it with a different file name.

Example: parent permssn clean 080709.doc

STEP 7: Remove all of the revision marks.

STEP 8: Word 2007: click the Review tab, then click the tiny arrow/pull down menu below the “Accept” icon, and select “accept all changes in document”. Re-save the document.

NOTE: Older versions of Word: go to Tools --> Track Changes --> Accept or Reject Changes and follow the prompts. After you have accepted all the changes, re-save your document. To specify whether Word should show tracked changes and how you want inserted, deleted, and changed text to

---

Revision mark: A mark that shows where a deletion, insertion, or other editing change has been made in a document.
appear, click the Track Changes tab in the **Options** dialog box (**Tools** menu).

You now have a strikethrough copy and clean copy to submit to the IRB. Use this procedure to complete revisions of documents uploaded to the iStar application.

**9. The system won’t let me submit my study.**

There are several possible reasons why iStar will not let you submit your study. Here are the most common:

- Only the Principal Investigator can submit the study. If you do not see the **Submit Application to IRB** button, you are not listed as the Principal Investigator in the application. You must be the assigned Principal Investigator (for the specified application) to submit the application. At the University Park Campus, students may submit application as PI.

- The application is incomplete. If after clicking the **Submit Application to IRB** activity you see a list of “errors”, you must complete the specified sections of the application in order to submit the application.

- Co-Investigators have not agreed to participate in the study. **All** assigned co-investigators must login, access the study, and click the **Agree to Participate** button prior to submission.

- You have not agreed to the assurances. You must indicate agreement to the PI’s assurances by checking the “I agree” box. If you are a student, you must agree to the student’s assurances by clicking the students’ “I agree” box.

**10. How do I know if I submitted the application to the IRB?**

Look under the **History** tab in the study workspace. To do this, login to iStar, and then click the name of your study (usually in blue letters). The screen will then change to the study workspace. Look in the middle of the screen and click the **History** tab. You will see various activities under this tab. If there is an **Application Submitted to IRB** activity, this means you have submitted the study. If you don’t see this activity, you have NOT submitted it.

**Note:** After you click the **Submit Application to IRB** button, it is routed to the faculty advisor (for students) and/or department/school for review and approval (sign-off). Once these approvals are received, the application is automatically forwarded to the IRB office for review. You will receive an email confirmation when the study is received by the IRB.

**11. My faculty advisor hasn’t approved my application. Is there a way to speed up the process?**

The best thing to do is call or email your faculty advisor. If they are unfamiliar with iStar, they can contact the iStar help desk at (323)276-2238 or email istar@usc.edu for help.
12. How can I give other users access to my application?

To give someone access to your application, they must have an iStar account. If they do not have one, you can request one on their behalf by emailing a new account request to istar@usc.edu. Once their account is created, you must add them to page 2 of the application.

13. I have a question about my IRB application and would like to talk to someone. Who should I call?

- If the IRB application has not been submitted to the IRB – call UPIRB (213-740-9299) or HSIRB (323-223-2340) or email (irbgara@usc.edu) the IRB student mentor for assistance.

- If you have already submitted your application to the IRB – call the IRB administrator assigned to your study or send an electronic message through iStar. To find out whom the IRB administrator is, log in to iStar and go to the study workspace. You can do this by clicking on the study title from your homepage. In the next screen, the IRB administrator will be listed in the top right of the screen. If the field is empty, call the respective IRB office. You can also send the IRB administrator a message through iStar by clicking the Send message to IRB button from the study workspace. Type your question or comment in the text box of the pop-up window, then click OK.

14. I don’t know which type of review I should choose for my study.

You can find more information about the types of IRB review in Chapter VI of this guide. If you are still unsure, you can contact the IRB for assistance. The IRB student mentor is also available to assist you.

15. Is there someone who can review my application before I submit it to the IRB?

Student investigators can contact the IRB student mentor (irbgara@usc.edu) and set up an appointment to go over the IRB application before they submit it. They can also ask their faculty advisors for assistance.

16. My faculty advisor cannot be reached to sign off on my IRB application. What can I do?

One option is to list one of your thesis/dissertation committee members as the faculty advisor in the iStar application. However, you must obtain permission from your department/school and the committee member in order to list them as the faculty advisor on your IRB application.
17. **The IRB requested a signed electronic copy of the Site Permission Letter. However, I only have a paper copy. How do I send this to the IRB?**

All documents relating to your study must be attached to the application in iStar. If you only have an original paper version of a document, you must scan the document as a PDF and attach it to your application. If you do not have a scanner, there are a number of computer labs at the University Park Campus. More information can be found at [https://itservices.usc.edu/spaces/computingcenters/](https://itservices.usc.edu/spaces/computingcenters/).

