

Wayne State University Human Investigation Committee	
Subject	Selection and Review of Institutional Review Board (IRB) Chairs, IRB Members and HIC Staff
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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 selection and appointment of IRB Chairs, Vice Chairs, and HIC staff.

Definitions

Community Representative: An individual (scientist or nonscientist) who serves as an HIC committee member whose primary concerns and membership interests and input reflect those of the population base from which research participants are drawn.

HIC: Human Investigation Committee, which is the name of the institutional review board at WSU, and refers to WSU's five institutional review committees separately or jointly.

HIC Chair: The individual who is a scientist and 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.

IRB: A specifically constituted review board 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].

IRB Chair: An individual who is a scientist and who has been appointed by the Vice President for Research to direct the proceedings of one of the IRB committees and who provides expertise and leadership in a wide range of areas related to IRB functions.

IRB Vice Chair: An individual who is a scientist and who has been appointed by the Vice President for Research to direct the proceedings of one of the IRB committees in the absence of the *IRB Chair* or when the IRB Chair must recuse him/herself due to a conflict of interest with a particular research proposal under review.

Nonscientist: An individual who is not a scientist and who neither works in one of the sciences nor has scientific training and whose primary concerns as a committee member are nonscientific areas.

Scientist: An individual who has scientific training and/or works in one of the sciences and whose primary concerns as a committee member are in scientific areas and whose expertise is relevant to one or more areas of research that are reviewed by the HIC.

Unaffiliated Member: An individual who is a scientist or nonscientist and is not affiliated with the University or any of its affiliates and whose immediate family does not have a University affiliation. Note: WSU students are not considered an “affiliated” member.

IRB Membership

Selection of members to the IRB committees is determined by member experience, expertise, and knowledge of the community. Diversity in race/ethnicity, gender, and cultural background is also a consideration in member selection. Members must have an in-depth understanding of applicable regulations relevant to the type of research being reviewed or have immediate access to that expertise (see “Expectations of IRB Membership”).

Each of the HIC committees has:

- At least five members;
- An IRB Chair and Vice Chair(s)
- 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 the scientific area;
- At least one nonscientist member;
- A member (scientist or nonscientist) who is not affiliated with the University and whose immediate family does not have a University affiliation

- At least one member (scientist or nonscientist) who serves 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 1200.05 7.c].
 - At least one VA representative must have scientific expertise;
 - The VA representatives serve as full members of the IRB and review non-VA research matters coming before the IRB.
- Members who are knowledgeable about and experienced in working with all vulnerable populations (e.g., children, prisoners) and who will review and be present for determinations concerning research that involves participants from vulnerable populations;
- For an IRB that reviews research that involves mentally disabled persons or persons with impaired decision-making capacity, the IRB membership includes at least one member who is an expert in that area of the research.
- For research funded by the Department of Education – National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, there must be at least one member who is primarily concerned with the welfare of these research participants.
- A representative from the Office of General Counsel, a voting member of a medical committee.

IRB members are appointed to (1) a specific committee and (2) may also serve as an alternate, if needed, on the other committees. In identifying an appropriate alternate, care is given in 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 (VPR) is the Institutional Officer responsible for the selection and appointment of IRB members. The need for a new member can be identified by an IRB Chair, HIC Chair, Director, Responsible Conduct of Research (D-RCR), Assistant Director, Responsible Conduct of Research (AD-RCR), or by the Associate Vice President for Research (AVPR). The need for new or additional members is based on the following:

- Maintaining an adequate number of members;
- Maintaining an adequate representation of expertise; and
- Maintaining an adequate representation of nonscientists or community representatives.

When need for a new member is identified, a meeting of administrative leadership takes place to define the characteristics required for a new member. Suggestions for potential new members are made, and if a consensus is reached, the AVPR or designee will contact the individual to discuss his/her availability and interest. If there are no suitable candidates identified, then the AVPR will contact the Chair of the department or college from which new member expertise is needed. If a nonscientist member is needed, the AD-RCR will enlist help of the Community Liaison to identify potential candidates. The AD-RCR or Community Liaison will then contact the candidate to determine his/her availability, qualifications, and interest.

When a candidate has been identified and has indicated his/her availability and interest in serving as an HIC committee member, the AVPR will send an "IRB Member Letter of Intent". Upon signing this letter, the candidate will begin the training process, which includes (1) completion of specific CITI training modules, (2) a one-on-one meeting with the Education Coordinator, and (3) planned attendance at an IRB meeting. If the candidate has continued interest in becoming an IRB member, an appointment letter will be sent by the VPR; the candidate must sign this letter indicating his/her acceptance of the appointment. A curriculum vitae/resume must be submitted which will be maintained in the member's IRB file as well as a signed confidentiality agreement.

