

Wayne State University Human Investigation Committee	
SUBJECT	Expectations of IRB Membership
Section	
Form Date	03/09
Approvals	General Counsel 12/04/06, Steering Committee 12/19/06, Administrative Approval 03-07-07, General Counsel 02/21/08, Administrative Approval 03/11/09

Background

The primary purpose of the Human Investigation Committee (HIC) is to protect the rights of human participants in research and to facilitate ethical research. In order to accomplish this goal, all research protocols involving human participants must first be reviewed by the Wayne State University (WSU) Institutional Review Board (IRB). Exempted or expedited research protocols are reviewed and acted upon by the HIC chair or his/her designee. Protocols requiring full board review are directed to the appropriate IRB committee by the HIC chair or his/her designee. Either the chairperson of each IRB committee or his/her designee assigns research protocols and amendments to a primary and secondary reviewer based on expertise of the reviewer and an equitable distribution of the workload. If necessary, the IRB chair will request the services of an outside consultant. [45 CFR 46.107-124]; [38 CFR 16.07]. (See also HIC Policy and Procedures "Selection and Review of Institutional Review Board Members" and "Selection of Alternative IRB Members for Duly Constituted Meetings")

HIC Policy/Procedures

Responsibilities of IRB Members

1. Attendance at Meetings

- IRB members are expected to attend at least 75% of the meetings (i.e., at least nine meetings per year).
- Members must promptly notify the HIC administrative office if they are unable to attend a scheduled meeting.
- IRB members are expected to arrive on time for the meetings and remain until its conclusion.
- Attendance will be recorded as follows:
 - Members present
 - Members late (10 minutes or more after the scheduled start of the meeting)
 - Members absent with notice

- Members absent without notice

2. Full Board Review of an Initial Submission or an Amendment

A. *Review of a new research proposal or an amendment to a previously approved project should include assessment of the following:*

- Merit and scientific validity (i.e., sound research design that minimizes risk);
- Minimization of Risk;
- Risk/benefit ratio;
- Equitable selection of participants, including race, gender, and cultural background;
- Consent process and documentation;
- Data and safety monitoring;
- Privacy and confidentiality for participants;
- Adequacy of protection to vulnerable participants;
- Protection from potential coercion;
- Compliance with local, state, and federal regulations (DHHS, FDA, VA, and HIPAA) and IRB policies;
- Conflict of Interest.

B. *Responsibilities of Primary and Secondary Reviewers PRIOR to the meeting:*

- Review all submitted materials;
- Complete the entire Reviewer's Form to document the appropriate IRB issues;
- Secondary reviewer should convey findings/issues of concern to the primary reviewer. The primary reviewer should contact the Principle Investigator (PI) or his/her study staff for any clarifications that may be needed;
- Ensure that all elements of the informed consent are in place and are conveyed in appropriate lay terms;
- An attorney (either an IRB committee member or the IRB representative with General Counsel) will pre-review all research conducted outside of the local jurisdiction to ensure that the PI has submitted adequate verification of the applicable local, state or federal laws and regulations and that the requirements will be met;

C. *Responsibilities of Primary and Secondary Reviewers AT the IRB meeting:*

- The primary reviewer should BRIEFLY: (i) summarize the protocol for IRB members (note: only the primary and secondary reviewers receive the complete research proposal and investigator brochure); and (ii) bring to the IRB's attention issues not satisfactorily resolved by contact with the PI prior to the IRB meeting;
- The secondary reviewer should make additional comments as necessary avoiding repetition of issues already discussed;
- Discuss elements of the informed consent form that do not meet HIC requirements;
- Primary and/or secondary reviewer makes recommendations to the committee for action;
- Revise the Reviewer's form to reflect discussion and consensus of the IRB.

D. *Responsibilities of the general IRB membership:*

- Review all supplied materials.

- Bring to the IRB's attention any concerns that: (i) were not discussed by the primary or secondary reviewers, and/or (ii) issues that require further clarification for understanding of the proposed research or amendment to the research.
- In addition to the privileges of full IRB membership, non-scientific and non-affiliated members will represent the views of the community and potential participants.

3. Full board Review of Continuation Reports

A. Responsibilities of the Primary Continuation Reviewer:

- Review all submitted materials.
- Ensure that the HIC Continuation Form has been completed appropriately.
- Review all adverse event reports to assess the risk/benefit ratio status.
- Complete the Continuation Reviewer's Form.
- Briefly present findings to the IRB membership.
- Make recommendations to the IRB for action.

B. Responsibility of the general IRB membership:

- Review all supplied materials.
- Bring to the IRB's attention any concerns that: (i) were not discussed by the primary reviewer, or (ii) issues that require further clarification.

4. Confidentiality of IRB Members, IRB Guests and HIC staff at IRB meetings

- IRB members, guests and staff keep the proceedings at all convened meetings confidential, the content of the protocols private, and the discussion and votes taken by the committee are not discussed with anyone outside the committee meeting.

Procedures at Monthly IRB Meetings

1. A quorum is the majority plus one (50% plus 1) of the total voting membership of a constituted IRB. No official action can be taken at an official meeting of an IRB in the absence of a quorum. Issues may be discussed, but an official vote cannot be taken until a quorum is present.
2. Each time a vote is taken, the meeting minutes will reflect the number of votes "for," "against," "abstentions" and "recusal". Votes "against" require the completion of a separate form by the individual, documenting the reason behind the negative vote. This form will become a part of the protocol record.
3. Members and consultants must recuse themselves from the meeting for the discussion and vote on a study in which the member or consultant has either a financial or non-financial Conflict of Interest. (See Conflict of Interest IRB Member and HIC Staff) They must recuse themselves and leave the meeting room during the discussion and vote except to provide information requested by the IRB [45 CFR 46.107(e)].
4. A member with knowledge about, or experience working with, a vulnerable population(s) (i.e., children, prisoners, pregnant women, those with physical or mental disabilities) must be present at a meeting where a protocol involving that specific vulnerable population(s) is being reviewed.

5. At least one member who meets the criteria of “non-scientific” must be present during a convened meeting.
6. One member that represents the Veterans Administration Medical Center (VAMC) must be present when a VA protocol is being reviewed; they must have scientific expertise.