Chapter 6:

# USC Institutional Review Boards (IRBs)

## Chapter Contents

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This chapter describes the purpose, role, composition and general procedures of the USC Institutional Review Boards (IRBs). The USC IRBs are responsible for the review all human subjects research conducted at USC.

## 6.1 Description of USC IRBs

This chapter covers the composition of the IRB membership, the roles and requirements of IRB members, Chairs, Vice-Chairs, and reviewers at the University of Southern California (USC). Additionally, this chapter explains the use of consultants, the role of IRB staff, voting requirements, and IRB record keeping.

There are four Institutional Review Boards at the University of Southern California (one on the University Park Campus, and three on the Health Sciences Campus). These IRBs review and approve research in accordance with Department of Health and Human Services (DHHS) regulations in 45 CFR 46. For studies involving products regulated by the Food and Drug Administration (FDA), the University of Southern California IRBs review research and comply with the requirements set forth in 21 CFR 50 and 56, as well as 21 CFR 312 and 812. In addition, the IRBs comply with HIPAA and its regulations set forth in 45 CFR 160 and 164 and California law as it pertains to human subjects research.

USC IRBs have been delegated the following authority by the Institutional Official in his delegation memo dated 11/23/2005:

- USC IRBs have the authority to approve, disapprove, or suspend human subject research projects. No USC faculty, staff, or student may conduct human subjects research without obtaining approval from the appropriate IRBs at either the Health Sciences or University Park Campuses.
- USC IRBs have the authority to observe, or have a third party observe, the consent process and the conduct of the research.

# 6.2 The Membership of the IRB Committees

## Number, Qualifications and Diversity of Members

Each IRB has a minimum of five, but generally between eight and fifteen members with varying backgrounds to adequately review the research activities commonly conducted by the Institution. Major clinical and selected basic science departments are represented to provide the experience and expertise sufficient for review of the research activities conducted at the Institution. The IRB member with appropriate scientific expertise for each protocol will be designated to review the application. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. Also, the IRB consists of at least one member is not otherwise affiliated with the Institution and is not part of the immediate family of a person who is affiliated with the Institution.

To enable each IRB to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice, each IRB includes persons knowledgeable in these areas and may include representatives of administration. Each IRB is sufficiently qualified through the experience, expertise and diversity of its members – including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes – to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Because the IRBs may review research that involves a vulnerable category of subjects (children, pregnant women, prisoners, and handicapped or mentally disabled persons), each IRB includes – as members or consultants as appropriate – individuals who are knowledgeable about, and experienced in, working with these categories of subjects.

Every nondiscriminatory effort will be made to ensure that each IRB does not consist entirely of men or entirely of women. The Institution will consider qualified persons of both sexes – so long as no selection is made to the IRB on the basis of gender.

## Alternate Members

When deemed necessary by the IRB Chair, and when requested by department Chairs or deans, alternates will be appointed for IRB members. Formally appointed alternate IRB members may represent IRB members, provided the alternate's qualifications are comparable to the primary member to be replaced. The IRB membership rosters identify

the primary member(s) for whom each alternate member substitutes. Prior to the IRB meeting, materials required for review are made available electronically through iStar to all members.

The IRB minutes document when an alternate member replaces a primary member. When an alternate member substitutes for a primary member, the alternate must receive and review the same material the primary member received or would have received. Members and their alternates may not both vote. Alternates are not counted as "members" in establishing the numerical quorum of the IRB, except when they substitute for members during the IRB meeting. Alternates are invited to attend all IRB meetings, whether they are eligible to participate as voting members or not, in order to assure familiarity with the IRB practices and continuing education.

### Ex-Officio Members

The IRB may include ex-officio members depending on the relevance of their office and their expertise and experience. The positions they hold preclude full IRB membership and therefore ex-officio members are not voting members of the IRB.

### IRB Student Member

The IRB student member is a USC student selected by the Office for the Protection of Research Subjects and the UPIRB for outstanding commitment to the USC community, knowledge about scientific research, and legal and ethical principles guiding research involving human subjects. The IRB student member reviews IRB applications, prepares review comments, and is a full voting member of the UPIRB.

The IRB student member's participation in the IRB process increases the level of student involvement in the effort to help USC research maintain the legal and ethical standards established by law and society.

