
Yale University Human Research Protection Program

HRPP Policy 900 Recruitment, Appointment, Terms and Evaluation of IRB Members and Chairs

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Scope

This policy describes the recruitment, appointment, terms and evaluation of members and Chairs of the Yale University Institutional Review Boards (IRBs).

Policy Statement

All Yale University IRBs shall maintain a membership that conforms with federal regulation 45 CFR 46 and, as appropriate, 21 CFR 56. Membership shall be appropriate in size and expertise to fulfill the IRB's obligations to safeguard the rights and welfare of human research participants, and to conduct the scientific and ethical review of protocols, reflecting the nature of research under a given IRB's purview. Recruitment, appointment and evaluation of IRB members and Chairs shall be conducted in a manner that supports the responsibilities of the IRB.

Reason for the Policy

The comprehensive review of human research required of the IRB necessitates multiple perspectives, scientific expertise, a firm grounding in ethical principles and legal and regulatory requirements, and knowledge of local context. Sound leadership is also required to ensure consistency in the application of ethical principles, University Human Research Protection (HRP) policies and procedures, and to guarantee that the IRB fulfills its obligations pursuant to federal regulations. This policy helps to ensure that Yale IRBs are led by and composed of individuals who have the knowledge and expertise to perform their critical roles.

Definitions

Human Investigation Committees

The University IRBs responsible for review and oversight of biomedical research.

Human Subjects Committee

The University IRB responsible for review and oversight of social, behavioral and educational research.

Institutional Signatory Official (IO)

A senior official named in the FWA who has the authority to commit the entire organization, as well as all of the components listed in the FWA, to a legally binding agreement. The IO also has the authority to assure compliance of the organization and all of its components to the Terms of the FWA.

Policy Sections

900.1 Recruitment

Members for each IRB will be recruited based on conformance with federal regulations and an assessment of need. The IRB will maintain diversity of membership, including race, gender, and sensitivity to community attitudes in order to fulfill its obligations to review the breadth of research that is conducted by investigators representing Yale University.

Additionally, an individual internal or external to the Yale community may be recruited to serve as a consultant to the IRB when an IRB Chair or Director requires expertise or knowledge that is not available within the current IRB but is needed by the IRB to fully consider a specific research protocol (see 100 GD 6 Review of IRB Protocols by Consultants).

Recruitment of members and consultants is the responsibility of the University Administration, IRB Chairs and Director, and IRB members and staff, as appropriate.

Recruitment of Chairs is the responsibility of the IO.

900.2 Appointment and Terms

Appointment to IRBs is made by the IO. Members are appointed for at least one year, pursuant to the individual Yale IRB's preferences.

Reappointment to an IRB may occur when a member has successfully completed his or her term and wishes to remain on the IRB. Reappointment is made by the IO, based on the recommendation of the Chair and the Director, after assessing the member's contribution over the course of the term and the current and future needs of the IRB. Reappointment terms are generally for the same duration as initial terms. Exceptions may be made, depending on individual circumstance and IRB need.

900.3 Evaluation of IRB Membership and Members

Whenever a member leaves the IRB and at least annually, IRB Chairs and Director perform an assessment of the IRB(s). The assessment considers IRB composition, including alternate members, areas of expertise, community representation and diversity. Decisions regarding future recruitment and education efforts are identified to ensure that membership and supplementary consultants possess the expertise and knowledge required for appropriate scientific and ethical review of research.

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.

During the course of their term, each IRB member completes a self evaluation assessing their understanding of regulations and policies, review and preparation of materials prior to meetings, participation in meeting discussion, interactions with investigators and IRB staff, and human research education during the previous year. This tool is reviewed by the IRB Chair or Vice Chair in a confidential meeting with the member. The self assessment and attendant discussion is used to determine areas of focus, if needed, and decisions about continued membership.

900.4 Consultants

Consultants may be sought to aid the IRB in the review of specific protocols that require expertise beyond the scope of IRB membership (see 100 PR1 Review by Convened IRB, and 100 PR 2 Expedited Review).

Consultants do not have appointed terms, as their participation is limited to the review of specific protocols. Consultants may not vote with the IRB membership.

900.5 Chairs

A Chair will be appointed by the IO for each IRB. IRBs may have a member appointed as Vice Chair or a member who may serve as an alternate for the Chair when necessary. Chairs must possess the appropriate expertise and skill required to fulfill the breadth of their responsibilities pursuant to University policy and federal requirements.

Appointment of the HSC Chair is made annually. Appointment of the HIC Chairs may vary, 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 the IRB Director and others as deemed appropriate. Standards of evaluation include leadership, committee oversight and performance, continued education to remain current in human research issues, and contribution to the University.

Related Information

HRPP Policy 800: Human Research Protections Orientation Training and Education

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

Contacts

Subject	Contact	Contact
IRB Biomedical Research	Human Investigation Committee I	203-785-4688 ysmhic@yale.edu
IRB Social, Behavioral, and Education Research	Human Subjects Committee	203-436-3650 Human.subjects@yale.edu
Institutional Signatory Official	Office of Research Administration	203-432-8630
Recruitment of IRB Members	Education and Community Outreach Manager	203-785-4688 hrpp@yale.edu

Roles and Responsibilities

Human Investigation Committees

The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human subjects research conducted at Yale University.

Human Subjects Committee

The HSC is responsible for the review and oversight of social, behavioral and educational research involving human subjects.

Institutional Signatory Official

The Associate Vice President for Research Administration serves as Institutional Signatory Official (IO) for Yale University. As such, this Official is responsible for ensuring that Yale fulfills the obligations and responsibilities promised in the terms of its Federalwide Assurance. The IO is responsible for the appointment of members and Chairs and for the evaluation of Chairs.

IRB Chairs

The IRB Chairs are responsible for the recruitment and evaluation of IRB members and consultants.

Revision History

October 21, 2010 and October 7, 2010