

Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.0
Policy Title: Institutional Review Board (IRB) - Membership

Purpose

The purpose of this policy is to set forth 1) the requirements and process to constitute an IRB and 2) the expectations and obligations of IRB members.

Definitions

See policy 2011-007 for definitions of the following terms:

Member – Experienced		Member – Nonscientific		Member – Nonaffiliated
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Policy

Membership: It is the policy of the HSPP that the membership of the IRB shall be constituted in accordance with the following regulatory criteria.

- each IRB panel shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution;
- the membership shall be sufficiently qualified through the experience and expertise of its members (e.g., professional competence), and the diversity of its members, including race, gender and cultural backgrounds and sensitivity to such issues as community attitudes,
- the membership shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (e.g., including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.
- the membership shall consist of at least one member whose primary concerns are in scientific areas; at least one member whose primary concerns are in nonscientific areas, at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution, and a member who represents the perspective of research participants (one member may fulfill more than one role);
- if a panel regularly reviews research involving a subject population that may be vulnerable (e.g., children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged who may be vulnerable to coercion or undue influence), consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with that population
- when reviewing studies involving prisoners
 - a majority of the board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the board
 - at least one voting member shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one board only on board need satisfy this requirement. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.

The Director of the HSPP (DHSP) appoints the members, including Chairs and Vice Chairs. Appointments are for an open-ended period.

The Chair will have at least 2 years of previous IRB experience, have a scientific background, be familiar with clinical research and have demonstrated an ability to work in committee. The Vice Chair must have at least one year of previous IRB experience, and have a scientific background. Consideration will be given to length of time on the IRB, thoroughness of reviews and attendance at meetings when selecting a Chair and Vice Chair.

Once appointed to a panel; a member of one panel may alternate for a member of another panel. The DHSPP may also appoint a specific, designated alternate IRB member as deemed necessary and appropriate, for example by appointing a designated alternate for the prisoner representative and that alternate is not a member of any other panel. An alternate member will have an area of expertise similar to the member for whom they serve as the alternate. Alternate members will be called upon as needed. Alternate members will have sufficient time for review of material prior to meetings and will receive the same material for review that the regular IRB member would have received.

Members of the IRB are either employees of the University of Connecticut Health Center or acting in a volunteer capacity in which case they are considered to be an agent of UConn Health. When acting in the capacity of either employee or agent, and in accordance with IRB standard operating procedures, members are indemnified (for actions not willful, wanton or malicious) by the State of Connecticut.

Individuals from within the Office of Research Administration and Finance will not be appointed as voting members. Individuals who are responsible for business development are prohibited from serving as members or ex-officio members and from carrying out day-to-day operations of the review process.

The membership of the IRB is registered with the Office for Human Research Protections (OHRP).

Member Responsibilities: The responsibilities of all IRB members include attending regularly scheduled meetings once per month, thoroughly reviewing all material to which they are assigned as a primary reviewer, being prepared to present and discuss the material at the meeting, reviewing and having a familiarity with all other material to be presented at the convened meeting such that they can participate in the discussion of all studies, possessing an understanding of the principles of the Belmont Report and regulations pertaining to human subject protections, applying those principles and regulations to the review process, reviewing IRB minutes, and providing input/feedback on new policies that relate to the IRB. No member may participate in any of the IRB's review of a study in which the member has a conflicting interest, except to provide information requested by the IRB. Therefore, members are responsible for excusing themselves from the deliberation and vote on any study for which they have a conflict of interest, inclusive of reviews of exempt studies, any expedited review activity, and any full board review activity. The IRB may invite individuals with competence in a special area to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. Such individuals do not have voting rights.

Additional Responsibilities of Chair: Chairpersons are generally the party responsible for reviewing and approving new expedited applications and making the final determination of the appropriate approval categories, assigning reviewers for full board reviews (new applications, continuing reviews, modifications, and discussion items which are inclusive of non-compliance and unanticipated problems), running the convened IRB meetings (keeping conversation on topic, soliciting motions for vote, ensuring all members have opportunity to express opinions/comments), giving final approval to new studies that had been approved with contingencies, and serving as a resource to investigators and IRB members.

Due to the absence or unavailability of the Chair the Vice Chair is authorized to perform all functions of the Chair. The Chair may also delegate some or all duties to another member of the IRB who is considered an experienced member.

Performance of Members: Each year the IRB Chairs will be asked to evaluate the performance of IRB members. Elements taken into consideration will include attendance, number of studies reviewed (new and continuing), the ability to apply ethical principles to the review process, the thoroughness and clarity of presentations, and contributions to discussions. Likewise, each year the members will be asked to evaluate the Chairs. The DHSPP will receive and review the forms and address any issues identified if necessary.

A member not fulfilling their obligations may be asked to step down by the DHSPP or the signatory official for the institution.

The operating budgets of the HSPP and IRB cover expenses associated with continuing education of members. For members who are also UConn Health faculty, service on the IRB is recognized by the faculty promotions committee, as well as in the annual faculty evaluations.

Procedure

Appointment of Members: On an as needed basis as determined by the DHSPP and/or IRB Chairs, the DHSPP will appoint new members. Designated IRB staff will set up an orientation meeting with the potential new member, the Chair, and the DHSPP to discuss the issue of being appointed to the IRB. If interested in serving on the IRB and acceptable to the Chair, the DHSPP will issue the official appointment letter.

Designated staff within the HSPP will:

- maintain a membership roster for each IRB panel
- when required (e.g., prior to 1/19/2018) register the IRB panel(s) with the OHRP through the on-line registration system when required (e.g. prior to 1/19/2018) report changes in IRB membership to OHRP through the on-line registration system and as applicable, indicate on the roster the identity of the member or class of members for whom a designated alternate may serve.

Performance of Members: Within a reasonable time (e.g. two months) after the end of a fiscal year, designated staff within the HSPP will distribute performance evaluation forms to the IRB Chairs and members for completion within approximately a two week period. The period to be evaluated will be July 1 – June 30. Completed forms are returned to the HSPP staff person and a copy is presented to the person being reviewed. The original evaluations are given to the DHSPP for reviews and, if necessary, action. After review, designated staff files the evaluations in the IRB membership booklet.

Related Policies

2011-006.2 – Vulnerable Populations: Prisoners

2011-009.4 – Institutional Review Board – Convened Meeting Operations

Basis

45 CFR 46

21 CFR 56

Document Attributes

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Reviewed and Approved By:

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Date

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