18. **I need to make changes to an IRB approved study. How do I do this?**

Changes must be submitted, reviewed, and approved by the IRB prior to implementation. Most changes must be submitted using an amendment application. You may change study personnel without an amendment provided the following is true: the new personnel has their CITI certification uploaded into their iStar profile and the personnel changes do not involve the PI or co-PI.

You can edit study personnel by going to the main page of the study, looking at the left menu titled “Manage” and clicking on the “Edit Study Personnel” button.

You can create an amendment application by clicking on the New Amendment button from the study workspace. Each question in the amendment application indicates the changes to be made to the original study application.

**Note:** The amendment application serves as a “cover memo” that lists and describes changes that will be made to the study application. Actual changes must be made in the original study application and submitted to the IRB with the cover memo. To make the actual changes, click the “View Modified Study” button and edit the originally submitted study application. Next, make the appropriate changes, click Save and then Exit. Once all changes are made, click the Submit to IRB button.

19. **Do I need to submit copies of the signed informed consent forms to the IRB?**

No. The IRB only needs to see the original, unsigned version of the informed consent form you are planning to use in your study. The IRB approved consent form has an electronic IRB approval stamp on each page. (See right margin of each consent page).

If any changes must be made to the approved informed consent form, you must submit an amendment application and receive an approval prior to using the revised document.

The approved stamped informed consent document is the only informed consent you may use in your study.

**Note:** Exempt studies generally use information sheets, which are different from informed consent forms and do not require signatures, but do require stamped IRB approval.
20. I am doing a classroom project for my methods class; does my project require IRB approval?

Classroom assignments designed to teach research methods do not require IRB approval. Faculty members design these assignments to engage students in interaction with individuals, gather data about individuals, and/or illustrate concepts covered in the course. These projects are not intended to create new knowledge or lead to scholarly publication.

Dissertations, theses, independent study projects and honors projects, however, do require IRB review and approval. These projects are designed to contribute to generalizable knowledge and do use human research subjects, thus meeting the federal definitions of human subjects research.

In the event that data obtained from a classroom project later results in new knowledge or useful/publishable information, an application should be submitted to the IRB for secondary data analysis of existing data.

For projects that do not require IRB review, faculty may direct students to experience an IRB application through the iStar Sandbox Training (http://istartraining.usc.edu). The Sandbox site allows students to familiarize themselves with iStar, the online application used for IRB submissions, and work on mock IRB submissions.

Library research or content analysis of public documents is not human subjects research. If students or faculty are uncertain if a classroom project must be reviewed by the IRB, they should contact the IRB.
X. Investigator Reporting Responsibilities after IRB Approval

After IRB approval is obtained, investigators must keep the IRB informed about study changes, problems, or updates. Certain events or circumstances require reporting within a specified amount of time depending on the risk they may pose to study participants. Additionally, study suspension and/or termination must also be reported to the IRB. These requirements and guidelines are described below.

Reportable Events

Adverse Events (AE) and Unanticipated Problems Involving Risks to Subjects or Others (UPX)

In the event of a Serious Adverse Event (SAE) or an Unanticipated Problem (UPX), the student investigator is required to submit a written report to the IRB, within the time frame required by USC policy depending on the type of event being reported. The student investigator's report must contain enough information for the IRB to determine whether the event increases risks to participants or requires a change to the research design.

Definitions

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.

Adverse events (AE) are undesirable and unintended, though not necessarily unanticipated, physical, or emotional harm, or occurrences in a human subject.

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

- **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.

- **Related or possibly related** to participation in the research (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 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.

• **Protocol Deviation** refers to those occasions when the procedures described in the protocol are accidentally or intentionally not adhered to. Deviations can result when new staff are not adequately trained, or when records are not properly maintained. The PI, research staff, faculty advisor or sponsor/monitor can determine which deviations or errors must be reported to the IRB. There is no regulatory language that defines those that meet the level of required reporting.

When the choice is made to report an adverse event or protocol deviation, it should be submitted through iStar as a reportable event.

### Proposing Changes to Previously Approved Research Projects

#### Amendments

An **amendment** is a change to an IRB approved research project. IRB review and approval of amendments are required before investigators can modify IRB approved research projects, except when modification is necessary to eliminate apparent immediate hazards to the subjects. Any proposed change to a previously approved **full board** or **expedited** study must be submitted to the IRB as an amendment to that project. It may be reviewed by the expedited review procedure (i.e. by one reviewer) or by the convened IRB (i.e. reviewed by a committee), depending on the risk associated with the change. Minor changes are those that do not significantly alter the project’s risk/benefit ratio and these may qualify for expedited review. All amendments must be submitted through the iStar system.

