

SOP 101: IRB Membership

Terms and Abbreviations

IO: Institutional Official – individual who is legally authorized to act for the institution and ensures the effective functioning of the IRB

IRB: Institutional Review Board

IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually

UWM: University of Wisconsin – Milwaukee

Overview

The IRB includes a minimum of 5 members. These individuals are diverse in terms of race, gender, expertise, and cultural background.

Through the combined experience and expertise of its members, the IRB is qualified to review studies in a range of health and behavioral sciences and to judge the acceptability of the research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice. The IRB has the professional competence necessary to review the various kinds of human subject research conducted at UWM.

Members include:

- At least one non-scientist
- At least one unaffiliated member
- At least one scientist
- A Chair and one or more Vice Chairs.

In addition to these basic criteria, the members are carefully selected to ensure the IRB includes:

- Expertise in a range of health and behavioral sciences.
- Familiarity with relevant standards of professional conduct and practice.
- Expertise in the problems and issues facing vulnerable populations, such as children, students, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons.
- Knowledge of various community perspectives in the Milwaukee area.

A single member may fulfill multiple roles. As a representative of the institution and the IRB, each member must exhibit high standards of moral integrity and ethical conduct. The protection of human subjects is the highest priority as members review research, above any personal or institutional interests.

Additional resources are available to the IRB:

- Non-voting ad hoc consultants
- IRB office staff for interpretation of federal regulations governing human subjects research
- UWM's Office of Legal Affairs for interpretation of applicable federal, state, and local laws

Member Liability Protection

The actions of IRB members with respect to their official duties as IRB members are covered by the State of Wisconsin Self-Funded Property and Liability Program (insurance).

Details and Procedures

Selection of members

- Scientist members are active or retired members of UWM faculty or academic staff, or current graduate students. They have experience in research with human subjects and are chosen for their expertise in the types of research most commonly conducted at UWM.
- An unaffiliated member is an individual who is not affiliated with UWM and does not have any immediate family members affiliated with UWM.
 - Unaffiliated members are chosen for their ability to represent community perspectives. Whenever possible, they are respected leaders in their communities, with close ties to, and understanding of, the issues facing the various cultural and ethnic groups in the Milwaukee area. They also provide a perspective from outside the university community.
 - A person is unaffiliated if they and their immediate family have NOT held any of the following positions at UWM within the past 10 years:
 - Faculty
 - Staff
 - Degree-seeking student
 - Ideally, the unaffiliated member is someone who has never attended or worked at UWM, and whose immediate family members have never attended or worked at UWM.
- Non-scientist members have expertise in an area that is relevant to human subjects protections, such as community attitudes, ethics, legal concerns, etc.
- The IRB will contain a minimum of 5 members. Beyond this minimum, the number of full voting members and alternates may be expanded or reduced as deemed appropriate by the IO.

Appointment process

1. When there is a vacancy on the IRB, the IRB office staff solicits member nominations through direct contact and via referrals from colleagues and IRB members.
2. The IRB office staff sends the CV(s) of nominee(s) to the members for input and feedback.
3. If member responses are favorable, nominee(s) are presented to the IO, the Vice Provost for Research, and the Vice Chancellor of Finance Administrative Affairs.
4. Once approved by the IO and Vice Chancellors, the IRB office staff forwards the nomination to the Chancellor, who issues the appointment letter.

5. Upon acceptance of the Chancellor's Letter of Appointment, the nominee officially becomes either a Primary Voting Member or an Alternate Member of the IRB.

Responsibilities of members

- Attend the required initial education program.
- Maintain confidentiality of all IRB-related activities and refrain from discussing them outside the context of these duties.
- Conduct reviews of research protocols in a timely manner.
- Attend and contribute to the IRB review and discussion of protocols during full board meetings.
- Attend any required continuing education for IRB members.

Resignation and Removal

Members who wish to resign from the IRB should do so in writing to the IRB office staff. Members attend all meetings and conduct all protocol reviews assigned up until the date their resignation takes effect.

The IO may remove an IRB member at any time after consulting with the Vice-Chancellors for Research and Finance and Administrative Affairs, the IRB Chair, and the IRB office staff.

Alternate Voting Members

The IRB may recruit alternate members to substitute for primary voting members of the IRB. Alternate members may attend, count towards quorum, and vote in place of any absent primary voting member.

The maximum number of votes that can be counted equals the number of full voting members. If the total number of primary and alternate members attending a given meeting exceeds the number of primary voting members, one or more alternates would not vote. The role of the individuals attending will determine who votes; an alternate who fulfills the same role as a full member in attendance would not vote.

Example: Suppose the IRB has 16 full voting members and 10 alternates. At a given meeting, 18 members attend, 3 of whom are alternates. The full member and alternate from Psychology are present, and the full member and alternate from Kinesiology are present. The alternate student member is present, but the full member is not. In this case, the alternates from Psychology and Kinesiology may contribute to the discussion, but they would not vote. The student alternate member would vote.

The procedures for appointment, the expectations for membership, and the procedure for removal of an alternate member are the same as that of a primary voting member.

Ad Hoc Consultant Reviewers

The IRB may invite individuals with special expertise to assist in the review of research protocols. They may be from within UWM or outside the UWM community.

Ad hoc reviewers may:

- Have access to all documents submitted to the IRB relevant to the specific research protocol under review.
- Participate in the IRB meeting during discussion.
- Make recommendations on the research protocol.
- Provide written comments in addition to, or in place of, attending the IRB meeting.

Ad hoc reviewers do not vote.

All *ad hoc* reviewers sign a statement of confidentiality prior to performing any review. By signing, they agree to maintain strict confidence relating to all activities performed during their course of consultancy and to refrain from discussing the activities outside of the context of these duties.

References

45 CFR § 46.107 (IRB Membership)

45 CFR § 46.304 (Prisoner Representative)

SOP 102: IRB Chair and Vice / Co-Chair

Revision History

Version	Date	Summary of Changes
1	5 Dec 2018	Initial version