
Yale University Human Research Protection Program

900 PR.1 Recruitment, Appointment, Terms and Evaluation of IRB Members, Consultants and Chairs

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Overview

This procedure describes the recruitment, appointment and evaluation processes of the Yale University Institutional Review Boards (IRBs) members and Chairs. Recruitment, appointment and evaluation of IRB membership is conducted in a manner that ensures that the IRB fulfills its obligations pursuant to federal regulation 45CFR46 and 21CFR56, as applicable. Yale University supports the Human Subjects Committee (HSC) which has oversight of social, behavioral and educational research and the Human Investigation Committees (HICs) which have oversight of biomedical research.

Recruitment

Recruitment of IRB members is based on an assessment of need for each of the Yale IRBs. New members are recruited by the IRB Chair, Director or designee in a variety of ways, including but not limited to;

- A broadcast email to faculty may be sent by the appropriate Dean’s Office, soliciting interest from faculty members
- An annual email to students of the School of Medicine and the School of Public Health, soliciting interested student members
- An annual appointment by the Yale College Council of undergraduate students to serve as members on the Human Subjects Committee
- A solicitation of interest conducted of students of the School of Nursing doctoral program
- Recommendation of faculty by department Chairs, or their designees, particularly those generating a large volume of protocol activity
- Recommendation of Yale New Haven Hospital leadership for members with expertise in nursing, pharmacy, social work, legal affairs and other relevant areas
- Recommendation of community representatives from community agencies and organizations
- Recommendation from current and former IRB members and staff
- Recommendation from the Office of Research Administration
- Recommendation from the Office of the Provost
- Unsolicited inquiries from interested parties.

When membership openings occur, IRB Chairs and/or Director or their designee(s) review the curriculum vitae of member candidates and identify those candidates whose qualifications best meet the needs of the IRB. Members are sought who, through their education and experience, have expertise that enables the IRB to conduct appropriate scientific and ethical review of protocols within the context of institutional policies and commitments, professional conduct, applicable law, and local community standards and concerns. The IRB seeks members with varied backgrounds of professional experience, race, gender

and culture. The IRBs also seek members who are knowledgeable about any potentially vulnerable populations that are regularly recruited to participate in studies under the IRB's purview. For example, the HSC routinely includes undergraduate members, as many behavioral research projects recruit participants from the student population. The HIC regularly recruits members of the Department of Psychiatry, due to the large number of research protocols involving participants with psychiatric diagnoses.

Selected candidates may then be invited to attend a meeting. Materials for the meeting may also be distributed to the candidates prior to the meeting, so that they may assess the amount of time required for meeting preparation. Following the meeting, the candidate is queried regarding his/her interest in joining the IRB. If the candidate wishes to join, the appointment and orientation process is initiated.

Appointment and Terms

All IRB appointments are made by the Institutional Signatory Official (IO). The IO appoints members to the HSC annually, and as new members join throughout the year. Members of the HIC are appointed by the IO as openings occur. For all IRBs, names of proposed members are sent to the IO, who reviews and approves (or disapproves) membership. If the proposed member is approved by the IO, a letter of welcome is sent to the new member by the IO, stating the expectations regarding length of term and attendance. Membership terms for the HSC are for one year. Membership terms for the HIC are for two years. Exceptions to the two year appointment may be made, depending on individual circumstance and IRB need. No appointment is for less than one year.

Reappointment

When a member has successfully completed his or her term and wishes to remain on the IRB, a letter of reappointment is sent by the IO, thanking the member for his/her contribution, stating the duration of the new term and the continued expectation regarding attendance at IRB meetings. Reappointment is based on the recommendation of the Chair and/or Director after assessing the member's contribution over the course of the term and the current and future needs of the IRB. Reappointment term durations are identical to initial terms. Exceptions to the two year reappointment may be made, depending on individual circumstance and IRB need.

Evaluation of IRB Membership and Members

Whenever a member leaves the IRB and at least annually, IRB Chairs and Director assess the composition and performance of each IRB to ensure that membership reflects the expertise required for appropriate scientific and ethical review of research. As part of this assessment, potential members and consultants who may be called upon for expertise are identified. Recruitment efforts are then guided by the assessment.

When a member term is concluding, the Chair and Director evaluate whether or not reappointment should be offered. A reappointment offer is made based on the member's attendance, meeting preparation and contribution to the IRB's work over the course of his/her membership as well as the projected needs of the IRB in the coming term.

Consultants

Consultants may be sought to aid the IRB in the review of specific protocols that require expertise beyond the scope of IRB membership. Such expertise may be scientific, cultural, or may be sought when there is an identified potential conflict of interest that would be best assessed outside the membership of the IRB.

The IRB Chair, Director, or designee is responsible for identifying specialized consultants and guiding their participation in protocol review to conform to all standards and regulations required for appropriate review.

Consultants may provide written comments, or may attend the IRB meeting in which the protocol is reviewed. Consultants may not vote with the IRB membership.

Consultants do not have appointed terms, as their participation is limited to specific protocols

Chairs

Recruitment of IRB Chairs is restricted to those individuals who have experience as an IRB member. This experience may be current or past, and may be at Yale University or at another institution. Recruitment may be conducted through a national search, internal solicitation of interest, recruitment of potential chairs by IRB directors, Deans, Office of Research Administration, Office of the Provost, or by the IO.

Appointment of Chairs is made by the IO. Appointment of the HSC Chair is made annually. Appointment of the HIC Chairs varies and is based on performance and the continued interest of the Chair in serving.

Evaluation of Chairs is conducted at least annually by the IO, with input from IRB Directors and others as deemed appropriate. Standards of evaluation include leadership, administrative performance, continued education to remain current in human research issues and contribution to the University.

References:

45 CFR 46.107
21 CFR Subpart B 56.107
IRB Policy 900, Recruitment, Appointment, Terms and Evaluation of Members
Job description, IRB Chair
Member Responsibilities Document
Johns Hopkins Medicine IRB, Policies and Procedures