

Wayne State University Human Investigation Committee	
SUBJECT	Selection and Review of Institutional Review Board Members and Staff
Section	
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Approvals	11/17/06 Steering Committee, 10/25/06 General Counsel, 12-05-06 Administrative Approval

Background

The Human Investigation Committee (HIC) is the Institutional Review Board (IRB) of Wayne State University (WSU). The HIC reviews and monitors all human participant research in compliance with the University's Federal Wide Assurance (FWA 00002460) and all local, state and federal law and University policy [38 CFR 16; 45 CFR 46; 21 CFR 56; VHA Handbook 1200.5]. The committee membership of WSU's IRB reflects the Institution's adherence to its FWA and its commitment to the highest standards in research compliance.

Scope

This Standard Operating Procedure (SOP) applies to membership of all HIC committees at Wayne State University. Procedures are described for the selection and appointment of IRB members, requirements of membership, training of members, and annual evaluation of members. It also describes the composition of the Steering Committee, and the selection and appointment of Chairs and HIC staff. Special considerations for review of research from the John D. Dingell Veterans Administration Medical Center (VAMC) are also addressed. No member may participate in an IRB committee meeting as a voting member when there is a Conflict of Interest (See IRB Member Conflict of Interest).

Definitions

Chair: the individual who directs the proceedings of one of the HIC committees or the HIC in its entirety, and who provides expertise and leadership in a wide range of areas related to IRB functions

Community Representative: an individual whose primary concerns are those of the population base from which research participants are drawn

HIC: Human Investigation Committee, which is the name of the IRB at WSU. Refers to the five committees separately or jointly

HIC Chair: the individual who directs the proceedings of the HIC in its entirety and who has administrative authority in a wide range of areas related to IRB functions. The HIC Chair is also Chair of the Steering Committee.

IRB: a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research in accordance with federal regulations [45 CFR 46].

Nonscientist: an individual whose primary concerns are in nonscientific areas

Scientist: an individual whose primary concerns are in scientific areas and whose expertise is relevant to one or more areas of research that are reviewed by the HIC

IRB Membership

The selection of members to the IRB committees is determined by member experience, expertise, knowledge of the community and diversity (race/ethnicity, gender and cultural background). The membership must have an in-depth understanding of applicable regulations relevant to the type of research being reviewed or have immediate access to that expertise. (Refer to Expectations of an IRB Member SOP)

Each of the HIC committees has:

- At least five members
- Members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by Wayne State University
- Knowledge of the community and community attitudes
- The expertise reflecting the areas of research that are most commonly reviewed
- At least one member whose primary concerns are in a scientific area
- At least one nonscientist member
- A member who is not affiliated with the university and whose immediate family does not have a university affiliation
- At least one member who serves as a community representative (A scientist or nonscientist member can also serve as a community representative).
- At least two representatives from the Veterans Administration Medical Center (VAMC) are on each committee that reviews VAMC protocols. [VHA Handbook 1200.5 5.a(3)(a)]
- Members who are knowledgeable about and experienced in working with all vulnerable populations (e.g. children, prisoners, the cognitively impaired) and who will review and be present for determinations concerning research that involves participants from these populations.

- A representative from the Office of the General Counsel is a member of the Steering Committee.

The Steering Committee is comprised of the Assistant Vice President for Research and various active members of an IRB committee. These include:

- The IRB Chairs and Medical Committee Vice Chairs
- A community representative
- The General Counsel representative
- At-large members of the IRB as recommended by a Chair
- The HIC Chair.

The HIC Chair serves as the Chair of the Steering Committee.

IRB members are appointed to (a) a specific committee and (b) as an alternate to the other committees. In identifying an appropriate alternate, care is given to meeting the regulatory requirements of 45 CFR 46.107 and 21 CFR 56.107. The alternate that is selected has comparable qualifications to the primary member being replaced and will review the same material that the primary member received (Refer to "Selection of Alternative IRB Member for Duly Constituted Meeting" SOP)

Identification and appointment of IRB members

The Vice President for Research is the Institutional Official who is responsible for the selection and appointment of IRB members. The need for a new member can be identified by an HIC Chair, the Human Investigation Committee's HIC Education Coordinator, or by the Assistant Vice President for Research. Needs are based on maintaining an adequate number of members, an adequate representation of expertise, and/or an adequate representation of nonscientists or community representatives. When the need for a new member is identified, the Assistant Vice President for Research, the Chair of the affected IRB committee, the HIC Chair, and the Education Coordinator meet to define the characteristics required of the new member. Suggestions for potential new members are made, and if a consensus is reached, the Assistant Vice President for Research will contact the individual to discuss his/her availability and interest. If there are no suitable candidates identified, then the Assistant Vice President for Research will contact the Chair of the department or college from which the new member expertise is needed. If it is a nonscientist member who is needed, the Education Coordinator will enlist the help of the Community Liaison to identify potential candidates. The Coordinator or Liaison will contact the candidate to determine his/her availability and interest.

When a candidate has been identified and has indicated his/her availability and interest, the Vice President for Research sends a letter of appointment that requires a signature by the candidate, indicating his/her acceptance of the appointment. Initial appointments are made for one year, then renewed for 2 years based upon mutual agreement between the new member and the Assistant Vice President for Research. The major requirements for renewal of the appointment are

continuing availability, effectiveness and the attendance record during the first year. Members are asked to attend a minimum of 75% of the meetings each year.

