

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 2.2
Member Appointment, Compensation, and Responsibilities

Policy

The UCSD-designated Institutional Official for Human Subjects Protection (i.e., FWA signatory), who is accountable for the HRPP, in consultation with the current IRB Chairs, the Director of the HRPP, and a majority of the IRB members on the IRB to which the Chair will be appointed, appoints a Chair for each IRB.

The Chair should have at least 1 year of experience as a regular IRB member. Typically, the Chair's experience would be with the Committee to which he/she is appointed. The Chair is appointed for 5 years and may be re-appointed based on their concurrence and that of the Institutional Official and the majority of the Chair's Committee.

The Chair is empowered to temporarily suspend the conduct of human research deemed to place individuals at unacceptable risk pending IRB review. The Chair is also empowered to temporarily suspend the conduct of a study pending IRB review if he/she determines that an investigator is not following federal, state, local, University of California, and/or UCSD IRB/HRPP standard operating policies and procedures and guidelines. The Chair may delegate any of his/her responsibilities, as appropriate, to other qualified and duly appointed members of the IRB including the IRB Vice-Chair.

A Vice-Chair will be appointed to each IRB. The Vice-Chair will be nominated by the IRB Chair and will be approved by a majority of the IRB member on the IRB to which the Vice-Chair will be appointed. The Vice-Chair is appointed for 5 years and may be re-appointed based on their concurrence of the IRB Chair and the majority of the Vice-Chair's Committee. The Vice-Chair may assume all the responsibilities of the Chair when so designated by the IRB Chair, as noted above.

IRB members will be selected in accordance with applicable UCSD policies on committee service. The selection of members and confirmation of alternates will be conducted by the IRB at a convened meeting by majority vote.

Members will serve on the IRB for a term of 3 years. Members may be re-appointed for terms based on their concurrence and that of their department chair and the Institutional Official.

A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. Performance standards apply to IRB participation: each regular member

is expected to attend at least eight (of 12) monthly meetings per year, and to submit reviews for ten of 12 meetings annually. A member who is not performing his/her responsibilities as expected may be removed by the Chair of the Committee in consultation with the Director of the HRPP. The Chair may be removed from that position by a two-thirds vote of the full membership of the Chair's Committee at a convened meeting. When unexpected vacancies occur, an alternate member may be selected to fill the vacancy.

IRB senior staff, including the Director and Associate Directors, will have training and experience appropriate to their management responsibilities and competencies including a thorough knowledge of applicable federal, state, and university policies relevant to research involving human subjects, and program management experience. IRB Administrative Staff will be clerical and administrative personnel with training, experience, and credentials appropriate for the day-to-day management of the IRB's activities. Evaluation and written performance of the IRB Director, Associate Director and other IRB staff occur on an annual basis in accordance with institutional policies. In compliance with institutional employment policy, the evaluations are maintained within Human Resources under the jurisdiction of the Dean's Office, School of Medicine.

The IRB Chairs will be evaluated biannually assessment based on 5 criteria: 1) leadership, 2) participation, 3) technical knowledge, 4) teamwork, and 5) communication. The evaluation will be done by the members of the each Chair's IRB. This information will be maintained by the Institutional Official or designee, who will also provide formal feedback of the evaluation to the Chair.

The IRB members will be evaluated every three years by both the Chair of their Committee and the HRPP Director. The Chair or the HRPP Director will provide formal feedback of this evaluation.

The membership of each IRB will be periodically evaluated, and if necessary, adjusts to the membership and composition of the IRB to meet regulatory and organizational requirements will be made.

All changes to IRB membership roster, including deletions, additions, and changes in role will be reported to OHRP in a timely manner by updating the IORG through the Office of Human Research Protections database.

IRB Chair Responsibilities

1. Chairs convened meetings.
2. Monitor quorum at meetings.
3. Call special meetings when necessary.
4. Make decisions in emergency situations to protect subjects and remain in compliance with regulations.
5. Confirms primary and secondary reviewer assignments made by HRPP staff as requested.
6. Personally reviews or designates IRB member(s) to review SAEs and IND Safety Reports and determines which ones require review by the full board.

7. Personally determines or designates IRB member(s) to determine whether studies qualify for expedited review.
8. Performs or delegates review of applications and revisions meeting expedited review criteria.
9. Personally reviews or designates IRB member(s) to review all submitted investigator reports and determines if there is reason for full IRB review.
10. Reviews policies, procedures and forms on an ongoing basis.
11. Relates concerns of IRB staff and members to administration regarding issues in human research review.
12. Acts as an advisor and educator in the institution's research community.

IRB Members

1. Review research applications and other appropriate materials prior to convened meetings.
2. Provide sufficient advance notice if unable to attend a meeting.
3. Attend convened meetings and contribute to Board discussion.
4. Review studies according to approval criteria offered in the regulations and SOPP.
5. Serve as primary, secondary reviewer or discussant on selected applications.
6. Disclose any potential conflict of interest to the IRB chair as soon as it is recognized.
7. Maintain confidentiality regarding any information contained in any review.
8. Participate in project audits as needed.
9. Review policies, procedures and forms on an annual basis.
10. Understand these operating procedures and applicable federal, agency-specific and institutional regulations regarding human subjects research.

HRPP Program Director/IRB Administrator

1. Maintains up-to-date knowledge of policies, procedures and regulations regarding human subjects research and IRB operations.
2. Represents the Chair and IRB in the institution's community by communicating IRB requirements and decisions with investigators, sponsors, and institutional officials.
3. Facilitates the review process with the IRB Chair, and members.
4. Obtains and distributes information required for Chair and/or IRB review.
5. Assumes additional duties and responsibilities as delegated by the Chair.

HRPP Administrative Staff

1. Maintain up-to-date knowledge of policies, procedures and regulations regarding human subjects research and IRB operations.
2. Perform administrative duties to assure systematic flow of work through the IRB.
3. Prepare and distribute review materials to members and consultants.
4. Maintain files.
5. Prepare minutes.
6. Assure accurate and timely documentation, data input, and database up-keep.

7. Send out notification of IRB decisions, requests for additional information, and correspondence to investigators in a timely manner.
8. Send out timely reminders and notification to investigators when applications for study re-approval are due.

Compensation

Service on the IRB fulfills the University service obligation of UCSD faculty. Because of the extensive time commitment required for IRB service, the Vice Chancellor for Health Sciences, UCSD, has approved the following:

1. IRB Chairs receive a \$15,000 annual stipend.
2. Community Representatives receive \$150 per IRB meeting attended.
3. Prisoner Advocates receive \$150 per IRB meeting attended.
3. IRB members receive no direct payment; however, members are eligible to receive a laptop computer and an annual \$500 Internet connection subsidy to offset costs of DSL or cable modem service. IRB members will be allowed to use the laptop computer for the duration of their tenure and to obtain replacement computers when deemed necessary. IRB members may request replacement or upgrade of the laptop computers as needed. All upgrade requests will be subject to available HRPP funds. All laptop computers remain property of the UC Regents. IRB members who leave IRB service are required to return the notebook computer to the HRPP.

Procedures

1. IRB Chairs and IRB members solicit regular and alternate IRB members from within and outside the institution, and the local community, following an appropriate schedule; follow established criteria to select new members; and replace members who resign or leave IRB service.
2. IRB Administrator maintains roster of IRB membership; prepares Dean's appointment letter and "welcome package" for new members; ensures availability of training materials and educational opportunities for IRB members; and creates accounting and disbursement infrastructure for compensation to Chairs and IRB members.

Applicable Regulations

[21 CFR 56.107\(a\)](#)

[45 CFR 46.107\(a\)](#)