

6.3 IRB Composition and Membership

Section revised: 04/03/2019

The IRB has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB are periodically reviewed and adjusted as appropriate. (AAHRPP Element II.1.B)

Each IRB has a qualified Chair, members and staff whose membership and composition is reviewed and adjusted annually by the RCO Director and the Vice Provost and Dean of Research. This review ensures that individual IRB Chairs and members have the knowledge, skills and abilities appropriate to their respective roles and perform their responsibilities in an acceptable manner.

Stanford policy requires that the IRB be constructed of at least 5 members according to DHHS regulations and FDA regulations (45 CFR 46.107 and 21 CFR 56.107). Additionally,

- The IRB shall include a nonscientific IRB member, educated and with experience in unambiguously nonscientific areas (see [Checklist for Determining if IRB Members are Nonscientists](#)), to represent the perspective of research participants. These individuals may not have meaningful scientific or medical training or experience. Health professionals, regardless of discipline, may not be considered nonscientists. At least one nonscientist IRB member must always be present to have a quorum. (See discussion of quorum in [Chapter 6.8](#).)
- The IRB shall include student(s), when nominated by the ASSU Committee on Nominations, who are either upperclassmen or preferably graduate students with previous human research experience.

The VA shall assist the IRB in recruiting VA representatives for IRB membership.

- VA representatives to the IRB shall be appointed by the VA Medical Center Director.
- VA Research and Development administration officials including, but not limited to, the Associate Chief of Staff for Research and Development and the Administrative Officer for Research and Development shall be prohibited from serving as voting members of the IRB.
- When VA research involves persons vulnerable to coercion or undue influence, the IRB membership should consider the inclusion of at least one member who is knowledgeable and experienced in this area of the research.

Appointment of Members and Alternates, Length of Service, and Duties

IRB members are nominated from a variety of sources, including previous IRB members, division chiefs, department chairs, compliance administrators, faculty, hospital pharmacy and nursing staff, research laboratories, administrative IRB staff with CIP or equivalent experience, Associated Students of Stanford University (ASSU), and various public groups. Consideration is given to balancing race, gender, expertise, and cultural backgrounds. People with active licensure from various clinical disciplines are sought. A background knowledge of and current familiarity with affiliated institutional concerns (e.g., the VA, LPCH, SHC) helps ensure that the

local research context is brought to IRB deliberations. Sensitivity to issues such as community attitudes and international dimensions is valued. Newly identified nominees are contacted by the HRPP Associate Director (or delegate) about their willingness to voluntarily serve on the IRB and their availability for the coming year. When a nominee agrees to serve on the IRB, the RCO Director and Vice Provost and Dean of Research review his or her CV and any relevant correspondence. Stanford has eight IRBs and members can be appointed to one or more of the IRBs depending on their availability and areas of expertise.

STANFORD has and follows written policies and procedures to separate competing business interests from ethics review functions. (AAHRPP Element II.1.C)

To avoid any possible conflicting interests or influence on IRB determinations due to competing business interests, individuals who are responsible for development activities (including raising funds), or are in a position to influence programmatic and budgetary decisions may not serve as IRB Members. See [Chapter 6.6.1](#).

After an extensive review of a potential member's education, experience and other characteristics that might add diversity to the IRB, a new IRB member is formally appointed by the Vice Provost and Dean of Research. Members serve one-year renewable terms (from October 1 to September 30). Members who are VA representatives are appointed by the VA facility Director (the IO) for a period of up to 3 years. They may be re-appointed to new terms of up to 3 years without a lapse in service at the end of each term. After initial appointment to the IRB, members may be asked to serve on a different or additional IRB(s) at the discretion of the HRPP Associate Director. At the conclusion of the IRB year (and interim, if needed), members' contributions are evaluated by the IRB Chair with the IRB manager (See [Chapter 4](#)). If their service is satisfactory, and continued membership is mutually desired, they are eligible for reappointment. All members may be re-appointed at the end of their terms without lapse in service. An IRB member may be removed at the discretion of the Vice Provost and Dean of Research in consultation with the Chair of the Panel and the Director of RCO.

Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or defer research submitted to the IRB. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their areas of expertise, and serve as general reviewers on all research. Members may also be asked to participate in subcommittees, audits, and education, as long as there is no conflict of interest with their IRB responsibilities or their other personal or professional roles.

Qualification to Perform Expedited Review

An IRB member may perform protocol review according to the expedited procedure when the IRB Chair, in consultation with the IRB manager, determines that the member is "experienced" with regard to this purpose. There are several ways a member may achieve sufficient experience, including attendance at IRB meetings, targeted education, working with a mentor, independent study, and previous IRB service. See [Chapter 7](#) for more information.