**Note:** Proposed changes to a study determined “exempt” by the IRB, do not require an amendment application unless the changes are more than minor and alter the risk/benefit ratio. Administrative changes in exempt projects 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.

### Annual Review or Study Closure

#### Continuing Review

The IRB will conduct continuing review of USC human subjects research studies at intervals appropriate to the degree of risk, but not less than once per year. Investigators should submit continuing review applications at least 30 days before the end of the approval period for their study in order to avoid lapses in IRB approval. Once the approval period for a given study has expired, it is considered a lapsed study and all research-related procedures must stop, except in situations in which doing so would jeopardize the welfare of the subjects. **If a study expires, 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, a new approval period (i.e. one year) is established and the study activities may resume.
Study Closure/Completion by Investigators

A research project is closed when subject accrual, subject follow-up and data analysis are completed at USC. Once a study is closed, no further research activity (including interactions with subjects and data) may occur and the researcher is no longer required to submit yearly continuing review applications.

Researchers must notify the IRB that a study is complete through iStar. If your study is exempt, complete a “Close Study” activity in iStar. For all other studies, submit a Continuing Review application. Once the continuing review application is reviewed by the IRB, the investigator is no longer required to submit 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. Therefore, an investigator should only close a study when he/she is no longer enrolling new subjects, using research interventions on existing subjects, collecting data (including follow-up data), or performing any other tasks that were identified as part of the study.

Noncompliance

Failure to follow the regulations governing human research, requirements or determinations of the IRB, or institutional policies constitutes noncompliance. This definition may include action of any University employee or agent, such as investigators, research staff, IRB member, IRB staff, employees or institutional officials.

Noncompliance is different from protocol deviations that occur during the course of clinical research. Very rarely, a protocol deviation may be considered noncompliance when the deviation compromises the rights and welfare of subjects.

All reports of alleged noncompliance or inappropriate involvement of human subjects in research may come to the attention of the IRB from different sources and by various means. Alleged noncompliance reports may come from an IRB member, an investigator, a subject or subject’s family member, institutional personnel, institutional committees, the Clinical Trials Unit (CTU), the USC Compliance Office, the media, anonymous sources, or the public. Reports can be submitted in writing or verbally (e.g. not submitted through iStar). Reports of alleged noncompliance or inappropriate involvement of humans in research are investigated by IRB, Office for the Protection of Research Subjects, or both when appropriate.

Study Suspension and Termination: PI and IRB Role

Suspension of a Study by the IRB

In cases of Serious Adverse Events (SAEs), Unanticipated Problems Involving Risks to subjects or others (UPXs/unanticipated events), researcher noncompliance, or protocol violations reported to the IRB, the IRB may suspend a study to ensure subject safety.

Termination of a Study by the IRB

Upon investigation of any SAE, UPX, noncompliance, or protocol violations, the convened IRB may vote to terminate a study. A PI can address the issues that caused a termination via an amendment in iStar unless the IRB specifically requires that the PI submit a new study.
Appendix A: UPIRB Submission Process

Pre-submission

Student Principal Investigator (PI) completes iStar application.

Click “Send Study Ready Notification.” Co-investigators are required to sign-off. Study will come back to PI once all signed-off. (*This action is only required for Thematic groups who have other students/faculty listed as co-investigators.*)

Faculty Review

Click “Submit Study to UPIRB.” Student PI signs off. Study then automatically routed to Faculty advisor for sign-off.

Departmental*

Study will be routed to IRB Advisor for Dept sign-off. Once signed off, study will be automatically routed to UPIRB.

Awaiting IRB Administrator Assignment

UPIRB Administrator takes ownership of the study and conducts staff review.

Staff Review

Study is sent back if additional information/clarification is required. If no concerns and the study qualifies for exemption it will be approved by UPIRB staff. If study is expedited or requires full review, it is routed to IRB Chair/Committee.

Changes required by IRB Staff

Student addresses IRB concerns, resubmits study for IRB review.

**In expedited/exempt review**

IRB staff reviews student PI responses. If all issues have been addressed and the study qualifies for exemption the study will be approved by the UPIRB Staff. If the study qualifies for expedited/full board review the study is routed to the IRB Chair/committee for review and approval.

Contingencies Pending

The application may be returned to the student for further clarification.

