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1. HUMAN SUBJECTS RESEARCH OVERVIEW

The University of Southern California is committed to conducting its biomedical and behavioral research involving human subjects under rigorous ethical conditions. All human subjects research at USC must receive IRB review. The University’s Institutional Review Boards (IRB) comply with federal, state, and local regulations.

The University has also agreed to adhere to the statements of ethical principles as described in The Nuremberg Code, The Belmont Report: Ethical Principles and Guidelines for the Human Subjects of Research, and the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

This fundamental commitment to the protection of human participants applies to all USC research involving human participants regardless of whether the research is funded through the university, the federal government, a non-profit or industry sponsor and regardless of the location of the research.

Among the goals of the USC Human Subjects Protection Program (HSPP) are to assure excellence of the HSPP, maintain innovative and compliant Human Subjects Policies and Procedures, and retain accreditation. A university-wide research ethics program and continuing educational programs assure that USC remains ahead of ever changing ethical and regulatory standards.

This chapter will describe the role of regulatory bodies, the IRB application process, and the role of RCs and investigators in human subjects research at USC including informed decision making, protecting subjects, and enabling research to proceed.

Overall, the PI is responsible for the entire study and the research coordinator is responsible for implementing the study and supporting the ethical, regulatory, and sponsor requirements.

HUMAN SUBJECTS RESEARCH/CLINICAL TRIALS DEFINED

At USC, studies that use human participants to evaluate or understand drugs, devices, biologics and answer questions of a social-behavioral nature are subject to federal, state, local laws and institutional policies. Human subjects research involving an unapproved FDA regulated test articles and one or more human subjects and/or the results are intended to be submitted later to the FDA as part of an application for a research or marketing permit is a clinical trial. For purposes of this chapter, “clinical trials” and “clinical investigations” are synonymous with human subjects research.

The federal definitions of both “research” and “human subjects” must be met for a study to be classified as “human subject research”.

**Research** – “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46).
**PROTECTING HUMAN RESEARCH SUBJECTS AT USC**

**Human Subject** – “a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information”. In FDA regulated research: a human subject is “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.”

**2. REGULATORY AUTHORITIES**

National, local, and institutional entities establish the laws and regulations by which human subjects research must be conducted. RCs and PI should have a familiarity with the general functions and missions of these organizations. An overview follows. The laws and policies governing the conduct of human subjects research can be complicated. If you are not certain what your obligations are in a given situation, contact Office for the Protection of Research Subjects (OPRS) or the Office of Compliance.

**OHRP**

The Office for Human Research Protections (OHRP/HHS), is charged with ensuring that institutions receiving federal funding protect the rights, welfare, and well-being of subjects involved in research. In order to receive research support from HHS, Department of Defense, Department of Energy, or other federal sponsors of human subjects research, an institution must execute a Federalwide Assurance (FWA) where it represents that it will comply with the Common Rule (45 CFR 46). Each department or agency that provides research funding may have requirements beyond what is described in the Common Rule.

In addition, OHRP provides educational programs and materials, maintains regulatory oversight, and offers advice on ethical and regulatory issues related to human subjects research. OHRP provides guidance documents on topics such as informed consent, vulnerable populations, and protocol review. These documents are all available on the OHRP website [www.hhs.gov/ohrp](http://www.hhs.gov/ohrp).

OHRP conducts not-for-cause audits of institutions/investor, and receives, reviews, and responds to incident reports from “assured” institutions. OHRP audits usually result in a “Determination Letter” issued to the institution/investigator associated with the research that it inspects. These Determination Letters are made public on the OHRP website and represent the office’s position on compliance issues.

An RC or Principal Investigator (PI) may contact OHRP directly for inquiries related to your studies.

8/15/2013
The U.S. Food and Drug Administration (FDA / HHS), regulates clinical research on drugs, devices, and biologics. The FDA is responsible for assuring the safety, efficacy, and security of these experimental therapies or diagnostics.

The FDA is also responsible for reviewing clinical trial applications for investigational drugs and devices and biologics. These are known as IND (Investigational New Drug), IDE (Investigational Device Exemption), and biologic license applications.

