

Michigan State University Human Research Protection Program	
<i>Subject:</i> Institutional Review Board Membership	
<i>Section:</i> 5-3	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel; Revision 1 & 2 reviewed by HRP/IRB Administrative Committee; Revision 3 reviewed by IRB, Education Coordinator, Director Compliance & Standards, MSU Legal Counsel, HRPP Director, Asst. VP Regulatory Affairs</i>	<i>Approved by: Vice President of Research and Graduate Studies, 4-21-2005; Revision 1 approved by the Vice President of Research and Graduate Studies on 11-2-2005, Revision 2 approved by the Vice President of Research and Graduate Studies on 2-1-2006. Revision 3 approved by VP Research & Graduate Studies on 3-9-2008.</i>
<i>Related Sections: 5-4, 10-1, 11-1-B</i>	

IRB Composition and Recruitment

Members of Michigan State University Institutional Review Boards, including alternates, are nominated by deans and others and appointed by the Vice President of Research and Graduate Studies. Nominations to the Vice President of Research and Graduate Studies should include a description of the individual's qualifications.

The Community Research Institutional Review Board (CRIRB) is a review committee comprised of members from MSU East-Lansing, the community campuses of MSU, and IRBs from affiliated hospitals and institutions.

1. MSU-East Lansing affiliated members.
2. Constituent Institutional Review Board (IRB) Representatives. Participating IRBs should identify their individual members with the requisite credentials and experience.
3. Non-affiliated members and non-scientific. This category of membership includes community members. These members may be from the participating communities or from centrally located communities.

Members of the IRBs will be recruited and added to ensure proper membership according to the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) including:

- A minimum of five members and a maximum of 25 members
- diverse scientific and clinical expertise
- scientific members from appropriate disciplines (e.g., behavioral, medical, etc.)
- gender diversity
- racial diversity
- community representation
- non-scientist representation
- inclusion of one or more individuals who are knowledgeable about and experienced in working with vulnerable subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons
- inclusion of "affiliated members". A member is considered "affiliated" if they or a member of their immediate family is a full or part-time employee (or has an

adjunct appointment) of the institution. A member is also considered “affiliated” if they or a member of their immediate family is affiliated with the institution on a basis other than employment or faculty appointment, such as consultant, student, retiree or former employee.

- inclusion of non-affiliated members who are “not otherwise affiliated with the institution and who are not part of the immediate family of a person who is affiliated with the institution” (45 CFR 46.107(d), 21 CFR 56.107(d))
- appropriate representation from college or partner institution

When appropriate the following types of people may be desirable for membership:

- attorney
- statistician or epidemiologist
- spiritual leaders
- ethicist

Alternate members may be appointed as needed for regular voting member(s). The appointment of alternate member(s) should be based on expertise similar to that of the regular voting member(s). If a regular member has an alternate, the rosters shall indicate such designation. An alternate member may vote at a convened IRB meeting only when the regular voting member is absent. Alternate members may be assigned as a reviewer on projects if the regular member is unavailable to conduct reviews.

The composition of the committee will be periodically evaluated and appropriate adjustments in membership and composition will be made. See Section 3-1, “Michigan State University Human Research Protection Plan”. HRP Manual for evaluation process.

Other persons may be called upon for their expertise to assist the IRB in reviews and analysis, but these persons may not vote unless they are formal members of the committee. See Section 5-4 “Additional Expertise” of the HRP Manual for policies and procedures.

An IRB administrator will report any changes in the composition of the IRB to OHRP. This may be done by submitting an updated roster through OHRP’s electronic renewal/update process.

Members shall be appointed for three-year terms. Reappointments are made by the Vice President of Research and Graduate Studies. There is no limit to the number of three-year terms an individual may serve, but it is suggested to serve two three-year terms, and then rotate terms with other individuals. When a member's term expires, notification will be sent prior to expiration. If a member wishes to continue service, a recommendation is made to the Vice President of Research and Graduate Studies for reappointment.

Experienced Reviewer Designation

The regulations state that only “experienced reviewers designated by the chairperson from among members of the IRB” may conduct expedited review. (45 CFR 46.110(b)) To be designated as an “experienced” IRB member, the IRB chair will evaluate the IRB member in light of:

- Completion of the orientation process
- Involvement in several protocols as a shadow reviewer (see Section 11-1-B, “Education: IRB Members” for a description of “shadow review”)
- Attendance and thoughtful contributions at two or more full board meetings
- Previous IRB experience, if any

The IRB chair will determine whether the member is “experienced”, or if further experience is needed. If the IRB member is deemed as “experienced”, the IRB chair shall notify the IRB member in writing of the determination. If the IRB member is not deemed as “experienced”, additional training will be required as appropriate.

IRB Member Responsibilities

1. Uphold federal, state, and local regulations, university policies and procedures and ethical standards for the protection of human research subjects.
2. Attend and contribute to discussion at IRB meetings.
3. Review IRB meeting materials prior to the IRB meeting.
4. Perform review of projects as assigned.
5. Act as lead reviewer on full board projects as assigned:
 - a. Provide a written summary of review (including reviewers’ comments).
 - b. Present results of reviews at IRB meetings.
6. Review application materials based on Federal regulations, state law, and University policies.
7. Review projects using current IRB policies and procedures.
8. Provide timely written or electronic feedback on all application materials assigned.
9. Disclose conflict of interest pursuant to the policy and procedures in Section 10-1, “Conflict of Interest”, HRP Manual
10. Communicate with investigators as needed.
11. Communicate with their home departments or IRBs (CRIRB) and provide updates concerning IRB activities.
12. Participate in activities to enhance development as an IRB member, such as:
 - a. Continuing education on human research activities.
 - b. Annual self-evaluation process.