Contingency Verification

Once approved, the IRB approval notification is sent via iStar to Student PI and Faculty Advisor.

*Departmental review not required by all departments
Appendix B: iSTAR Guidance

The IRB Submission Tracking and Review System (iStar) https://istar.usc.edu is the online IRB application system used at USC. All IRB related correspondence and documentation is submitted online through iStar, resulting in an efficient process for both the investigators and the IRB.

There is also an iStar training site (http://istartraining.usc.edu/) where student investigators can familiarize themselves with the system before submitting a real application. The training site may be used by student investigators as a classroom exercise. For classroom projects, IRB submission is not required.

What you can do in iStar System:

- Create and edit an electronic application for submission of studies and grants to the Institutional Review Board
- Submit a single application electronically to any of the three participating IRBs
- Add investigators and study personnel to an application
- Prepare the application via “smart forms” that present only those sections that are applicable and relevant to your study
- Attach electronic or scanned documents to the study (.pdf, .doc and .xls documents are allowed)
- Print out the application in a printer-friendly version
- Use context-specific guidance to assist in answering questions consistent with guidelines and regulations
- Validate the application before submission to catch common mistakes and reduce the number of changes required after submission
- Track the progress of the application as it is automatically routed for review and signoff to the appropriate organizations (i.e., faculty advisor, division and department reviewers) before being received by the IRB
- Receive email notifications any time the application is sent back for requested changes by a reviewer
- Receive the approval letter via email once the study is approved
- Download a copy of the approval letter and approved consent forms (posted online with the study and available at any time)
- View a time stamped log of all changes made to the application and any correspondence sent between the study team and the IRB
Reminder when Picking Level of IRB Review:

As previously mentioned, Human Subjects Research projects generally fall under one of the following three types of IRB review: **exempt, expedited, or full-board**. A unique category, **Not Human Subjects Research (NHSR)**, is used when the research **does not** meet the federal definition of human subjects research, or in specific cases when using coded data.

**Minimal risk** or **less than minimal risk** projects generally fall under the exempt or expedited categories of review. For studies that are deemed greater than minimal risk, a full-board review will be required.

Studies meeting the **exempt** studies criteria generate an application of approximately 20 questions long; below is a detailed explanation of the online iStar IRB application.

Studies meeting the **expedited and full board** studies criteria consist of approximately 40 questions with various sub-questions.

Student investigators should consult with the IRB, faculty advisor, and/or the student mentor if they are unsure about the level of review required for their research.

**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.

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8 The explanations provided in this appendix are generally written for students on the University Park Campus conducting social and/or behavioral research.
Page for Dalar Shahnazarian

Welcome to your Personal Folder, the central resource for managing your Study applications. Your Personal Folder provides all the tools you need in order to complete and submit a Study application for consideration by the IRB/COI. Use the following guidelines to submit your Study:

- Use the New Study button on the left to open the smart form application for a new study proposal.
- Remember that all questions marked with a red asterisk are required.
- Use the Continue >> button to save and move to the next screen in the application.

The area shows all Study Applications, Amendments, Continuing Reports, and Reportable Events which currently require you to perform an action. Click on the item name for more information.

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Committee on Clinical Investigations, CHLA, Los Angeles, CA 90021, (323) 361-2265
Health Sciences Institutional Review Board, USC, Los Angeles, CA 90033, (323) 223-2640
University Park Institutional Review Board, USC, Los Angeles, CA 90086, (213) 821-5272
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)  
- [ ] USO/CHLA Collaborative Review  
  
1.2. * Full Title of Research Protocol  
  
1.3. * Short Title  
  
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. * Select which IRB you are requesting review from:  
- [ ] USC - Health Sciences IRB (HSIRB)  
- [ ] USC - University Park IRB (UPIRB)  
- [ ] CHLA - Committee on Clinical Investigations (CCI)  
  
Save | Exit | Hide/Show Errors | Print... | Jump To: | 61. Project Identification and Abstract | Continue...
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

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
Section 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

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

1. Provide a brief (1 to 2 paragraph) description of the study in \textit{LAY LANGUAGE}. This should not be a scientific abstract.

2. Describe the subject population being studied.

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

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

Available Submission Activities

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

[Submit Request]
Appendix C: Tips for Better IRB Submissions

The following is an overview of issues that frequently arise from student submissions to the IRB. USC student research varies greatly, and thus not all issues apply to every study, but it is useful to note commonly identified IRB concerns. Using these tips to avoid common problems can speed up the IRB review process.