## 6.3 IRB Member Requirements

### Selection and Appointment

The members and alternates of the IRBs may be recommended for appointment by their Dean or Department Chair. Non-affiliate members not associated with the Institution are identified by interest and relevance and are recommended for appointment by members

of the IRB, IRB staff, Departments or Schools. The formal appointments of IRB members are made by the Vice President of Research. Typically, individuals who are responsible for business development are not selected to serve as IRB members.

IRB committee membership lists can be found on the IRB websites:

- **HSIRB** http://oprs.usc.edu/hsirb/hsirb-membership-list/
- **UPIRB** http://oprs.usc.edu/upirb/membership/

## Length of Service

Appointments to the IRBs are for a period of 1 year. Expertise and diverse membership are expectations for both campuses. Continued tenure on the IRB is at the discretion of the IRB Chair/Director.

Evaluations of IRB composition and individual members are conducted at the end of the fiscal year at the time of IRB budget review/approval. Appointment letters indicating satisfactory evaluation of returning members are sent to IRB members at the end of one fiscal year for the next fiscal year. The duties and responsibilities of IRB members are stated in appointment letters from the Vice President of Research. Members who fail to meet IRB expectations, as outlined in the IRB appointment letters, are sent correspondence informing them that their service is no longer needed.

## Duties

Members of each IRB or their designated alternates are required to:

- Participate in agreed upon number of convened IRB meetings
- Review the IRB application and informed consent form for research proposals
- Pre-review and complete a written critique of research proposals including review of clinical trial protocol, grant application, questionnaire(s), advertisement(s), investigator's drug brochure, and informed consent form when assigned as a reviewer by the Chair, Vice Chair, or IRB staff
- Review expedited review actions of the Chair, Vice Chair, and IRB designee

- Review and promptly inform the Chair of corrections or additions to Full Board meeting minutes
- If designated by the IRB Chairperson, review and verify that contingencies have been satisfied and further review by the IRB is not required. This does not constitute expedited review.

Selected IRB members may be appointed as expedited reviewers and can review changes to previously approved research during the period covered by the original approval. Changes that may be reviewed by an expedited reviewer are those that do not alter the original approval criteria. Additional training is provided to IRB members who are appointed to be expedited reviewers.

For additional information and examples, refer to Appendix I – Verification that IRB Contingencies were Satisfied.

The IRB prohibits the participation in IRB review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Refer to Section 5.5 – IRB Members and IRB Consultants Conflict of Interest for more information.

## Attendance Requirements

Members and alternates serve at the discretion of the OPRS, IRB Chair and/or Institutional Official. Members who do not attend meetings will be removed from the IRB. If a member is unable to attend a meeting, the IRB office must be informed, sufficiently in advance, so that an alternate can be invited to attend. Frequent absences among members will be cause for removal.

## Honorarium to Non-Affiliate IRB Members

An honorarium is paid to non-affiliate IRB members based on meeting attendance. Faculty members are not paid to attend meetings.

## Liability for IRB Members

IRB members and alternates fulfill their administrative and institutional service responsibilities to the University, in part, by serving on an IRB committee. Accordingly, the University will indemnify IRB members in the event of a legal dispute relating to the

actions of the committee, provided that the IRB member has acted in good faith and in accordance with federal requirements, state and local laws and University policy.

## Training of the Chair, Vice Chairs and Members

Chairs and Vice Chairs are expected to attend professional conferences (including PRIM&R conferences) to enhance their education and IRB expertise. IRB members and alternates are initially trained as guests (non-voting capacity) of the IRBs, and also offered support to attend appropriate courses, and local or national meetings. Ongoing education of the IRB membership includes an education session preceding an IRB meeting approximately once per month. In addition, access to educational materials is provided to all IRB members (such as "IRB: A Review of Human Subjects Research"). IRB members and alternates are required to take the Protection of Human Subjects education modules provided online through the CITI website https://www.citiprogram.org/.

## Evaluation of IRB Members

The duties and responsibilities of IRB members will be stated in appointment letters from the Vice President of Research. Expectations and subsequent evaluation of IRB members will be addressed through different mechanisms at HSC and UPC.

