

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

Section 2.1
Composition of IRBs

Policy

The IRB consists of at least five regular voting members. Qualified persons from multiple professions and of both genders will be considered for membership. IRB membership will not consist entirely of men, women or of members of one profession. The UCSD HRPP will make every effort to have diverse IRB committees, within the scope of available expertise needed to conduct its functions, and that the IRB possesses appropriate knowledge of the local context in which research for which it is responsible will be conducted. IRB committees may consist of regular and alternate members, and may use the services of special consultants, as required, to provide expertise not available among regular or alternate members. A quorum, defined as attendance of the majority of the members listed on the roster, must be present in order to hold a convened IRB meeting. If at any time during a convened meeting a quorum is lost, the IRBs cannot vote on actions until the quorum is restored. Members present by conference or video-phone who can hear and be heard may be counted as present in meeting quorum requirements. For research to be approved at a convened meeting, the project must receive approval of a majority of members present at the meeting.

Regular Members

There will be at least one member in attendance whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There will be one member who is not otherwise affiliated with UCSD, and who is not part of the immediate family of a person who is affiliated with UCSD. Whenever possible, non-affiliated members will be drawn from the local community, such as clergy, attorneys, representatives of legally recognized veterans organizations, or practicing physicians. A licensed physician, who is a voting member, must be present for research involving an FDA-regulated article.

In general, at least one unaffiliated member will be present at 10 out of 12 IRB meetings per year.

In general, at least one member who represents the general perspective of subjects will be present at 10 out of 12 IRB meetings per year.

The backgrounds of the regular members will be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. The regular members will be capable of reviewing research proposals in terms of regulations, applicable law, and standards of professional conduct and practice. Each IRB membership roster must include sufficient information about member's expertise to permit verification that

there is appropriate representation at the meeting for each protocol under review. This includes ensuring that at least one person who is knowledgeable about or experienced in working with a specific field or vulnerable population, for instance, will present at a meeting where such protocols are reviewed.

The Director and/or an Associate Director of the Human Research Protections Program will be voting/alternate members of one or more IRBs, so that each IRB has a representative of the senior management staff of the HRPP.

Regular members are expected to make every effort to attend each meeting of IRB, and their presence or absence will be used in establishing a quorum for each meeting. A quorum is composed of a majority of the regular members of the IRB or at least five members in attendance, whether in person or by phone/video conference, whichever is greater. Performance standards apply to committee participation: each member must, on an annual basis, attend at least eight of 12 monthly meetings, and submit reviews for at least 10 of 12 monthly meetings.

One regular member will be designated as the Chair. The Chair will serve as the official representative of the IRB, and will chair all IRB meetings. In the absence of the Chair, the Vice-Chair will lead the IRB meeting. In the event that the Vice-Chair is unavailable as well, the Chair or Vice-Chair will designate another regular IRB member to chair the meeting.

Alternate Members

Alternate members are qualified voting members, but they are not expected to attend each meeting. The Chair or his/her designee may ask an alternate member to attend a meeting in order to draw on his/her expertise in an area that may be relevant to that meeting's deliberations and/or to establish a quorum for that meeting. An alternate member's presence at an IRB meeting in the place of an absent regular member may be used in establishing a quorum. Even when not serving as a voting member in place of a regular member, alternate members are encouraged to attend any meeting and they may participate in discussion if they have received applicable meeting materials in advance. An alternate member's absence is not used in establishing a quorum for a meeting.

Special Consultants

The Chair or his/her designee may 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 IRB. These individuals may not vote with the regular and alternate members of the IRB and their presence or absence will not be used in establishing a quorum for an IRB meeting. In some cases it may be necessary to appoint such an individual to the IRB as a full voting member for initial and/or continuing review of a project for which their presence is required, e.g., a prisoner representative for studies involving prisoners.

The decision to engage a consultant will be made by vote at a convened meeting of the IRB. Internal consultants will be identified by a process of communicating the committee's request to the relevant Department Chair within the institution, or by knowledge of relevant local expertise possessed by IRB committee members or HRPP staff. External consultants will be

identified by literature searches to identify nationally prominent experts in the area under review. Consultants are required to communicate their findings to the IRB in writing. Reasonable compensation will be provided for external consultants, as well as reimbursements for any costs they incur in the course of providing review services.

Special consultants may be used for all aspects of IRB review as determined by the Chair or his/her designee including initial review, amendments, adverse event reports, safety monitoring reports, responses to committee, and continuing review. The Chair is obligated to ask consultants about conflict of interest. Any consultant would be considered to have a conflict of interest if he or she is listed as a collaborator on the project, received financial compensations from the sponsor for any reason, or meets the Institutional definition for conflict of interest. When a consultant self-identifies conflict of interest a conflicting interest, this conflict must be disclosed to the IRB members reviewing the research and the consultant may not participate in the review.

Procedures

Characteristics of members, including appointment term, committee assignment, departmental affiliation, and professional expertise, are maintained in the HRPP database system. In addition, curriculums vita for members are maintained in binders in the HRPP office available for review by the appropriate authorities. The same process will be followed for pre-identified consultants.

1. IRB Chairs and IRB Administrator maintain a roster of all regular and alternate members for inspection purposes; a file on all members, to include their curriculum vita, letters of nomination and other evidence of professional ability; and a roster of available consultants who are eligible and qualified to attend meetings as invited consultants.
2. IRB Administrator and HRPP designated staff maintain a roster of all regular and alternate members for inspection purposes; a file on all members, to include their curriculum vita, letters of nomination and other evidence of professional ability; and a roster of available consultants who are eligible and qualified to attend meetings as invited consultants.

Applicable Regulations

[21 CFR 56.107 \(a-d, f\)](#)

[21 CFR 56.115 \(a\)\(5\)](#)

[45 CFR 46.103 \(b\) \(3\)](#)

[45 CFR 46.107 \(a-d, f\)](#)

[45 CFR 46.115\(a\) \(5\)](#)

[ICH 3.2.1](#)

[ICH 3.2.6](#)