Maintenance of IRB roster and updated reports to Office of Human Research Protection

The IRB membership roster includes:

- Name of IRB members
- Earned degrees of IRB members
- The representative capacity of IRB members
 - Scientist or nonscientist
 - Affiliated or non-affiliated
 - Representative of a vulnerable population
 - VAMC representative
- Indications of experience of IRB members significant enough to determine expertise and contribution to the IRB

Changes in IRB membership are promptly reported to Office of Human Research Protection (OHRP) by the Assistant Vice President for Research.

Training of new members

When a newly appointed IRB member returns his/her signed acceptance letter, the Education Coordinator sets up a training session. During this training session, the "HIC Member Handbook", which contains the IRB expectations, HIC submission forms, HIC policy and procedures, 45 CFR 46, 21 CFR 50 and 56, 38 CFR 16, information sheets about devices and the glossary is reviewed with the new member. After this review, the member is given the option, if possible, to observe an IRB meeting. During this observation or his/her first IRB meeting, the education coordinator explains the actions of the meeting and answers any questions the member may have. The new member is usually not assigned new protocols until his/her third meeting. All new members will be evaluated 6 months into his/her one year appointment.

Evaluation of IRB members

Each scientific member of the IRB is evaluated by the Chair of his/her committee at least annually. The evaluation is in writing and signed by the Chair, and a copy is given to the member. For non-scientific or community members, there is no formal evaluation but the performance of these members is discussed by the Chairs and the Assistant Vice President at least annually.

In addition to annual evaluations, the Chair and Vice Chair of each committee have the responsibility to monitor the members present at convened meetings and to determine that meetings are appropriately convened and that members meet the attendance requirements.

Selection and Appointment of IRB Chairs

The Vice President for Research is the Institutional Official who is responsible for appointing IRB Chairs. Candidates are required to be scientists and to have had considerable experience with IRBs and/or research compliance. Ideally they have served on the IRB at this Institution for at least 3 years and have shown diligence, dependability, and interest in serving on the IRB. They should have demonstrated leadership skills, and must be willing to commit to the time necessary to pre-review protocols, assign protocol reviews to members, perform expedited reviews of revised protocols and amendments (that need only specific minor revisions), and serve on the Steering Committee.

When a new Chair is needed, the outgoing Chair, the HIC Chair, and the Assistant Vice President for Research discuss the potential candidates for the position based on the qualifications above as well as the area of expertise represented by the candidates. It is important to keep the committee's expertise balanced as needed for reviewing the protocols it receives. The Vice Chair is typically the first choice for Chair because he/she has already demonstrated the required qualifications. If he/she is not willing or able to fill the position, other members of that committee are considered. If there are no appropriate candidates, members of the other HIC committees are considered. When an appropriate candidate is found, and states that he/she is agreeable to filling the Chair position, then the Vice President for Research sends a letter of appointment that requires a signature by the candidate, indicating his/her acceptance of the appointment. Appointments are made for a three (3) year term. The IRB keeps a resume on file for each IRB committee member.

Evaluation of IRB Chairs

The Assistant Vice President for Research meets annually with each of the IRB Chairs for an evaluation of their performance and level of interest in continuing to serve in this capacity. A written evaluation is provided only if the Chair requests it.

Selection and appointment of HIC staff

The Assistant Vice President for Research is responsible for the selection and appointment of IRB staff. Positions are posted through the University's employment services in accordance with the policies and procedures of the Division of Human Resources. Applications are reviewed by the Assistant Vice President for Research and the Program Project Coordinator of the HIC. Candidates are selected based on their qualifications for the posted position. Candidates are interviewed by the Program Project Coordinator and at least 2 other members of the HIC HIC staff. The top 2 or 3 candidates are then interviewed by the HIC Chair and the Assistant Vice President for Research. Following these interviews, Human Resources offers the position to the candidate identified as the first choice of the interviewers.

Training of HIC staff

IRB staff are trained by the Program Project Coordinator as well as by other staff members who are currently filling, or who had previously filled, this position. The Program Project Coordinator is trained by the outgoing Coordinator if possible, and by the Assistant Vice President for Research.

Staff members are encouraged to attend an educational conference on research compliance within one year of assuming their positions, and whenever it is deemed appropriate by the Assistant Vice President for Research.

Evaluation of IRB staff

IRB staff are formally evaluated, in writing, and in a personal interview with their supervisors, at least once annually. Staff or supervisors can request an interim review at any time during the year. New staff members are given at least on interim evaluations during their first year of employment.

Requirements for IRB review of VAMC research

As noted above, each IRB committee that reviews VAMC protocols must have at least two VAMC employees as full voting members. At least one of the VAMC members must be present during the review of VA research. A licensed physician who is an IRB member must be included in the quorum during review of VA research involving an FDA-regulated article. [1200.5 5. a. (3) (a)]

At least one IRB member must have expertise in the area of the research being reviewed, as well as research that involves cognitively impaired persons or persons with impaired decision-making capacity.

Appointments of VAMC representatives to the IRB

The VAMC Medical Center Director recommends individuals to be appointed to the IRB. At least one of these representatives must have scientific expertise. These representatives serve 3-year terms. VA Research and Development Administration officials are barred from serving as voting members of the IRB.