

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

Section 4.1
IRB Meeting

Policy

Except when an expedited review process is used, the IRB will review proposed research at convened meetings. Each IRB will meet at least monthly, or more often as needed, at a date and frequency determined by the Chair and the IRB Administrator. IRB meetings will be held at locations convenient to the majority of the committee members; whenever feasible, meetings will be held in the HRPP office conference area or other UCSD conference facility with wireless coverage, to take advantage of the wireless network capabilities of the office for access to computerized project tracking, real time MEDLINE and drug database searching, and other Internet-accessible information resources.

Meeting Procedures

Prior to the meeting, the IRB professional staff will designate one primary reviewer whose professional interests are in the scientific areas for each research proposal, and one secondary reviewer. The reviewer(s) must be voting IRB members or alternate IRB members who will vote. Physicians and Ph.D.-level physical, biological, or social scientists are considered to have primary concerns in the scientific area. Also included in this group are nurses, pharmacists and other biomedical health professionals. Additional reviewers or special consultants may also be designated. In general, two reviewers will be assigned, but for proposals of low risk and/or complexity, the Chair may choose to assign a single reviewer.

The meeting agenda and the meeting materials will be available to IRB members prior to each meeting via the UCSD IRB website. A copy of the agenda and attached materials will be maintained on file with the meeting minutes.

A summary of expedited reviews conducted since the previous meeting will be made available to IRB members, as a component of the meeting agenda and time will be allotted during the meeting for discussion.

An HRPP protocol analyst will take minutes of each meeting. Minutes will be written in sufficient detail to document the activities of the IRB. Draft minutes will be distributed to members prior to the next IRB meeting. The draft minutes will be discussed at the meeting and corrections requested by the IRB members will be made by the administrator or designee. The minutes will then be committed to final form and made available for members. Once finalized, no one, including a higher authority, may make any changes in the final minutes except the IRB at a convened meeting. Draft minutes are also made available to the VASDHS R&D Committee for review at a subsequent meeting. The IRB Administrator will maintain copies of the minutes.

Telephone Conference Call Meetings

Every effort will be made to convene meetings at which all members are present. However, should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using teleconferencing methods. The member who is not physically present will be connected to the rest of the members via speakerphone or interactive audio and video connection. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by conference call may vote; provided they have had an opportunity to review all the material the other members have reviewed.

No member who is absent from a convened meeting and is not participating in a teleconference may vote on an issue discussed during a convened meeting (no proxy written or telephone polling).

Rarely, in an emergency, meetings may be convened via a teleconferencing. A quorum must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Procedures

1. IRB Chair and IRB Administrator will schedule meetings.
2. IRB Administrator and IRB staff will distribute notice of meeting and ensure appropriate meeting materials are available to IRB members.
3. Primary and Secondary Reviewers will review all relevant meeting materials, prepare IRB meeting presentation (summary, issues and recommendations) and complete review worksheets.
4. IRB members will review materials for all projects prior to meeting.

Applicable Regulations

[21 CFR 56.103\(a\)](#)

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

[21 CFR 56.108\(c\)](#)

[38 CFR 16.101 \(a\)](#)

[38 CFR 16.107 \(e\)](#)

[38 CFR 16.108 \(b\)](#)

[45 CFR 46.101\(a\)](#)

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

[45 CFR 46.108 \(b\)](#)

[ICH 3.2-3.5](#)

[VHA Handbook 1200.05](#)