Grand Valley State University Institutional Review Board (IRB)	
Title: *IRB Composition and Member Responsibilities*	
Section: 010.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 11/08/2011 Revised: 10/28/2014 Reviewed: 10/28/2014 Reviewed: 3/23/2017 Revised by IRBPPC: 4/23/2019 Revised by IRBPPC: 03/29/2022 Revised by IRBPPC: 02/12/2026 Revised by IRBPPC: 10/09/2026	Approved by RIO/HRPA: 11/21/2011 Revisions approved:10/28/2014 Revisions approved by AIO/RIO: 3/24/2017 Revisions approved by AIO/RIO: 4/26/2019 Revisions approved by AIO/RIO: 04/12/2022
Effective Date: 10/09/2026	
Related Documents: *020: Conducting IRB Meetings* *030: Operational Support of the IRB* *050: Records Retention and Destruction* *140: IRB Member Conflict of Interest* *OP-1: Charge to the IRB*	

Policy

1. The IRB shall be composed of at least five (5) members with diverse professional and educational backgrounds, including at least one scientist, one nonscientist, and one unaffiliated member.

2. The IRB must have sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews. If IRB members do not possess the necessary knowledge, additional expertise can be sought from outside consultants.

Procedures

1. Membership
    a. IRB member appointments are made by the Institutional Official (IO), and are generally for three-year terms, with appointments being renewable. Should either the member or the IO choose not to renew an appointment, justification for such a decision is not required by either party.

    b. Membership is selected to assure appropriate diversity, including representation by various professions (both scientific and nonscientific) and members of diverse age, ethnicity, gender identity, languages, culture, race, education, religion, etc.

    c. The Office of Research Compliance and Integrity (ORCI) is responsible for maintaining an active membership roster. Membership rosters and records will include members' names, affiliation, degree(s) earned, role on the IRB (scientist, nonscientist, affiliated/unaffiliated, regular/alternate member, etc.), representative capacity, and indication of experience to serve in their appointed IRB role.

d. If a member's status (scientific, nonscientific, unaffiliated) changes during the appointment term, the member must immediately notify the Chairperson of the IRB, the ORCI, and the IO of the change in the membership status.

2. Chairperson and Vice Chairperson
    a. The Chairperson manages the IRB and the matters brought before it according to Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) regulations pertaining to the rights and welfare of research participants.

    b. The Chairperson must hold a terminal degree, be a GVSU employee, and have previously served on the GVSU IRB as a committee member.

    c. Should the Chairperson be unavailable to conduct committee business, a designated Vice Chairperson serves on the Chairperson's behalf. Should neither the Chairperson nor Vice Chairperson be available, the IO may designate a senior IRB member to assume the Chairperson's responsibilities during the period of absence.

    d. Specific responsibilities of the Chairperson include:
        i. Maintaining a thorough understanding of federal regulations pertaining to human subject protections, federal guidance, the GVSU IRB Policies and Procedures, and other applicable state, and local regulations.

        ii. Overseeing ORCI staff members' screening of IRB protocols to determine which of the following is necessary: (1) review of the protocol as exempt, (2) assignment of the protocol for expedited review to at least two IRB committee members, or (3) referral of the protocol to the convened IRB for discussion/action at the next scheduled meeting.

        iii. Assisting, as necessary, with review of IRB protocols and unexpected problems affecting the safety of participants.

        iv. Facilitating protocol clarification between the Principal Investigator and the IRB.

        v. Serving as the primary signatory official for IRB correspondence to researchers.

        vi. Reviewing, as necessary, research determinations made by the ORCI.

        vii. Completing, as necessary, exempt determinations with assistance provided by ORCI.

        viii. Leading the convened IRB meetings in an efficient and orderly fashion and in

accordance with the GVSU IRB Policies and Procedures.

e. The Chairperson is additionally expected to adhere to the following provisions:
    i. Providing attentiveness to the details and requirements of the Federal regulations and GVSU IRB policies and procedures.

    ii. Fostering ethically and scientifically sound research among researchers.

    iii. Establishing a tone of openness that encourages dialogue among IRB members.

    iv. Providing respect for the diverse backgrounds, perspectives, and sources of expertise of all IRB members, especially for the contributions of the nonscientists, and the ability to foster such respect among the IRB members.

    v. Exhibiting the confidence and courage to uphold IRB judgments that may not always be popular with Principal Investigators.

    vi. Investing adequate time, interest, and commitment to provide guidance and expertise to IRB members, scientists and others on the IRB.

f. In addition to the regular member training (Section 8 below), the Chairperson is required to complete a Chairperson training course prior to assuming this role, and every three years thereafter. Additionally, prior to assuming the Chairperson role, the ORCI will provide training regarding specific activities required to be completed by the Chairperson (e.g., operating the electronic submission system as the Chairperson, running IRB meetings, documentation of Chairperson reviews, etc.).