RCs and PIs should be familiar with the sections of Title 21 of the FDA Code of Federal Regulations that pertain to drugs, devices, biologics and financial disclosure. The FDA also publishes guidance and updates each year on topics such as drug safety, pharmacology, IRB responsibilities, and monitoring practices, in addition to others. You may read or download these documents from the FDA website. Determination letters detailing findings that the FDA has identified for correction in clinical trials it regulates are found here.

www.fda.gov

The Health Insurance Portability and Accountability Act (HIPAA), also known as the “Privacy Rule”, establishes minimum Federal standards for safeguarding the privacy of individual’s identifiable health information. The law, overseen by the Office of Civil Rights within HHS, generally prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from using or disclosing protected health information (“PHI”) without written authorization from the individual.

USC requires all faculty, staff and other USC employees, as well as students, volunteers, agents and certain other individuals who have access to patient health information through USC providers, to complete an online course on the HIPAA Privacy Rule. The course may be accessed on the Office of Compliance website:

http://ooc.usc.edu/hipaa-privacy-education-program

In addition to federal regulations, researchers are also expected to follow California laws addressing human subjects research. The California Health and Safety Code contains provisions addressing human subjects research (HSC 24170). If you have questions regarding how to apply state regulations to a specific research project, you should contact the Chair of the IRB and/or the Office of Compliance.
PROTECTING HUMAN RESEARCH SUBJECTS AT USC

**USC INSTITUTIONAL POLICIES AND PROCEDURES**

The USC Human Subjects Protection Program (HSPP’s) addresses the regulation, approval, and oversight of human subjects involved in research conducted under the auspices of the University. USC’s Policies and Procedures for Human Subjects Research are periodically revised to remain current with federal and state regulations as well as institutional policies and Good Clinical Practices (GCP). Research Coordinators and other study staff are encouraged to regularly consult the policies and procedures during the submission, review, and conduct of human subjects research.

These policies and procedures address most research situations involving human subjects. If an issue arises that is not addressed by the policies, or you do not know how to apply policies, contact the IRB.

http://oprs.usc.edu/rules/

**3. REVIEW AND APPROVAL OF RESEARCH**

Institutional Review Boards are committees charged with reviewing research activities involving human subjects that are conducted at an institution or by an institution's faculty and students. The federal government and many organizations that fund research require IRB review of the research they fund. Unfunded or investigator-initiated research also requires IRB review.

**IRB DEFINED**

USC’s Institutional Review Board (IRB) is charged with assuring that the rights, safety, and well-being of human subject participants is maintained and that research is conduct in a manner consistent with the approved protocol. The IRB reviews research protocols to ensure the activity complies with University policies as well as federal, state, and local laws. The IRB has the authority to approve, require changes to the study procedures, or disapprove proposed research projects.

At USC, there are four IRBs: one on the University Park Campus that primarily reviews social/behavioral research and three on the Health Sciences Campus that primarily review biomedical research. Researchers may be required to get approval from additional bodies before the IRB will conduct a review. These are called ancillary committees. Examples include institutional biosafety and radiation safety.

Federal regulations require that the IRB have at least five members. These members must include individuals from academic disciplines relevant to the research being reviewed and must include at least one non-affiliated member (at USC this person is referred to as a Community Member). The IRB should be diverse in terms of race, gender and cultural background. IRB members can be faculty, staff or students from the institution, as well as members of the local community. IRB members must have the necessary experience and expertise to competently evaluate the proposed research.
In the review process, the IRB may approve, defer, or approve with contingencies. Contingencies are modifications required by the IRB.