Appointment of IRB Chair, Length of Service, and Duties

IRB Chairs are nominated from a variety of sources, including previous and current IRB members, division chiefs, senior deans, department chairs, and compliance administrators. In addition to the characteristics sought in an IRB member, these individuals possess demonstrated skills in leadership and group process. Typically, they have served on an IRB previously.

IRB Chairs are formally appointed by the Vice Provost and Dean of Research. Chairs serve one-year renewable terms (from October 1 to September 30). At the conclusion of the IRB year (and interim, if needed) the IRB Chairs' contributions are evaluated by the Vice Provost and Dean of Research with the RCO Director (See [Chapter 4](#)). If their service is satisfactory, and their continued service is mutually desired, they are eligible for reappointment. An IRB Chair may be removed at the discretion of the Vice Provost and Dean of Research in consultation with the Director of RCO.

In addition to the responsibilities of IRB membership, the Chair has primary responsibility for conducting IRB meetings and working with staff to ensure effective and efficient operation of the IRB within all applicable regulatory requirements. The IRB Chair works with IRB members, institutional officials, and investigators to ensure that the rights and welfare of research participants are adequately protected.

Compensation of IRB Members

IRB Chairs' departments receive a percentage of their salaries to offset the time dedicated to IRB duties. IRB members generally do not receive monetary compensation for their service on the IRB. However, it is recognized that service on the IRB requires a significant investment of time for all members.

IRB members who are not otherwise affiliated with STANFORD or its collaborating institutions are compensated for their service by the issuance of an honorarium. As stated in OHRP [guidance](#), compensating unaffiliated members in this way does not create an affiliation or cause a conflict of interest.

Alternate IRB Members

Alternates replace regular IRB members who are unable to attend convened meetings of the IRB. They are required to have similar qualifications and characteristics of expertise and diversity as the regular IRB members (i.e., alternates for scientists are scientists and alternates for non-scientists are also non-scientists) and the primary member for whom each alternate is substituting must be named ([VHA Directive 1200.05](#) §7k). When an alternate substitutes for a regular member, the IRB staff provides the alternate member the same material that the regular member received or would have received.

In some cases, alternate members are able to represent similar specific vulnerable populations; however, VA alternates need not be VA themselves as long as VA membership requirements are met at the meeting. Terms of appointment, length of service, and duties are the same as for regular IRB members. Alternate members must adhere to the same conflict of interest standards and documentation requirements as regular IRB members.

If an alternate member attends a convened meeting at which his or her regular member is in attendance, one of them does not vote.

Ex Officio IRB Members

An ex officio member is designated as an IRB member by virtue of that individual's office. For example, if the chair of the Administrative Panel on Radiological Safety changes hands, that ex officio IRB membership changes hands accordingly and does not remain with the individual who has left that office. Some ex officio members serve on other STANFORD compliance panels and may provide expertise to IRB members. Ex officio members may participate in the IRB deliberations to provide information and expertise as requested by the IRB. Ex officio members are expected to adhere to the same conflict of interest standards and documentation requirements as regular IRB members and alternates. Ex officio members may not vote on any IRB action or determination, and for this reason are sometimes referred to as "non-voting" members.

The medical IRBs accept permanent ex officio representatives from the following areas:

- Office of the Vice Provost and Dean of Research
- Office of the General Counsel
- Biosafety Panel
- Radiological Safety Panel
- Research Management Group
- VAPAHCS Research and Development Office
- Palo Alto Veterans Institute for Research (PAVIR)
- Institutional Animal Care and Use Committee (IACUC/APLAC)

The nonmedical IRB accepts permanent ex officio representatives from the following areas:

- Office of the Vice Provost and Dean of Research
- Office of the General Counsel

The IRB may accept additional permanent ex officio members with the agreement of the IRB Chair and the RCO Director.

Liability Coverage for IRB members

Stanford University provides liability coverage under its insurance programs for IRB members acting in good faith in the performance of their IRB duties. The Stanford University Office of Risk Management provides liability coverage of volunteer individuals, including community IRB members. All Stanford University-related faculty, staff, and students are likewise covered in their capacity as employees and students.

Support of IRB Membership

The IRB has a qualified staff, dedicated to supporting the IRB in its mission to protect human participants in research. The IRB staff teams are reviewed at least annually by the RCO Director and the Vice Provost and Dean of Research to ensure they continue to provide sufficient resources to the IRB. The IRB staff has knowledge, skills and abilities appropriate to their

respective roles. The RCO Director oversees the RCO Deputy Director and the HRPP Associate Director, and is responsible for the overall management of the RCO.

For policies on qualifications, education and periodic evaluation of RCO staff, see [Chapter 4](#).