3. Unaffiliated Members
    a. An IRB member is considered *unaffiliated* with GVSU for the purposes of IRB member status if *all* the following four questions can be answered "No" by the individual:
        i. Are you, your spouse, domestic partner, or any of your dependents an employee, paid entity, or agent of any GVSU institution? Residing in the same household as a person affiliated with GVSU does not in and of itself constitute being a dependent.

        ii. Have you been employed by or under paid contract to GVSU within the past year?

        iii. Do you receive any funding or perquisites under the control of GVSU, except as compensation for IRB, Institutional Animal Care and Use Committee (IACUC) or other GVSU committee-related work or other GVSU volunteer-related expenses?

        iv. Have you, your spouse, domestic partner, or any of your dependents been enrolled as a student at GVSU within the past year?

b. Unaffiliated members of the IRB may not be current university employees, students or vendors.

c. An individual with no affiliation to the university other than as a member of the IRB or other volunteer university committee, or whose only association with GVSU is that of health care patient or research participant, may be considered *unaffiliated*.

d. Paying an unaffiliated member reasonable market value for the costs associated with participation as a member of the IRB (e.g. transportation and parking costs, IRB required training, etc.) shall not affect the member's status as unaffiliated.

e. A former university employee or student who has not been employed by or enrolled as a student at the university for at least one year may be considered unaffiliated.

4. Alternate Members
   a. Alternate members are appointed to serve as a substitute for a regular member and/or to ensure the IRB has appropriate expertise to review research (e.g., prisoner representative), and fulfill the member status commensurate with their background (scientist, nonscientist, unaffiliated).

   b. Alternate members are appointed by the IO, in consultation with the IRB Chairperson, Vice Chairperson, and ORCI staff. The IRB roster will indicate which regular member(s) for whom the alternate member may substitute.

   c. Alternate members are invited to attend all IRB meetings and receive, and are expected to review, the same meeting materials as regular members.
      i. When alternate members substitute for a regular member during an IRB meeting, they count toward quorum, and the meeting minutes will document the substitution. An alternate member may substitute for a regular member for an entire meeting, or at any time during a meeting.

      ii. If both a regular member and their alternate(s) attend the same IRB meeting, the alternate member does not count toward quorum, and the regular member acts as the official voting member during IRB voting, unless the minutes clearly indicate otherwise.

   d. Alternate members with adequate experience may be designated to conduct expedited and/or exempt reviews.

5. Scientist and Nonscientist Members
   a. For the purposes of determining IRB member status, a scientist is a person who routinely utilizes the scientific method in the conduct of their discipline-related scholarship. Fields, disciplines, and professions in which persons designated as scientists commonly practice may include, but are not limited to: *medicine, dentistry, nursing, pharmacy, physical therapy, nutrition, anthropology, economics, political science, psychology, sociology, physics, biology, chemistry, math, statistics, and earth*

sciences.

b. For the purposes of determining IRB member status, a nonscientist is a person who does not routinely utilize the scientific method in the conduct of their discipline-related scholarship. Fields, disciplines, and professions in which persons designated as nonscientists commonly practice may include, but are not limited to: *art, classics, drama, English, music, philosophy, and religion.*

c. Not everyone from a scientific field is automatically considered to be a scientist, nor is everyone from a typically nonscientific field automatically considered to be a nonscientist. Classification for purposes of appointment to the IRB depends primarily on the extent to which the individual has familiarity with and experience utilizing the scientific method. The final determination shall be made by the IO in consultation with the IRB Chairperson, ORCI staff, and/or the prospective board member's Appointing Officer.

d. With the exception of the Chairperson, there are no specific degree requirements for any member. However, all members must exhibit an ability to process complex information, possess strong interpersonal communication skills, and be sensitive to unique populations and cultures.

6. Consultants
    a. If no member possesses the necessary scientific expertise to review a protocol, the IRB Chairperson is responsible for identifying the need for a consultant and will arrange for a consultant to provide a scientific review. Consultants may be GVSU faculty, staff, or students, or may be unaffiliated with GVSU.

    b. Consultants will be given the relevant and necessary review materials and may be invited to attend one or more IRB meeting(s), either in person or by electronic means, to assist the board's deliberations, and/or provide a written report to the IRB. Consultants are allowed to provide recommendations related to a protocol, but they are not allowed to vote on IRB protocols. For protocols reviewed at a convened meeting, the minutes of the relevant meeting(s) shall reflect that the consultant was participating and/or provided a written report.

    c. Each protocol for which the consultant provides input shall include the following documentation related to the consultant:
        i. The consultant's qualifications to serve as an expert as relevant to the protocol.
        ii. If applicable, a copy of the contract, including compensation plan.
        iii. A confidentiality agreement, including a conflict of interest disclosure statement, signed by the consultant.