**Anticipating Questions from the IRB:**

The questions below reflect items the IRB will evaluate in reviewing the research application. Careful consideration of these questions, when applicable, will help expedite the submission process and can prevent IRB requests for clarification or additional information.

- 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?

**Justify Data Collection Methods:**

When designing a project, investigators should use only those procedures necessary for answering the hypothesis and avoid implementing unnecessary procedures or obtaining data that will not be used.

Removing unnecessary procedures can save investigators considerable amounts of time in gaining IRB approval. The following procedures should be used only when required 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
- Video-taping or photographing human subjects in field observations
- Using experimental techniques
- Employing deception as part of study design
- Physical or psychological intervention or treatments

Avoiding Pitfalls:

The following section lists common errors students encounter when submitting an application to the IRB. These issues are seen on both USC campuses.

- Not allowing enough time for IRB review and approval
- Submitting inconsistent information between the iStar application, protocol, and informed consent documents
- Lack of human subjects education (CITI) by Principal Investigator or Faculty Advisor
- Failure to obtain IRB Authorization Agreement and/or permission letter when conducting research at non-USC sites
- Failure to identify revisions made to protocol or consent documents (i.e., not using Track Changes)
- Not understanding the difference between research and patient care/program delivery
- Failure to delineate research procedures from medical care in iStar application and in informed consent
- Failure to document or provide documentation of:
  - Study logistics
  - Billing procedures (who gets charged - Medicare/insurance/research participants/etc.)
  - Credentials of researchers performing medical procedures
  - Locations of services and procedures (evidence of hospital privileges, physician referrals, and budget for procedures must be documented)
- Confusion about HIPAA requirements when conducting research using protected health information (Does HIPAA apply? Do I need to request a HIPAA waiver?)

Save Time–Provide Sufficient Detail in the iStar Application:

- Identify PI, Co-investigators and Faculty Advisors
- Identify those who will obtain informed consent
- Check the box for Prospective Collection of Specimens/Data when applicable
Define inclusion/exclusion criteria
Provide complete study abstract (include all elements requested in question)
Provide clear regulatory status of medical devices used in study
Clarify procedures for data gathering, recording, or sharing
Include data collection form
Assess risk/benefit ratio (Is R/B favorable? Do benefits outweigh risks?)
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 Issues:
- The publication of compensation amounts is not allowed at HSC
- Using the word “Free!” (may be perceived as coercive by the IRB)
- Potential benefits overstated (medical care is not a benefit)
- Emphasis on medical treatment instead of research

Acceptable IRB Submissions:
- Include complete answers to avoid returned submissions
- Include appropriate IRB forms and required study documents
- Are submitted to the correct IRB
- Use clear language and well described concepts
- Do not use jargon
- Are reviewed by the Faculty Advisor for completeness and merit
Who Can Help?

A Faculty Advisor is the most important student resource. Faculty advisors should maintain close oversight of student research before it is submitted to the IRB, oversight should continue throughout the life of the study. For more information on Faculty Advisors, refer to booklets “Are You a Faculty Advisor” and “Mentoring USC Student Researchers”.

The IRB Student Mentor is also available to assist student investigators with the IRB process. Contact the mentor via email irbgara@usc.edu or by phone (213) 821-4219 to make an appointment.

Other Resources:

Office for the Protection of Research Subjects
Tel: (213) 821.1154
Fax: (213)740.9299
E-mail: oprs@usc.edu
https://oprs.usc.edu/

USC Institutional Review Board
Tel: (323) 442.0114
Fax: (323) 224.8389
E-mail: irb@usc.edu
https://oprs.usc.edu/
Appendix D: Helpful Links

**Department of Defense Directive (DoD)**: Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research

**Food and Drug Administration (FDA)**

**Office for Human Research Protections (OHRP)**

**National Science Foundation (NSF)**
- National Science Foundation (NSF) - Social, Behavioral & Economic Sciences
- NSF - Frequently Asked Questions and Vignettes (Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research)

**National Institutes of Health (NIH)**
- NIH - Human Subjects Research and IRBs
- NIH - Recombinant DNA Advisory Committee (RAC) on Recombinant DNA and Gene Transfer Certificates of Confidentiality.
- National Human Genome Research Institute
- OER Human Subject Web Site: FAQs from Applicants (Office of Extramural Research)

**U.S. Department of Education**
- U.S. Department of Education Protection of Human Subjects in Research Website
  (Research involving minors in school settings)
- Protection of Pupil Rights Amendment (PPRA) 34 CFR Part 98
  (Research involving surveys with minors in school settings)
- Family Policy Compliance Office

**U.S. Department of Energy - Protecting Human Subjects Homepage**

**U.S. Department of Health and Human Services (DHHS)**
- Office of Research Integrity (ORI)
- Office of Research Integrity Policies, Regulations and Statutes

**Other Federal Agencies and Guidance**
- Code of Federal Regulations Index at the General Printing Office
- National Bioethics Advisory Commission (NBAC)
Appendix E: Glossary of Common IRB Terminology

ADVERSE EVENT/EFFECT (AE)
Any untoward physical or psychological occurrence in a subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, or a symptom/disease associated with the research. Adverse events may or may not have a causal relationship with the research.