- At UPC, IRB members will be re-appointed annually if expectations are met. The re-appointment letter will acknowledge that the IRB member has been evaluated and satisfied the membership criteria described in HSPP policy and as provided in the appointment letter.
- At HSC, the IRB appointment letter will provide the criteria upon which a member will be evaluated and retained but will not state a term of service. An annual letter will acknowledge that their performance has been evaluated and found satisfactory.
- For any member who fails to meet the expectations outlined in the IRB appointment letter correspondence will be sent informing them their service is no longer needed

The IRB members will be informally evaluated annually by the IRB Chair and Director. During the evaluation, the following areas will be considered when applicable:

- Knowledge and application of federal regulations and ethical principles

- Knowledge and application of IRB policies and procedures
- Constructive participation in IRB discussion
- Attendance (notifies staff when confirming or declining to attend meetings)
- Participates in educational sessions/completes required member training
- Reviews projects as requested in a timely, comprehensive, knowledgeable manner and resolves as many issues with the investigator as possible, prior to meetings
- Reviews all IRB application materials, meeting minutes, and expedited actions

The IRB Chairs/vice Chairs are informally evaluated by the Vice President of Research, and the OPRS on an annual basis. They are evaluated on how well they manage IRB meetings, attendance, knowledge of federal regulations and state laws, collegiality with fellow members, IRB staff, and their review (quality / quantity / timeliness) of IRB applications.

## 6.4 IRB Use of Consultants

Each IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that available on the IRB. These consultants are not counted as "members" in establishing the numerical quorum for each IRB and may not vote with the IRB. An honorarium for consultants may be provided at the discretion of the IRB Chair and/or the IRB Director.

If it is determined that a consultant is needed for the review of a protocol, the IRB Chair or Vice Chair will ask the IRB members and colleagues to refer them to individuals that would have experience with the specific type of research being reviewed. The consultants will be provided with the same information that the primary and secondary reviewers receive.

The IRB member Conflict of Interest policy also applies to consultants. The IRB prohibits the participation in IRB review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Refer to Section 5.5 – IRB Members and IRB Consultants Conflict of Interest for more information.

Copies of the consultant review are supplied to the IRB members. Consultant(s) may be asked to attend the meeting for further clarification, if deemed necessary by the IRB

Chair or Vice Chair. Key information from the consultant will be included in the IRB meeting minutes and a copy of all documentation will be kept in the study file.

## 6.5 IRB Support Staff

The IRB support staff assists the Chair and Vice Chairs in IRB activities. The support staff is responsible for submitting written correspondence to investigators regarding IRB actions. IRB staff shall document meeting minutes in accordance with federal regulations and guidance. Required documents are listed in Section 6.8 – IRB Records.

IRB staff training may be provided by the IRB Director, OPRS, or IRB Chair. Staff member training also includes taking the CITI education courses, familiarity with federal, state, and local regulations, and institutional the policies and procedures. A Bachelor's Degree or prior IRB experience is required. Annual reviews are conducted to evaluate IRB staff.

The IRB staff will be evaluated annually, at the time of budget reviews, by the IRB Chair/Director. The following criteria: knowledge of the IRB process and regulations, continuing training, work attendance, and, overall ability to function as an asset to the IRB, will be measured. If a staff member is found to be deficient in a particular area or areas, they will be further educated on the IRB process. If gross errors have been uncovered, further actions, as described in University policies will be taken. The evaluation will be reflected in the annual salary determination.

### IRB Support Staff Duties:

- Screen submissions before IRB review
- Prepare IRB meeting agenda
- Prepare meeting minutes (see "Meeting Minutes" in Section 6.8 – IRB Records)
- Prepare correspondence
- Facilitate review of IRB applications
- Customer service
- Database and information management
- Train student mentors

- Respond to subject concerns
- Follow office procedures
- Follow IRB policy and procedures and make suggestions/recommendations
- Undertake and provide education and training
- Intra-institutional relationships
- Handle meeting logistics
- Review and approve non-material contingencies such as those related to personnel changes (excluding change of PI), punctuation and wording or verification that something missing has been supplied
- Preliminary review of initial/continuing review documents (confirm all required documents have been submitted by the investigator, confirm the consent document submitted by investigator matches the one on file, identify issues and concerns for IRB consideration)

Selected IRB staff may be appointed as IRB members (or alternate members). Additional training is provided to IRB staff who are also IRB members.

For additional information and examples, refer to Appendix I – Verification that IRB Contingencies were Satisfied.

## 6.6 IRB Chairs and Vice Chairs

### Chairperson

#### Selection and Appointment

The Chair is selected from among the faculty of the Institution and appointed by the Institutional Official. The Chair should have previously served as a member of the IRB.