The IRB reviews the following aspects of each study:

- Description and research methodology*
- Equitable selection of subjects*
- Risks minimized*
- Acceptable ratio of risks to benefits*
- Vulnerable status of subjects*
- Incentives for participation
- Privacy and confidentiality*
- Monitoring (frequency and mode)*
- Informed consent content (required elements and types) and process*
- Conflict of interest
- Departmental resources/appropriate expertise of PI and study staff
- Sponsor Requirements
- Scientific values
- HIPAA requirements

* Approval criteria for IRB review of research

**ISTAR IRB APPLICATION SYSTEM**

The IRB Submission Tracking and Review System (iStar) is the online IRB application system used at USC. All IRB related correspondence and documentation must be submitted online through iStar. An iStar training site, FAQ's, how to create an iStar account and other information may be found at oprs.usc.edu/istar

iStar is used for the following functions, among others:

- Create and edit an electronic application for submission to the IRB
- Identify study staff
- Attach study documents
- Track the progress of an application as it is automatically routed for review and signoff to the appropriate organizations (i.e., division and department reviewers) before being received by the IRB
- Communications between IRB and study staff
- Receipt and download of approval letter and all approved study documents

The RC is often responsible for the iStar submission. The PI, however, must always review and approve it before it is submitted for IRB review. The PI must personally answer conflicts of interest questions though the RC may verify that this is completed. Changes to the IRB submission required by the sponsor as well as other sponsor interactions are the responsibility of either the RC or PI.
The IRB requires that the RC, PI and all other study personnel complete training on conducting human subjects research. These requirements vary according to the type of research, funding, and roles of the individuals involved in research. All training required by the USC IRB is available online through CITI.

http://www.citiprogram.org

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<tr>
<th>COURSE</th>
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<th>DESCRIPTION</th>
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| Human Subjects Protections    | Mandatory for Principal Investigators and Key Personnel conducting human subject research.  
                                  | “Refresher” training must be repeated every 3 years.                         | Pertains to ethics and principles, laws and regulations, informed consent, vulnerable populations, and more. |
| Good Clinical Practice (GCP)  | Mandatory for Principal Investigators and Key Personnel conducting Full Board clinical trials research.  
                                  | GCP training is only required once.                                          | Pertains to data credibility and accuracy, protection of subject rights, safety, and confidentiality of subjects/data. |
| Responsible Conduct of Research (RCR) | Mandatory for all students on NSF grants, as well as some NIH training awards, and PHS traineeships. Cannot be substituted for Human Subjects Protections training. | Pertains to ethics, data integrity, collaborative research, and more. The USC Office of Compliance provides the certificate of completion. |
| Conflict of Interest          | Mandatory for all HHS investigators. Must be retaken every four years.       | Pertains to the responsibilities of investigators and institution in managing conflicts of interest |
| Health Insurance Portability and Accountability Act (HIPAA) | Mandatory for Principal Investigators and Key Personnel who have access to private identifiable health information. | Pertains to Federal Privacy Rules (available on USC Office of Compliance). |
INFORMED CONSENT

RCs may be responsible for writing or administering informed consent and therefore need to be knowledgeable about both content and process. Informed consent is about protection and respect for research subjects. The requirement and content of consent varies according to the level of review and nature of the research. Informed Consent must contain:

- The purpose and procedures involved in the research
- Alternatives to participation
- All foreseeable risks and discomforts to the subject (e.g. physical injury, psychological, social, or economic damage)
- The benefits of the research to subject and/or society
- Person to contact for answers to questions or in the event of a research-related injury or emergency
- In the state of California, clinical trial subjects must be presented with a copy of the Experimental Subject’s Bill of Rights

The USC IRB Informed Consent template can be found online at: http://irb.usc.edu/hsirb-forms.

Waiving one or more of the elements of informed consent may be permitted by the IRB for some research activities when justified. Informed consent elements that do not apply to a specific study need not be provided in the consent.

