

P&P: OR 202 Version No: 1.1 Effective Date:1/31/2014	IRB MEMBERSHIP	Supersedes: CPHS Policies and Procedures 9/1/2007
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1. POLICY

The management of the membership of the IRBs and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the Human Research Protection Program (HRPP), the Office for the Protection of Human Subjects (OPHS) in cooperation with the Associate Vice Chancellor for Research (AVCR), Assistant Vice Chancellor for Research Administration and Compliance (AVCR-RAC). However, all appointments to the IRB are made by the Vice Chancellor for Research as the Institutional Official (IO).

Specific Policies

1.1 Terms

- 1.1.1 The IRB Chair(s) will serve in this capacity for a one-year renewable term. Reappointment for additional terms may occur by mutual agreement of the Institutional Official (IO), Director of OPHS, and IRB Chair.
- 1.1.2 The IRB Vice Chair(s) will serve in this capacity for a term of one year. Reappointment for additional terms may occur by mutual agreement of the IRB Chair, Director, and IRB Vice Chair.
- 1.1.3 The IRB Acting Chair(s) will serve in this capacity on an as-needed basis indefinitely, as appointed by the IO.
- 1.1.4 IRB Members will serve on the IRB for a term of one year. Reappointment for additional terms may occur, by mutual agreement of the IO (or his/her designee), IRB Chair, AVCR-RAC, Director, Assistant Director or IRB Administrator and IRB Member.

1.2 Appointments

Members of the IRBs are appointed by the Institutional Official upon recommendations received from the IRB Chair(s), AVCR, AVCR-RAC, OPHS Director, Faculty Senate Committee on Research and OPHS Assistant Director or IRB Administrator. Members will be solicited from University of California Berkeley and surrounding communities.

1.3 Resignations and Removals

- 1.3.1 In the event that a member resigns before the conclusion of his/her term, the vacancy will be filled as quickly as possible.
- 1.3.2 The IO may remove an IRB Chair or IRB member from serving if it is in the best interest of the institution's obligation to protect human subjects and/or to ensure institutional compliance.

1.4 Compensation

Participation by UC Berkeley faculty or staff as IRB members is considered a component of their job responsibilities as established by their supervisors. Regular or

alternate members who are not affiliated with the university and participate in full convened meetings may receive modest reimbursement as consultants and miscellaneous expenses (e.g., parking).

Individuals serving as IRB Chair or Vice Chair may receive compensation as determined by the IO in accordance with the responsibilities and time commitment of the position.

1.5 Liability

Regular and alternate members have liability coverage as part of their IRB membership in their capacity as agents of UC Berkeley.

2. SCOPE

These policies and procedures apply to the IRB regular and alternate membership.

3. RESPONSIBILITY

IRB Chair is responsible for management of the activities of the IRB members relevant to meeting conduct and review of research.

IRB Members (including the IRB Chairs) are responsible for providing a current CV to the OPHS Director or designated OPHS staff at the time of their initial appointment, and annually thereafter.

IRB Members must complete all training and orientation activities as required prior to be added to the institution's IRB Membership Registration associated with UCB's Federalwide Assurance.

4. PROCESS OVERVIEW

The IRB Chair and OPHS Director in consultation with the IO (or his/her designee), Faculty Senate Committee on Research, AVCR, and the AVCR-RAC, identifies members of UC Berkeley's faculty and staff and members of the local community to serve on the IRB. The IRB Chair, OPHS Director, AVCR and/or AVCR-RAC participate in recruiting new members.

The IO (or his/her designee), IRB Chair and / or Director will discuss the responsibilities and time commitment of IRB membership with the interested parties. If the person is interested, his/her name is submitted to the Institutional Official recommending appointment of the individual to a particular IRB. If the Institutional Official (or his/her designee) concurs with the recommendation, the IO sends an appointment letter to the interested party, with copies to his/her department head (for affiliated members), the AVCR-RAC and the OPHS Director.

The OPHS Director and an IRB Chair arrange for training and orientation activities of new members prior to the new members being officially added to the IRB's membership roster and becoming voting members of the IRB.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107