



HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Selection of Alternate IRB Member(s) for Duly Constituted Meeting
Section	
Form Date	01-16-09
Approvals	03/02/04 Administrative Approval, 03/17/04 Approved by Steering Committee, 09/10/06 Administrative Approval, 8/13/08 Administrative Approval, 8/13/08 General Counsel Approval, 1/16/09 Administrative Approval

Background:

Wayne State University (WSU) maintains four Institutional Review Boards (IRB), each consisting of approximately 18 to 22 members (M1, MP2, B3, and MP4). The Phase I Committee (PH1) has at least 7 members and specializes in the review of industry-sponsored Phase I clinical trials. There is also an IRB with at least 6 members that reviews protocols that require a rapid turnaround (CTS1). These IRB members are highly qualified individuals with appropriate knowledge and background for reviewing a wide variety of research. In addition to the service that they provide the IRB to which they have been appointed, these IRB members may also be available to serve as an alternate when a particular IRB is having difficulty in obtaining a quorum or in maintaining a duly constituted committee. As a result, IRB members are appointed to: a) a specific IRB; and (b) can also serve as an alternate to the other IRBs. In identifying an appropriate alternate, care should be given to meeting the regulatory requirements of 45 CFR 46.107, 38 CFR 16.107, and 21 CFR 56.107. The alternate that is selected should have comparable qualifications to the primary member to be replaced with appropriate scientific expertise or community competence. For Veterans Administration Medical Center studies, one member of the VAMC must be present for the discussion and the vote and must have scientific expertise.

Scope:

This Policy/Procedure applies to all IRB Committees at WSU.

Definitions:

Quorum- one more than half of the members of a specific committee. For example, a committee of 13 members would require 8 members present to meet quorum.

Duly Constituted- An IRB this is comprised of at least five members with varying backgrounds to promote

adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition, the IRB will consist of the following: persons knowledgeable in institutional and professional standards, applicable law, and vulnerable groups; someone who is considered a non-scientist, at least one scientist, and one person who is not affiliated with the institution or is not part of the immediate family of a person who is affiliated with the institution. [45 CFR 46.107(a)(b)(c)(d)(e), 38 CFR 16.107(a)(b)(c)(d)(e) & 21 CFR 56.107(a)(b)(c)(d)(e), VHA 1200.5.6.j., Page 9]

HIC Procedures:

When members of an IRB know that they will be absent from a scheduled meeting of their committee, they are asked to notify the Compliance Coordinator for that IRB in sufficient time to arrange for an alternate, if needed. If the absence of the member(s) for a particular meeting would result in: 1) the absence of a quorum; or 2) the committee membership would not be duly constituted to review protocols; or 3) a protocol under review requires the presence of a vulnerable group representative, then the IRB Coordinator will contact a member of another IRB to with comparable skills and experience to request that he/she serve as an alternate for the absent member.

A roster of all IRB members on each of the six Committees (MI, MP2, B3, MP4, CTS1 and PH1) is maintained by the HIC. The information on the roster includes the expertise, experience, and other specific qualifications of each member. This enables the IRB Research Compliance coordinator to select an alternate with comparable knowledge, expertise and experience that would enable the committee to review research activities appropriately and thoroughly.

The selection of an alternate member of an IRB will be done in such a way as to prevent alteration of the necessary professional or academic expertise, experience, ethnic, gender and cultural diversity required of the committee. For example, for those members who are non-scientists, a non-scientist alternate will be selected. For those who are scientists, a scientist will be chosen as an alternate. For those who represent the community in a non-affiliated capacity, an alternate with similar qualifications will be selected. Special attention should also be given to making sure that individuals with knowledge of vulnerable populations are present at specific IRB meetings at which such populations are scheduled to be reviewed.

If an IRB member is a VA employee and requires an alternate, another IRB member from the VA affiliate must serve as that alternate. [VHA 1200.5, 5.a.(3)(a) page 7]

Whenever an alternate member is utilized for a convened IRB, it should be duly noted in the minutes for that meeting. The minutes are to include the name of the alternate and the primary member for whom they are substituting. The HIC staff will hand deliver a packet to alternates containing all of the information sent to committee members. When hand delivery is not possible, the material will be sent overnight delivery. If the meeting is scheduled for the day following notification that a member will not attend, the alternate will be contacted and the most efficacious means of delivery will be determined. In any event the material to be reviewed will be made available to all of the members the HIC office five

days prior to the meeting. The alternate member receives the same packet of materials that is sent to all committee members.