In all cases, the informed consent must:

- Be presented in a language understandable to the subject
- Minimize the possibility of coercion or undue influence
- Allow subjects sufficient time to consider participation
- Allow subjects to refuse or discontinue participation at any time
- Distinguish between research and routine medical care
- Be appropriately presented for the subject’s physical, emotional and psychological capacity, and vulnerable status
- Assure that subject understands what participation entails

Other types of informed consent include: parental permission, assent, verbal consent, short form, and information/fact sheet. The study protocol and study population will dictate which of these are required. For further information on each, see the OPRS website.

http://oprs.usc.edu/informed-consent/

CERTIFICATES OF CONFIDENTIALITY (COC)

Certificates of Confidentiality are documents issued by the National Institutes of Health (NIH) and other federal agencies to protect identifiable research information from compelled disclosure. Certificates of Confidentiality are designed to protect subject data that, if disclosed, could have adverse consequences.
for subjects’ financial standing, employability, insurability, or reputation. A Certificate of Confidentiality allows the researcher and others who have access to research records to resist providing subject information in any civil, criminal, administrative, legislative, or other proceeding at the federal, state, or local level. NIH funding is not necessary to obtain a Certificate of Confidentiality.

DEPARTMENTAL REVIEW

At USC, all research conducted on the Health Sciences Campus must have departmental approval before the IRB will conduct its review. The department chair must attest to the scientific merit and feasibility of the application, the availability of needed resources, and departmental acceptance of the study. This process also serves to alert department chairs of all research under their purview, as well as provide an opportunity to note potential conflicts of interest which they may be aware of due to their role of reviewing all outside consulting under the Relationships with Industry policy.

ANCILLARY COMMITTEES AND OTHER ENTITIES

Depending on the nature of the study being proposed, approval from certain ancillary committees may be required before the IRB will issue final approval.

At USC, authorizations or approvals for research may be required from:

- Clinical Investigations Committee (CIC)
- Clinical Trials Office (CTO)
- USC/LAC Departments of Pathology
- Stem Cell Research Oversight Committee (SCRO)
- Institutional Biosafety Committee
- Radiation Safety Committee
- Scientific Conduct Committee
- Data Safety Monitoring Board/Committee
- Conflict of Interest Review Committee (CIRC)

While certain approvals must be obtained before IRB will issue final approval, others such as CTO and pathology provide information or specimens and may be concurrent. The IRB will provide guidance to study staff questions regarding what ancillary approvals must be obtained based on materials, methods, or protocol. The CIC reviews all cancer studies before submission to the IRB.

DATA SAFETY MONITORING BOARDS

The purpose of a Data Safety Monitoring Boards (DSMB) is to independently evaluate data, ensure evaluate adverse event reporting, and suspend or terminate research when necessary. This oversight is distinct from areas the IRB reviews and approves. DSMBs may be required for clinical trials that are
blinded, involve high risk intervention(s), and/or include vulnerable populations. There may be other cases where the IRB decides that DSMB oversight is necessary. The Clinical Investigations Support Office (CISO) has an ongoing Data Safety Monitoring Committee that regularly evaluates all cancer studies. All studies submitted to HSIRB must include a monitoring plan even when a DSMB is not required.

**CLINICALTRIALS.GOV**

ClinicalTrials.gov is a federal database for all publicly and privately supported clinical studies of human subjects conducted around the world. The FDA Amendment Act (FDAAA) of 2007 requires responsible parties in applicable clinical trials to register trials and submit summary results to ClinicalTrials.gov.

In addition to the FDA, some funding agencies may require registration. The site is a resource to patients who are seeking to participate in clinical trials, and helps ensure that null studies (studies with negative results) are published. Study subjects must be informed in the consent document that clinical trial information will be submitted to the National Institutes of Health/ National Library of Medicine (NIH/NLM) for inclusion in the clinical trial registry databank.

It is the sponsor’s responsibility to register clinical trials when they begin, provide timely updates, and submit summary results to clinicaltrials.gov. Sponsor-investigator trials must be registered by the Principal Investigator.