ASSENT FORM
An assent form is used when subjects are between 7-17 years of age. Assent is a minor’s affirmative agreement to participate in research. The assent form must include simple language written at the appropriate reading level of the youngest subject in a given age range.

BENEFITS
Most research does not provide direct benefit to subjects. Furthermore, it may be many years before the results of the research are publicly known and/or made useful to society or to affected subjects. Vague promises to benefit science or society are not adequate descriptions of benefit whether in a consent form or a research application. When there is no direct benefit, subjects should be told that they will not benefit from participation. However, they can also be so informed when their participation may benefit society. Compensation to subjects is not considered a benefit.

BIAS
Occurs when objectivity is impaired by personal gain or personal judgment. In clinical studies, bias is minimized by blinding and randomization.

BIOLOGICS (OR BIOLOGICAL PRODUCTS)
Biologics, as regulated by the U.S. Food and Drug Administration, are made from a variety of natural sources. Like drugs, biologics are used for the prevention, treatment, or cure of disease or injury. Examples include vaccines, blood and blood products, allergenic extracts, human cells and tissues, gene therapies and test to screen potential donors for infectious agents.

CERTIFICATES OF CONFIDENTIALITY
Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifiable information from research participants to any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects,
Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

**COGNITIVELY IMPAIRED**
Having a disorder (psychiatric or developmental) that affects cognitive or emotional functions that impair the capacity for sound judgment and reasoning. Other conditions that may impair judgment and reasoning are: being under the influence of drugs or alcohol, having a degenerative disease, having a terminal illness or disability.

**CODED PRIVATE INFORMATION**
Coded private information means that all identifying information that would enable anyone to ascertain the identity of the individual to whom private information or specimens belongs to is coded with a letter or symbol.

Note: A key to the code enables linkage of private information or specimens. A study may qualify as not human subjects research (NHSR) if the coded data was not collected for the proposed study AND the investigator does not have access to unlink the coded information. The IRB must make this determination. Guidance regarding coded private information and the IRB process can be found at: [http://www.hhs.gov/ohrp/policy/cdebiol.html](http://www.hhs.gov/ohrp/policy/cdebiol.html).

**CONFIDENTIALITY**
Confidentiality refers to the process of protecting private data or specimens and its use. Plans for managing data in a confidential manner must be appropriate to the study being proposed.

Care should be taken to explain a plan to maintain confidentiality the iStar application (e.g., the use of numbering or code systems, encryption of data, the use of passwords for electronic data access, or safely locked files in private offices). Replacing names with pseudonyms or codes also adds protection. Furthermore, the investigator should describe who has access to the data and under what circumstances, if any, a code system may be broken. Subjects should be informed whether the data collected will be retained, and, if so, for what purpose, what period of time, and whether (and when) data will be de-identified or destroyed.

**CONSENT FORM**
A consent form is used in a study when the subject is 18 years of age or older and competent to make the decision to participate. Parents/legal guardians of minors must provide consent to allow their children to participate in a study.

Informed consent templates and guidance are available at:
UPIRB: [http://oprs.usc.edu/upirb/forms/](http://oprs.usc.edu/upirb/forms/)
HSIRB: [http://oprs.usc.edu/hsirb/forms/](http://oprs.usc.edu/hsirb/forms/)

**CONTINUING REVIEW**
A periodic IRB review of a research study to evaluate whether risks to participants remain reasonable in relation to potential benefits and to verify that the study continues to meet regulatory and institutional requirements. Continuing review should be conducted at intervals appropriate to the degree of risk but not less than once per year. ([45 CFR 46.109(e); 21 CFR 56.109(f)](http://www.hhs.gov/ohrp/policy/cdebiol.html))

**DEBRIEFING**
Occurs when subjects are provided with previously undisclosed information about the research project.
DECEPTION
Deception is the intentional misleading of subjects or the withholding of full information about the nature of the study. Use of deception increases ethical concerns of a study because it interferes with the ability of the subject to give informed consent. Deception is arguably necessary for certain types of behavioral research, because full knowledge by the subject might bias the results.