#### Selection Criteria

The criteria used to select a Chair include experience with, and knowledge of, applicable federal regulations, state laws, and Institutional policies. They must be willing to commit their service to the IRB; must have past experience as an IRB member; and must

demonstrate excellent communication skills, along with an understanding of clinical research. They must also demonstrate a thorough understanding of ethical issues involved in clinical/social behavioral research.

### Length of Term/Service

The term of appointment of the Chair is determined by the Institutional Official in consultation with the Executive Director of the Office for the Protection of Research Subjects.

### Attendance Requirements

The Chair is required to attend the majority of the convened IRB meetings.

### Duties

The Chair of the IRB convenes and chairs the meetings of the IRB. The Chair may conduct or delegate expedited review of research that qualifies as expedited, review the responses of investigators to contingencies in expedited studies or studies that qualify for the expedited procedure. The Chair reviews and approves expeditable amendments in previously approved research, unless the change affects the approval criteria. The Chair may delegate such authority to IRB expedited reviewers.

### Project Referrals

The Chair may, at their discretion, refer the review of a research project to the IRB of the other campus if it is determined that more appropriate expertise lies in the other IRB.

## Vice Chairpersons

### Selection and Appointment

Vice Chairs are selected from among the faculty at the Institution and are appointed by the Institutional Official (the Vice President of Research) in consultation with the Chairs / IRB Director and Executive Director of the Office for the Protection of Research Subjects. The Vice Chairs must have previously served as members of the IRB.

### Length of Service

The term of appointment of the Vice Chair is determined by the Institutional Official in consultation with the Chairs / IRB Director and the Executive Director of the Office for the Protection of Research Subjects.

### Attendance Requirements

Vice Chair will be assigned to Chair an IRB meeting when the Chair is unable to conduct the meeting.

### Duties

The Vice Chairs of the IRB are designated by the Chair to carry out expedited review of research that qualifies for such review. The Vice Chairs shall be authorized by the Chair to review the responses of investigators to contingencies of the IRB (to secure IRB approval) and to review minor changes in previously approved research during the period covered by the original approval. The Chair, Vice Chairs, IRB Director, or IRB staff assigns the primary reviewers to pre-review new research proposals submitted to the IRB for consideration at the Full Board meetings.

## 6.7 IRB Voting Requirements

Reviews of proposed research are conducted at a convened IRB meeting at which a majority of the members are present. At least one IRB member whose primary concerns are in non-scientific areas, one member whose primary concerns are in scientific areas, and one non-affiliate member must be present. In the event a majority of members are not present, or there is no member whose primary concerns are non-scientific, or a non-affiliate member is not present, the meeting will not be called to order (or if any of these circumstances arises after the meeting has been called to order, it will be adjourned or suspended until quorum is reestablished) and will be rescheduled. The IRB staff will monitor the members that are present at the meeting and determine that the meetings are appropriately convened and remain so.

In order for the research to be approved at the convened meeting it must receive the approval of a majority of the members present at the meeting. The IRB roster will show which members are in attendance for each vote taken during an IRB meeting.

Votes submitted prior to a convened meeting by mail, telephone, fax or e-mail are not permissible. Comments of the absent members may be submitted and considered by the attending IRB members.

## 6.8 IRB Records

### IRB Membership Roster

The IRB maintains rosters of IRB membership including: name, earned degrees, representative capacity, experience (such as board certifications and licenses) sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the Institution. Changes to the IRB membership roster are reported to OHRP by the IRB Staff or IRB Director.

### Written Procedures and Guidelines

The IRB maintains written procedures as required by 45 CFR 46.103(b)(4), (5).

### Meeting Minutes

For each IRB, an IRB administrator will maintain detailed records of meeting minutes that will specify which members were present, that a quorum was maintained for each action, the number of votes for each action during the meeting, documentation of a non-scientist member for each vote, and documentation that an IRB member knowledgeable about or experienced in working with specific/vulnerable populations was assigned as a reviewer and/or was present for the vote.

Each IRB will keep a roster of all members and, for each action, record which members voted. This document will be kept separate from the distributed minutes.

Additionally, IRB staff shall document all meeting minutes according to federal regulations and the requirements listed below.