“Applicable Clinical Trials” include:

- **Drugs and biologics trials**— clinical investigations, other than phase I clinical investigations, of drugs or biological products subject to FDA regulation

- **Device trials** – trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance required by FDA


**LEVELS OF IRB REVIEW**

The population being studied or the level of risk associated with a research activity will influence the level of IRB review. There are three levels of review:

- **Full Board Review**
  - Presents more than minimal risks to subjects and/or
  - Does not qualify for Expedited or Exempt Review

Examples of human subjects research activities reviewed by a Full Board convened IRB include novel investigations with experimental drugs or devices and documentation of illegal behaviors with links to subjects’ identifiable information.
• **Expedited Review**
  - Meets one of the [9 federally defined Expedited Review Categories](45 CFR 46.110)
  - Reviewed by an IRB Chair/designee/staff
  - Not greater than minimal risk (including privacy risk)

Examples of expeditable research activities include collection of blood samples from healthy adults, and collection of biological specimens or data by noninvasive means (saliva, cheek swab, x-rays).

• **Exempt Review**
  - Must meet one of the [6 federally defined Exemption Categories](45 CFR 46.101)
  - Must be reviewed by an IRB Chair/designee/staff
  - Must not present greater than minimal risk* (including privacy risk)

  * Minimal risk means 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.

Examples of Exempt research activities include measuring blood pressure and conducting anonymous educational tests.

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**CONTINUING REVIEW**

In accordance with federal regulations, the USC IRB requires that ongoing research protocols undergo continuing review at intervals appropriate to the degree of risk, but not less than once per year. The frequency and extent of continuing review for each study is based upon study type, risk, uniqueness of procedures, and vulnerability of subjects.

The continuing review application (in iStar) involves updates on the items requested in the initial submission, including any adverse events and any changes in number of subjects. Continuing review affirms that the study continues to sufficiently protect subject safety and welfare and that documentation of the study is complete, accurate, and up-to-date.

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**AMENDMENTS**

Amendments are changes to an IRB-approved research protocol. Amendments must be submitted in iStar and approved by the IRB before being implemented. Examples include revisions to consent documents, changes in PI, and inclusion of additional risks. Amendments involving more than minor changes or changes that pose more than minimal risk will be subject to Full Board Review.
REPORTABLE EVENTS

Federally funded and/or FDA-regulated research must disclose the following to the sponsor, IRB, and (when requested) FDA or OHRP:

- Adverse Events
- Unanticipated problems involving risks to subjects or others
- Protocol violations
- Serious or continuing noncompliance with federal regulations
- Serious or continuing noncompliance with requirements of the IRB
- Suspensions or terminations of IRB approval

Reportable events must be disclosed to the IRB through the Reportable Events Application in the iStar system. Report contents must include the IRB study number; a detailed description of the event, incident, experience, and or outcome; and a description of corrective actions that have been taken or are proposed. The IRB determines when these events must be reported to federal agencies.

The different terms used by OHRP (Unanticipated Problems involving risks to subjects or others) and FDA (Adverse Events) are among the most common reportable events and easily confused. The table below distinguishes the two.

<table>
<thead>
<tr>
<th>Regulatory Terminology for Unanticipated Problems vs. Adverse Events</th>
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<tbody>
<tr>
<td><strong>Event Type</strong></td>
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<tr>
<td>Context</td>
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<tr>
<td>Scope</td>
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<tr>
<td>Involve</td>
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### Expectation vs. Reporting

| Expectation   | Unanticipated | • Anticipated (an increase in frequency, duration or intensity beyond expectations)  
|               |               | • Unanticipated  
| Reporting     | Prompt reporting to IRB required (not to exceed 10 working days)  
| How to Report | iStar reportable event application  

### Significant New Information/Findings (SNIF)

Federal regulations require that subjects be provided with any significant new information or findings (SNIF) obtained during the course of the research that may affect a subject’s willingness to continue participation.

A SNIF may be reported to the IRB by a study sponsor, PI or study staff. The IRB may require that all previously-enrolled subjects be provided with the new information one of two forms: (1) a summary of changes subjects need to know to remain in the study (SNIF form), (2) a revised consent form. The IRB must review and approve the new information to be provided to the research subject prior to implementing changes that would result from the SNIF. When study changes are necessary to eliminate apparent immediate hazards to subjects, they may be implemented prior to IRB approval but must be reported to the IRB. Keep in mind that the consent may have to be rewritten for all new subjects and re-consent may be required for currently enrolled subjects.