7. Member Responsibilities: Regular and Alternate Members
   While serving an IRB appointment, regular and alternate members have the following responsibilities:

a. Complete required training (see Section 8 below)

b. Complete assigned reviews in a timely fashion as assigned by the Chairperson or ORCI staff.

c. Review the IRB meeting agenda prior to the convened meeting, ensuring that all materials are reviewed for familiarity of protocol and be prepared to participate and contribute to discussion.

d. Speak freely to discuss their point of view and listen respectfully regarding studies under review.

e. Participate openly in appropriate discussions, and motioning and/or voting related to each submission during the IRB meetings. (See *IRB Policy 020: Conducting IRB Meetings*.)

f. Maintain confidentiality of protocols, decisions, and discussions both inside and outside of IRB meetings.

g. Work collegially with investigators and other IRB members to facilitate human subjects' protections.

h. Announce conflicts of interest with research under review and recuse themselves from the review of studies where conflicts of interest exist or may appear to exist (See *IRB Policy 140: IRB Member Conflict of Interest*).

i. If a regular member, attend at least 75% of scheduled IRB meetings and notify ORCI staff when unavailable to attend meetings or conduct reviews. Meetings can be attended via teleconference if necessary.

j. If an alternate member, attend at least 1 meeting every six months as either voting or non-voting member, unless excused by the IRB Chairperson.

k. Provide prior notice of intention to resign from the committee to the IRB Chairperson and the IO when possible.

8. Member Training
    a. Prior to functioning as a voting member, all new IRB members must complete the following requirements:
        i. Review and agree to follow IRB Policy 140: IRB Member Conflict of Interest

        ii. Review and agree to the IRB Membership position description and responsibilities

        iii. Review IRB policies and procedures

iv. Orientation session with ORCI staff. This orientation will provide an overview of the IRB, a discussion of committee member requirements, and training in the use of ORCI's electronic management system.

v. Orientation session with the IRB Chairperson, or designee. This orientation will provide an overview of the protocol review process.

vi. IRB member training course.

vii. Human subjects research and responsible conduct of research courses.

b. IRB members are required to complete human subjects research and responsible conduct of research refresher courses every three years.

c. IRB members will receive, on an on-going basis, continuing education related to human subject protection issues and requirements. This may include, but is not limited to, the following:
   i. Educational presentations/discussions held throughout the year on topics related to the protection of human subjects training. These may occur during regular IRB meetings or as separate events.

   ii. External training opportunities, such as attendance at a local or national professional conference.

   iii. Instruction and feedback from the IRB Chairperson, IRB Vice Chairperson, and/or ORCI staff. These individuals are routinely available to address any questions or concerns from IRB members.

9. Member Compensation
   The IO (or designee) manages compensation standards for service related to duties of Chairpersons, Vice-Chairpersons, and IRB members.

10. Member Liability
    IRB members function as employees and agents of GVSU. As such, when acting in accordance with federal, state, and local regulations and the GVSU IRB Policies and Procedures, their actions are covered by GVSU's insurance policy, which protects individuals serving on all GVSU committees.

11. Recruitment of IRB Members
    a. The IRB Chairperson, ORCI staff members, and the IO will review the membership roster on an annual basis to ensure the membership represents the expertise, diversity, and required composition necessary to effectively review the research protocols.

b. In the event a new member is needed, the IO will be responsible for recruitment. Additional input will be sought from the Chairperson and ORCI staff, as well as from the potential member's Appointing Officer. Individuals who are interested in serving on the IRB may also contact the IO, Chairperson, and/or ORCI staff directly for consideration.

12. Evaluation of Members and Chairpersons

a. Members and Chairpersons will be evaluated periodically and no less than every three years to determine if the responsibilities of the appointment are being sufficiently met.

    i. The IRB Chairperson and ORCI staff members will evaluate members and determine follow-up action as necessary, including any recommendations to the IO as needed.

    ii. ORCI staff members will evaluate the IRB Chairperson and make recommendations to the IO as needed.

b. In addition to the formal evaluation process, the IRB Chairperson and ORCI staff members have the authority to review IRB member performance and make recommendations to the IO regarding membership appointments and terminations at any time. Members have the right to appeal to the IO regarding any membership decisions they believe have been determined unjustly.

c. Any concerns regarding member or Chairperson activities related to the IRB should be directed to the IO.