Members of Michigan State University (MSU) Institutional Review Boards (IRB), including alternates, are nominated by deans and others and appointed by the MSU Institutional Official (IO). Nominations to the IO should include a description of the individual’s qualifications.

Composition
The Biomedical and Health Institutional Review Board (BIRB) and the Social Science / Behavioral / Education Institutional Review Board (SIRB) are comprised of members affiliated with MSU and non-affiliated and non-scientific members. The Community Research Institutional Review Board (CRIRB) is comprised of members affiliated with MSU, members affiliated with CRIRB partner institutions, and non-affiliated and non-scientific members. When providing nominations for membership, CRIRB partner institutions should identify their individual members with the requisite credentials and experience.

Members of the IRBs will be recruited and added to ensure proper membership according to the U.S. Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration (FDA) including:
- Minimum of 5 members and a maximum of 25 primary members
- Diverse scientific and clinical expertise
- Scientific members from appropriate disciplines (e.g., behavioral, medical)
- Gender diversity
- Racial diversity
- Community representation
- Non-scientist representation
- 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
- Affiliated members
- Non-affiliated members
- Appropriate representation from colleges or partner institutions
When appropriate the following types of individuals may be desirable for membership:

- Attorney
- Statistician or epidemiologist
- Spiritual leaders
- Ethicist

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 MSU. A member is also considered affiliated if they or a member of their immediate family is affiliated with MSU on a basis other than employment or faculty appointment, such as consultant, student, retiree, or former employee. A member is considered not to be affiliated if they are not otherwise affiliated with MSU and who are not part of the immediate family of a person who is affiliated with MSU. 45 CFR 46.107(d), 21 CFR 56.107(d).

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

The composition of the IRB will be periodically evaluated and appropriate adjustments in membership and composition will be made. See HRPP Manual 3-3 “Evaluation and Quality Improvement” for the evaluation process.

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

Individuals involved in business or research development may not serve as IRB members and may not be involved in the day-to-day operations of the review process.

An IRB administrator will report any changes in the composition of the IRB to OHRP and the FDA (via OHRP). This will be done by submitting an updated roster through OHRP’s electronic renewal/update process. The registration information for an IRB must be updated within 90 days after changes occur regarding the IRB chairperson. 45 CFR 46.505 (b), 21 CFR 56.106(e).

Appointment Term
Members shall be appointed for three year terms. Reappointments are made by the IO. There is no limit to the number of terms an individual may serve, but it is suggested that a member serve two terms and then rotate terms with other individuals. If a member wishes to continue service, a recommendation is made to the IO for reappointment.

The IO may remove a member from the IRB before the end of his/her appointed term. The IRB chair in consultation with the HRPP director may submit a request for removal
to the IO based on the member’s failure to carry out the responsibilities of an IRB member (e.g. failure to attend meetings regularly, failure to comply with regulations and policies). The IO makes the final decision on removals. If removed, prompt notification will be provided to the member. IRB members may request to be removed from the IRB without providing a reason (e.g. time commitment, personal reasons) and will be removed with notification to the IO. Efforts will be made when possible to retain the IRB member so that the three year term may be completed.

**Experienced Reviewer Designation**
The regulations state that only “experienced reviewers designated by the chairperson from among members of the IRB” may conduct expedited reviews. 45 CFR 46.110(b), 21 CFR 56.110(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 studies as a shadow reviewer (see HRPP Manual 11-1-B “Education: IRB Members” for a description of shadow review)
- Involvement in the review of convened IRB studies
- Attendance and thoughtful contributions at six or more convened 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 to be experienced, additional training will be required as appropriate. The IRB chair will determine which members designated as experienced may conduct reviews using expedited procedures.

The IRB chair, with input from appropriate administrators, provides information to the HRPP director and/or the IO for evaluation of IRB members. See HRPP Manual -3 “Evaluation and Quality Improvement” for the evaluation process.

IRB members shall:

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 studies as assigned.
5. Act as lead reviewer on full review studies as assigned, including:
   a. Provide a written summary of review (including reviewer comments).
   b. Present results of reviews at IRB meetings.
6. Review application materials based on federal regulations, state law, and university policies.

7. Review studies using current HRPP policies and procedures.

8. Provide timely written or electronic feedback on all application materials assigned.

9. Disclose conflict(s) of interest pursuant to the policy and procedures in HRPP Manual 10-1 “Conflict of Interest.”

10. Communicate with researchers as needed.

11. Communicate with their departments or partner institutions 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. Evaluation processes.