

Wayne State University Human Investigation Committee	
<b>Subject</b>	<b>Selection of Alternate IRB Member(s) for Duly Constituted Meeting</b>
<b>Form Date</b>	January, 16, 2009 (Rev. 03/07/11)
<b>Approvals</b>	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, 9/30/10 Administrative Approval, 03/07/11 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). A fifth IRB committee, Phase I Committee (PH1) has at least 7 members and specializes in the review of industry-sponsored Phase I clinical trials. 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 is 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*- A majority (e.g., membership of 13, quorum is 7; membership of 12, quorum is 7).

*Duly Constituted*- An IRB that 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, 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 their committee's Research Compliance Administrator (RCA) 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, the RCA will contact a member of another IRB 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 five Committees (MI, MP2, B3, MP4, and PH1) is maintained by the HIC. Information on the roster includes the expertise, experience, and other specific qualifications of each member. This enables the RCA 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 must 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; and for those who represent the community in a non-affiliated capacity, an alternate with similar qualifications will be selected. Special attention must also be given to ensuring that individuals with knowledge of vulnerable populations are present at specific IRB meetings at which such populations are scheduled to be reviewed.

Whenever an alternate member is utilized for a convened IRB, it must 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.