When appropriate, the SNIF form must clearly state that the information in the previously signed consent form remains current and valid. When the new information addresses several elements of informed consent and/or changes not easily described, the information should be incorporated into a revised consent document to provide sufficient context regarding new information and document the participant’s decision to remain in the study.

Examples of situations that may require you to provide new information to subjects are as follows:

- Changes to the procedures that may affect a subject’s willingness to continue in the research
- Identification of new risks or that risks previously described are known to occur with greater frequency or severity than previously reported
- Significant changes in costs to subjects
- New conflict of interest for a researcher
- Notification of findings from this study or related studies
STUDY CLOSE OUT

Upon study completion, the PI or other study personnel must submit a Close Study application to the IRB through the iStar system indicating the study status as “closed”. Doing so confirms the study is finished and that no further interactions with subjects or their data will take place. A research project must be closed when subject accrual, subject follow-up and data analysis are completed. The IRB, in consultation with the RC or PI, may also close a study when active data analysis and publication have ceased, even if the researcher retains records that may identify individual subjects. Once a study is closed, no further research activity, including data analysis, may occur. Once the study is closed in iStar, yearly continuing review applications are no longer required. Additional research activities using data collected in an approved study may constitute new human subjects research studies subject to separate IRB review.

If a PI wishes to enroll new subjects to a closed study, a request can be made in iStar to reactivate the study. Once the study has been reactivated, a continuing review application must be approved by the IRB before study activities can resume.

It is permissible for a study to be closed at USC, and still be open to accrual at other sites. In the event that a serious adverse event or an unanticipated problem occurs at a non-USC site after closure of the study at USC that may affect the study subjects, the USC RC is required to submit a report to the IRB via iStar.

4. SUMMARY OF THE IRB SUBMISSION PROCESS FOR CLINICAL TRIALS AT USC

Once the negotiations between the Clinical Trials Office (CTO) and the sponsor have taken place and the contract is established, the IRB submission may proceed:

- RC/PI obtain iStar account
- Takes required training
- Completes and submits IRB application (including Informed Consent)
- Obtains departmental review/approval
- IRB/Ancillary Committees review/approve application
- PI/RC address contingencies
- IRB accepts contingencies and issues approval
- PI/RC submit amendments, continuing review, adverse events as required
- Study Closeout
5. REFERENCES

Conflict of Interest in Research: USC policy that addresses financial and other interests that have the potential to compromise research integrity
http://ooc.usc.edu/Conflict-Interest-Research

Certificates of Confidentiality: Issued by NIH to protect identifiable research information from forced disclosure
http://grants.nih.gov/grants/policy/coc/

ClinicalTrials.gov: Registry and results database of clinical research studies
http://clinicaltrials.gov/

Collaborative IRB Training Initiative (CITI): Online training program for Human Subjects Protection, Good Clinical Practice, Responsible Conduct of Research and Conflict of Interest
www.citiprogram.org

iStar: IRB electronic submission system
https://istar.usc.edu/

Office for Human Research Protections (OHRP): Federal entity responsible for protection of research subjects and regulatory oversight of research supported by the US Department of Health and Human Services
http://www.hhs.gov/ohrp

Office for the Protection of Research Subjects (OPRS): USC Office responsible for protection of research subjects and oversight of USC IRBs
http://oprs.usc.edu/

U.S. Food and Drug Administration: Federal entity responsible for protecting public health by assuring the safety and efficacy of drugs, devices, biologics, cosmetics, food, and products that emit radiation
http://www.fda.gov/

USC Health Sciences IRB: IRB responsible for review of studies conducted at the USC Health Sciences campus (mostly biomedical clinical studies)
http://oprs.usc.edu/hsirb/

USC Human Subjects Protection Program (HSPP): USC Policies and Procedures related to the protection of research subjects
http://oprs.usc.edu/rules/
USC University Park IRB: IRB responsible for review of studies conducted at the USC University Park campus (mostly socio-behavioral studies)

http://oprs.usc.edu/upirb/