Wayne State University Human Investigation Committee	
Subject	Expectations of IRB Membership
Form Date	March 2009 (Rev. 03/07/11)
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, Administrative Approval 9/30/10, Administrative Approval 03/07/11

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, IRB members must familiarize themselves with all HIC policies and procedures, as well as understand the federal regulations pertinent to the research under review. All research protocols should be assessed to ensure that the proposed study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with Good Clinical Practice (ICH-GCP) and the applicable regulatory requirements.

All research protocols involving human participants must first be reviewed by 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 reviews 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”.)

Scope:

This policy/procedure addresses the responsibilities of IRB members as it relates to attendance at scheduled IRB meetings and education/training seminars, review of research proposals with clarification of the responsibilities of each reviewer (i.e., primary and secondary reviewers and the general IRB membership), confidentiality requirements of IRB processes, and procedures at each of the monthly IRB meetings.

Responsibilities of IRB Members:

Attendance at Annual Education/Training Seminars

- The HIC Education Coordinator, in collaboration with HIC Administration, schedules an annual fall training seminar for which attendance is required. Notification of this education/training session will be sent via e-mail, campus mail, included in the review packets, and is announced at IRB meetings well in advance of the scheduled date. This training session provides clarification of HIC policies/procedures; updated federal, state, and local regulations; and addresses current "hot" research topics that may affect the protection of human participants in research.
- For research sponsored by the Department of Defense, initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participant research. Researchers, HIC staff, IRB members, and the research community at large will be notified of specific research requirements under a Department of Defense Addendum and educated about these requirements when appropriate.

Attendance at IRB Meetings

- IRB members are expected to attend at least 75% of the meetings (i.e., at least nine meetings per year). A schedule of IRB monthly meetings is posted on the HIC website. Special attention should be given to November and December meetings as the meeting dates are often affected by the holidays occurring in those months. IRB members are strongly urged to mark their calendars and clear their schedules to ensure availability for attendance at the regularly scheduled IRB meetings.
- 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

Full Board Review of an Initial Submission or an Amendment

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);
- Determine if the research design is sound enough to yield the expected knowledge.
- Evaluate available clinical and nonclinical information on an investigational product to determine if the information is adequate to support the proposed clinical trial.
- Review clinical trial protocols to determine if scientifically sound and information is described in clearly and in detail.
- 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, as well as any other applicable federal entity (e.g., EPA, ICH-GCP, DoD, etc.) and HIC policies/procedures;
- Conflict of Interest.

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 Principal 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.

Responsibilities of Primary and Secondary Reviewers AT the IRB Meeting:

- The primary reviewer should BRIEFLY: (1) summarize the protocol for IRB members (note: only the primary and secondary reviewers receive the complete research proposal and investigator brochure); and (2) 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;
- Complete the Reviewer's form to reflect discussion and consensus of the IRB.

Responsibilities of the General IRB Membership:

- Review all supplied materials.
- Bring to the IRB's attention any concerns that: (1) were not discussed by the primary or secondary reviewers, and/or (2) 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.

Full Board Review of Continuation Reports

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.

Responsibility of the General IRB Membership:

- Review all supplied materials.
- Bring to the IRB's attention any concerns that: (1) were not discussed by the primary reviewer, or (2) issues that require further clarification.

Confidentiality of IRB Members, IRB Guests and HIC Staff at IRB Meetings

IRB Members, guests, and staff must keep the proceedings at all convened meetings confidential and the content of the protocols private. The discussion and votes taken by the committee are not to be discussed with anyone outside the committee meeting. HIC staff and each IRB member must sign a confidentiality agreement; this document is maintained by the Assistant Director, Responsible Conduct of Research, in the IRB member's file. IRB guests are also asked to sign a confidentiality agreement. (see "IRB Member Letter of Intent", "Confidentiality Agreement for IRB Members", "Confidentiality Agreement for IRB Member Guests.")

<u>Procedures at Monthly IRB Meetings</u>

- A quorum is a majority (e.g., membership of 13, quorum is 7; membership of 12, quorum is 7). 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.
- Each time a vote is taken, the meeting minutes will reflect the number of votes "for", "against", "abstentions", and "recusal". The vote process begins with a recommendation by the primary reviewer, followed by the confirmation of that recommendation by the secondary reviewer, followed by any further discussion from the general IRB members. The Chair will then ask for a vote, which is taken by the raising of hands to signify a vote "for", then "against", followed by a request for any members "abstaining" from the vote. The Research Compliance Administrator will then reflect the vote results in the minutes, including a statement regarding any members who had left the room due to a conflict of interest. Approval of a research proposal requires a majority vote. Votes "against" require the completion of a separate form by the individual, documenting the reason behind the negative vote. This form will become part of the protocol record.
- Members and consultants who have either a financial or non-financial Conflict of Interest (see "Conflict of Interest IRB Member and HIC Staff"). must recuse themselves and leave the meeting room during the discussion and vote. The only exception to this ruling would be to provide information if requested by the IRB [45 CFR 46.107(e)].

- 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.
- At least one member who meets the criteria of "non-scientific" must be present during a convened meeting.
- At least one member who meets the criteria of "non-affiliated" must be present at least 75% of the meetings (i.e., at least nine meetings per year).
- Two members that represent the Veteran's Administration Medical Center (VAMC) must be present when a VA protocol is being reviewed; these individuals must have scientific expertise.

Materials used to conduct IRB meetings

A projector is used for the committees that meet in the HIC conference room. The agenda items are displayed, as are new or revised policies that require review by the Committee, a summary of Unexpected Problem reports (if applicable); the IRB Assignment and Deliberation Form (if revised) are distributed to all members at the IRB meeting.

All submissions requiring review at the meeting are available online via "Blackboard". Only the primary and secondary reviewers receive hard copies of the submissions. A packet, including the hard copies of submissions and reviewer forms are mailed or hand-delivered to primary and secondary reviewers approximately one week before the meeting. The reviewer form includes a detailed set of questions that prompt reviewers to check for all required elements regarding the protection of human subjects. The reviewer forms serve as documentation of the review and voting decision.

Prior to the MI, MP2, and MP4 meetings, Unexpected Problem reports and any accompanying documents are e-mailed to Committee members. An AR/UE summary is distributed to all M1, MP2, and MP4 members at the meeting. For the B3 Committee, the reports are not emailed and a summary is not distributed. Instead, the B3 Chair presents the Unexpected Problem summary at the meeting for discussion and voting.

IRB meeting minutes are e-mailed to all Committee members prior to the meeting. The minutes are voted on at the beginning of each meeting.

A meeting reminder is emailed to all committee members approximately two weeks prior to the meeting. Hard copies of the meeting reminder are mailed to those members who do not have access to the internet.

The Phase 1 IRB members obtain access to electronic documents via Blackboard, where the protocol documents are posted. Only IRB members who are granted access have the capability to log into Blackboard/HIC site and review documents. The documents can be saved on the members' computers for reviewing. The IRB Chair receives paper documents to review prior to each Friday morning teleconference. Teleconferences are held on Friday mornings at 7:00 AM via telephone; but in rare circumstances, when there is not a quorum available on Friday, the teleconference may be held at an alternate day and time.