Subjects have the right to full disclosure as soon as possible after participation in deception research. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects must still receive full disclosure of the purpose of the study as soon as possible. Deception in research should be used rarely and may only be employed with the approval of the IRB.

DEVICE/MEDICAL DEVICE
A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Examples of devices are diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic equipment.

ELIGIBILITY CRITERIA
These are defined requirements for subject inclusion in a given experiment. Eligibility criteria examples are age, sex, state of health, a defined range for a biologic measure (e.g. glucose level or cholesterol), blood cell counts, etc.

ETHNOGRAPHIC (FIELDWORK/ANTHROPOLOGY RESEARCH)
Ethnography is the study of people and culture. Ethnographic research involves observation of a person or group in their own environment, often for long periods of time.

EXEMPT RESEARCH
Exempt research is Human Subjects Research that meets one of the minimal risk categories in the federal regulations (45 CFR 46).

EXPEDITED REVIEW
A review of proposed or continued research involving no more than minimal risk and/or for minor changes in approved research. Review is performed by IRB Chair or designee, rather than the full board.

FULL BOARD REVIEW
Review of proposed or continuing research (primarily greater than minimal risk research) by a convened IRB meeting, at which a majority of the voting membership is present.

GRANT
Financial support provided for a research study. Fund givers typically do not exercise strict control over the grants they have awarded (whereas contracts are prescriptive).

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
HIPAA's Privacy Rule of 2003 prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from disclosing protected health information without written authorization from the individual (HIPAA Authorization).

IDENTIFIABLE PRIVATE INFORMATION
Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “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 health care record) (45 CFR 46.102(f)(2)). “Identifiable” means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g. Social Security #).

INCLUSION/EXCLUSION CRITERIA
The pre-determined conditions of a clinical trial that allow or excludes subject participation. These criteria are factors such as age, gender, type and stage of a disease, previous treatment history, and/or other medical conditions.

INFORMED CONSENT
Informed consent is the process of informing potential subjects about the key facts of a research study. Subjects in a study must be informed of the details of their participation, the possible risks and benefits of study participation and the voluntary nature of their participation. The process of informing and discussing research with potential subjects is a critical ethical principle in human subjects research. The informed consent document serves as documentation that consent was provided by the subject or legal representative, before any study procedures took place.

INSTITUTIONAL REVIEW BOARD (IRB)
A specially constituted review body designated by an entity to review human subject research protocols to protect the welfare of human subjects participating in research.

INTERNATIONAL STUDIES
International research must adhere to recognized ethics codes or regulations such as: 45 CFR 46 (Policy for the Protection of Human Research Subjects), the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. Consent and recruitment documents must be in the language of the subjects and be readable and understandable by the subjects.

Ethical regulatory responsibilities for research involving human subjects may differ outside the United States from those set forth in federal and institutional policies. Differences in language, cultural and social history, and social mores can be challenging for U.S. researchers. In addition, national policies such as the availability of national health insurance, philosophically different legal systems and social policies may make U.S. forms and procedures inappropriate. However, federally funded research activities in a foreign country may be approved if accommodations to U.S. regulations are made.

Note: the U.S. Health and Human Services agency has yet to deem another country’s policies “equivalent” to those of the U.S.

The investigator is encouraged to contact the IRB to discuss these issues. Investigators will be required to obtain a research ethics review board (IRB equivalent) approval letter for research conducted outside the U.S. for studies that are more than minimal risk. Many institutions outside of the United States have ethics committees to review and approve research. For minimal risk studies an approval letter or permission letter from the research site may be acceptable by the USC IRB; however, this decision will be determined on a case-by-case basis.
MINIMAL RISK
The federal regulatory definition of minimal risk is 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” (45 CFR 46).

MINORS
Persons who have not attained the legal age to consent to treatment or procedures in research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

PLACEBO
A chemically inert substance used in controlled clinical trials to provide data that helps distinguish and determine whether improvement and side effects reflect imagination or anticipation rather than the actual power of a drug.

PRIMARY DATA
Primary data is data obtained from direct contact with, or observation of, one or more people for the purpose of collecting data from or about them.

PRINCIPAL INVESTIGATOR (PI)
The scientist or scholar with ultimate responsibility for the design and conduct of a research project.

PRIVACY
Privacy refers to a research participant’s willingness to allow access to themselves and their personal information. Privacy considerations include the timing and setting where private information is obtained, the nature of the information requested or obtained, and who receives/uses this information.