Initial appointments are made for one year, then renewed for two years based upon mutual agreement between the new member, IRB Chair, and the AVPR. The major requirements for renewal of an initial appointment member are continuing availability, effectiveness of protocol review, and record of attendance during the first year (members are asked to attend a minimum of 75% of IRB meetings each year). Review of the member is again accomplished following the total three years of service. If the member's service continues to meet expectations (as previously described), and if he/she has continued interest in IRB membership, a renewal appointment letter will be generated by the VPR for IRB member signature. A current CV/resume will again be requested, and refresher CITI training courses completed, if applicable.

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
 - Affiliation or non-affiliation with WSU
 - VAMC representatives

Changes in IRB membership are promptly reported to the Office of Human Research Protection (OHRP) by the AVPR.

Training of New Members

Upon receipt of a signed "IRB Member Letter of Intent" from a newly appointed IRB member, the AD-RCR will notify the Education Coordinator to schedule a training session with the new member. The training schedule will include review of the following:

- HIC policy, "Expectations of IRB Membership"
- IRB meeting schedule
- HIC website containing policies/procedures/forms, etc.
- HIC submission forms
- HIC policy and procedures
- Federal regulations discussed in detail, including: 45 CFR 46, 21 CFR 50 and 56, 38 CFR 16, 45 CFR 46.111, etc.
- Information sheets about devices

The potential new member will also attend at least one IRB meeting, during which time the Education Coordinator will explain the proceedings. New members will usually be required to attend a couple of meetings before they are ready to be assigned a review. At the first meetings in which they are assigned protocols for review, the Education Coordinator will provide mentoring, if needed.

Evaluation of IRB Members

Each IRB member, scientist and non-scientist, is reviewed by the AVPR, IRB Chair, IRB staff (who regularly attend the IRB meetings), HIC Chair; AD-RCR; and D-RCR. The evaluation consists of a review of an individual's attendance at meetings, active participation in discussion, adequacy of protocol review, and appropriate understanding of rules and regulations pertaining to research (including HIC policies and procedures, the federal code of regulations, local and state laws and statutes).

Selection and Appointment of IRB Chairs and Vice Chairs

The Vice President for Research (VPR) is the Institutional Official responsible for appointing IRB Chairs. Candidates are required to be scientists who have had considerable experience with IRBs and/or research compliance. Ideally, potential IRB Chairs must have served on the IRB at this Institution for at least three years and have shown diligence, dependability, and continued interest in serving on the IRB. The requirements for selection of a Vice Chair are the same as that for an IRB Chair. Candidates should demonstrate evidence of leadership skills and availability of time to commit to the IRB duties. Duties of the Chair include, but are not limited to, a pre-review of protocols, assignment of protocols for full board review, and expedited review of revised protocols and amendments that meet the criteria for specific minor revisions. The Vice Chair carries out the duties of the IRB chair as needed.

When a new IRB Chair is needed, the outgoing IRB Chair and the Associate Vice President for Research discuss potential candidates for the position based on the qualifications described above as well as the area of expertise represented by the candidates. 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 identified, and states that he/she is agreeable to fill the Chair position, the VPR will send 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.

Evaluation of IRB Chairs

The AVPR meets with each of the IRB Chairs when it is time for reappointment for an evaluation of their performance and level of interest in continuing to serve in this capacity. A written evaluation is provided only if requested by the Chair. Refresher CITI training courses must also be completed as a requirement for reappointment to the IRB.

Selection and Appointment of HIC Staff

The AVPR is responsible for the selection and appointment of HIC staff. Positions are posted through the University's employment services in accordance with policies and procedures of the Division of Human

Resources. Applications are reviewed by the D-RCR and AD-RCR Candidates are selected based on their qualifications for the posted position. Candidates are interviewed by the AD-RCR and/or D-RCR and any other administrative or HIC staff as deemed appropriate.

Training of HIC Staff

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 AVPR. Attendance at the annual IRB education seminar is also expected. The Education Coordinator and other administration provide training on an ongoing basis to address new or revised policies, procedures, regulations, etc. Refresher CITI training courses must also be completed as a requirement for reappointment to the IRB.

Evaluation of HIC Staff

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

Appointments of VAMC Representatives to the IRB

The Medical Center Director recommends individuals to be appointed to the IRB. The representative must have scientific expertise and be available to serve a three year term. VA Research and Development Administrative officials are barred from serving as voting members of the IRB.