The IRB meeting minutes include:

- Confirmation that quorum was maintained for each vote
- Attendance for each action
- Summary of discussion of controversial issues (if any) and their resolution

- Record of IRB decisions (actions taken by the IRB)
- Record of voting (including the number of members voting for, against, and abstaining) for each action
- The basis for requiring changes in or disapproving research
- Names of IRB member(s) recused and not present during the discussion or vote in any research protocol under review and of those who abstain due to conflicts of interest
- Description of the materials reviewed for both new and continuing review proposals. Such materials might include the IRB application, clinical protocol, investigators brochure, informed consent form documents, continuing review form, primary reviewer's evaluation (for continuing review) and any other materials submitted for review
- All applicable waivers are discussed and documented (with justification) in the IRB minutes including, waiver or alteration of informed consent and written informed consent
- Protocol specific determinations on studies involving vulnerable populations (45CFR46 Subparts B, C, D) are documented and justified according to the regulations
- Approval period for initial and continuing reviews
- Rationale for significant risk/non-significant risk device determinations
- If an IRB member has a Conflict of Interest regarding a study being reviewed, they will recuse themselves from the review of the study. The name and reason for absence will be included in the minutes
- When an alternate member replaced a primary member

Minutes from each IRB meeting are distributed to all IRB members, to the Vice President of Research and relevant institutional administration for review according to the Federalwide Assurance. IRB members are required to review the minutes and note any corrections or additions at the first meeting following distribution of the minutes.

## Records Retained in the IRB Files

IRB files contain the following documents and information for each study:

- iStar application
- Draft/Approved consent documents
- Clinical protocol, including amendments/revisions
- Investigators brochure(s)
- Grant application(s)
- Scientific evaluations, if any, that accompany the proposals
- Budget
- Supporting information that accompanies the studies (staff reviews, recruitment documents, IRB reviews)
- Amendments
- Reportable events
- Category of approval for exempt, expedited, Full Board (when necessary), and continuing review submissions
- Progress reports submitted by investigators
- All continuing review activities
- Reports of injuries to subjects
- Statements of significant new information/findings provided to subjects
- Emergency use reports
- IRB minutes
- Correspondence between the IRBs and investigator

## Record Retention Requirements

Copies of all documentation relating to IRB review, even when a project is cancelled without subject enrollment, are maintained by the IRB office. Generally, records are maintained for a minimum of three years after completion of the research or as determined by the University's policy or sponsor requirements. Additionally, in accordance with federal HIPAA privacy regulations, records containing protected health information are retained for at least six years after completion of the research. However, USC, like many research institutions, retains IRB research records indefinitely.

For additional information, refer to the USC Record Retention Policy.

## Access to Files

IRB records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

# 6.9 Development, Approval, and Maintenance of IRB Policies and Procedures

The USC IRB Policies and Procedures are written and applied according to federal regulations and state and local laws. In addition, University policies and procedures, and accrediting and funding agencies policies will be considered. To assure continued compliance, the following will be conducted:

- USC IRB policies and procedures are to be reviewed every three years and when changes in regulations, laws, and institutional policies necessitate revision
- USC IRB policies and procedures are developed and maintained by the Human Subjects Working Group under the direction of the Executive Director for the Office of the Protection for Research Subjects
- The HSPP is charged with the appropriate implementation and enforcement of IRB policies and procedures consistent with other University policies and procedures

## Investigator Responsibilities with Respect to Policies

The investigator will review USC IRB policies and procedures as part of the required initial training for conducting human subjects' research at the University of Southern California. Current policies and procedures are located on the IRB website at http://oprs.usc.edu/rules/. It is the responsibility of the investigator to routinely view the IRB website for new or revised IRB policies and procedures. The investigator should contact IRB staff for clarification of policies and procedures, when necessary.

## IRB Staff Responsibilities with Respect to Policies

IRB staff will routinely view the OHRP and FDA websites for issuance of guidance documents, changes in regulations, and determination letters. The IRB Working Group will contact the Office of General Counsel and Office of Compliance, when necessary, to discuss changes and assist in the interpretation of federal, state and local regulations affecting IRB policies and procedures. The IRB staff and Office for the Protection of Research Subjects staff will provide educational sessions to the IRB members and staff regarding IRB policies and procedures, as well as updates or revisions.

The IRB staff will use the IRB policies and procedures posted on the IRB website when reviewing IRB applications. The IRB staff may consult with other IRB officials for guidance in applying the IRB policies and procedures. If the IRB staff notices that a policy or procedure is inaccurate or out of date, he/she should bring it to the attention of the IRB Director who will communicate to the Human Subjects Working Group. It is the responsibility of all IRB staff to assist in keeping the IRB policies and procedures current and applicable to the daily processes of the IRB offices and to follow the policies as stated.