The IRB considers the protection of subject data/privacy during all stages of a study. The manner in which subjects are identified and approached for participation in research may be also be of concern. For example, a participant might not want to be identified in a place that could potentially embarrass them, such as a pregnancy counseling center or drug rehabilitation facility.

The IRB requires investigators, or other relevant parties, to explain how the privacy of study participants and their private data will be maintained during the course of the study and how study data will be retained after study closure. Investigators are required to provide this information in the IRB application.

PROSPECTIVE STUDIES
A study designed to follow groups of subjects for an extended period of time with defined outcomes.

PROTECTED HEALTH INFORMATION (PHI)
PHI is health information transmitted or maintained in any form or medium that includes ALL of the three following parts:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
• relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

**PROTOCOL**
The formal design or plan of an experiment or research activity.

**RANDOM ASSIGNMENT (RANDOMIZATION, RANDOMIZED)**
A method of assigning subjects to different treatment groups based on chance.

**RECRUITMENT/RECRUITMENT MATERIALS**
Recruitment is a process by which potential subjects are informed about study participation. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls, must accurately describe the study and be non-coercive. The use of all recruitment materials in a non-exempt research project must be approved by the IRB before use.

**RESEARCH**
Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 102(d)].

**RETROSPECTIVE STUDIES**
Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews, surveys or measurements.

**RISK**
Risk is the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study. Both biomedical and behavioral research may entail some levels of risk to a person's health or physical or social well being. Student researchers must consider the following risks when conducting their study:

**STRESS FROM STUDY QUESTIONS/SURVEYS**
Subjects may feel stress caused by the research questions or procedures. Questions can raise painful memories, embarrassment, or unresolved issues. Interviews with survivors of personal or state violence may be at risk. Questions about illegal behaviors or immigration status may cause embarrassment, feelings of guilt or distress or raise legal concerns.

Although most psychological risks are minimal and transitory, investigators must be aware of the potential for harm. The IRB will want to know how such outcomes will be minimized or addressed.

**BREACH OF CONFIDENTIALITY**
A breach of personal confidentiality is often the greatest risk to participants in social and behavioral human subjects research. Reputation or employment may be affected or insurance coverage may be jeopardized if confidentiality is compromised.

Information about subjects' activities may place them at risk of legal action. For example, if a researcher asks children about discipline, information about child abuse may be disclosed and must be reported to the appropriate authorities. Similarly, if subjects divulge information about gang activities, disclosure of that information could place the subjects at risk of harm or legal action.
RISK/BENEFIT RATIO
A comparison of the potential benefits to the risks of participating in a research study.

SECONDARY DATA
Data that has already been obtained, either individually or in aggregate form. Use and sharing of secondary data which contains personal identifiers are subject to the requirements set forth under federal regulations. Secondary data, which do not contain personal identifiers, are exempt from these requirements (the IRB must make this determination).

SERIOUS ADVERSE EVENT (SAE)
A SAE is defined by the FDA as an undesirable experience associated with the use of a medical product in a subject that results in death, a life threatening experience, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly and/or birth defects or requires intervention to prevent permanent impairment or damage.

SPONSOR
A person, federal agency, corporation, or other entity that provides funds for a research project.

STUDY ARM
Any of the treatment groups in a randomized trial.

SUSPENSION/TERMINATION
IRB approval is suspended/terminated and all research activity is halted as the result of: unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR Part 46, or not following IRB requirements/determinations.

UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS (UPX)
Any event that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

VOLUNTARY
Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's willingness to participate (or to continue to participate) in a research activity.

VULNERABLE POPULATIONS
Any subject may be “vulnerable” when a power differential exists between researcher and subject.

Federal regulations specifically define only groups as vulnerable: pregnant women/fetuses/neonates (45CFR46, Subpart B), prisoners (45CFR46, Subpart C), and children (45CFR46, Subpart D).

Pregnant women, fetuses, and neonates (Subpart B)
Pregnant women, fetuses, and neonates are considered vulnerable because of the shared risk and/or compromised health status.

Prisoners (Subpart C)
Prisoners are considered vulnerable because incarceration impacts their ability to make a voluntary and non-coerced decision regarding whether to participate as subjects in research.

**Children (Subpart D)**

Children are considered vulnerable because they may not be able to completely understand the information presented, nor the risks and benefits the study may entail.

People who cannot competently understand the information regarding a study and cannot give true consent, (e.g., individuals with psychiatric, cognitive, or developmental disorders, substance abusers, students, and workers) may also be considered vulnerable populations in certain human subjects research.