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1. PURPOSE

1.1. This policy establishes the composition, appointment, resignation, and education of the IRB committee.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY


**3.1. Composition:** The IRB is composed mostly of members representing the University and includes members who are scientists, members who are non-scientists, and members who are not affiliated with MU. The IRB has a balance of men and women, drawn from a diverse cross-section of the Milwaukee community racial and ethnic groups. (45 C.F.R. § 46.107 and 45 C.F.R. § 46.304).

The members bring sufficient experience, expertise, diversity of membership, (including race, gender, and cultural backgrounds) and sensitivity to issues such as community attitudes, to promote respect for the IRB’s advice and counsel in safeguarding the rights and welfare of human subjects. The collective experience and the professional preparation of IRB members includes: expertise in a range of health and behavioral sciences; familiarity with relevant standards of professional conduct and practice; and knowledge of vulnerable or special populations, including children, prisoners, pregnant women, handicapped children, mentally disturbed persons and others (i.e., disabled persons). The members of the IRB possess the professional competence necessary to review the various kinds of human subject research that are conducted at MU. The IRB composition meets the requirements of the 45 C.F.R. 45.107.

This diverse membership ensures that the IRB has the competence to judge the acceptability of the research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice.

IRB involves *ad hoc* consultants as needed. The IRB has access to ORC staff for assistance in interpretation of federal regulations regarding human subjects research and to MU’s Office of General Counsel for interpretation of applicable federal, state, and local laws.

**3.2. Membership Appointment:** The IRB conducts its business with the participation of the following persons: Chair, Vice-Chair, IRB voting members, alternate IRB voting members, and occasionally non-voting *ad hoc* consultants. All IRB appointments are made as follows: Individuals volunteer to be considered for IRB appointment. The

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IO consults with the RCO regarding the candidates for IRB membership. The IO issues the appointment letter.

- 3.3. IRB Chair: The Chair of the IRB is a respected, active MU faculty or staff member who is concerned about human subjects protection and ethical issues, and is well informed about federal and state regulations relevant to human subject research. The Chair is knowledgeable about the application of ethical principles and regulatory requirements when reviewing human subjects research, and sets an example for IRB members. The Chair also leads the IRB meetings and facilitates communication between investigators and the ORC. As a representative of the institution and the IRB, the Chair exhibits high standards of moral integrity and ethical conduct.

The Chair meets on a weekly basis, or as needed, with ORC staff to review research actions that do not require review by the full board, including reviewing expedited continuing reviews and amendments. The Chair is available for consultation with ORC staff members as needed regarding any human subjects research concerns.

The Chair serves a term of three-years and may serve additional terms. The IRB proposes a nominee for Chair to the IO. If acceptable, the IO issues the appointment letter. Acceptance of the IO's Letter of Appointment carries with it the acknowledgement of the primacy of ensuring human subject protections


Whenever the Chair is not available, the Vice-Chair assumes the responsibilities of the Chair during the period of absence or other unavailability.

The IO may remove an IRB Chair at any time.

- 3.4. IRB Vice-Chair: The IRB proposes a nominee for Vice-Chair to the IO. If acceptable, the IO issues the appointment letter for a three-year term and may serve additional terms. Acceptance of the IO's Letter of Appointment carries with it the acknowledgement of the primacy of ensuring human subject protections.

The position of Vice-Chair is a learning position with the intent of being Chair-in-Training. The potential candidate for this position should consider these responsibilities when accepting the Vice-Chair position. As a representative of the institution, and the IRB, the Vice-Chair must exhibit high standards of moral integrity and ethical conduct.

The IO may remove an IRB Vice-Chair at any time.

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3.5. IRB Voting Members: As mandated by 45 C.F.R. 46.107, the IRB has more than five regular, voting members. The membership roster must include at least one IRB member who is a scientist, at least one member who is a non-scientist and at least one member who is not otherwise affiliated directly or through any immediate family members with MU.

Many IRB members are recruited from among both active and retired members of the faculty and academic staff of MU. Ideally, the scientist IRB members have experience in research involving human subjects.

The unaffiliated members may be scientists or nonscientists. They or their families do not have any affiliation with MU, and they are recruited from the community of Milwaukee and its vicinity. These persons are included in the IRB in order to provide a perspective on the research that is from outside of the university community (as required by law).


The ORC solicits member nominations through direct contact from interested individuals within and outside the University for affiliated and non-affiliated members. These nominations are solicited as needed and typically when board members resign, take a leave of absence, or their terms end. One or more qualified nominees are presented to the IO for approval. The appointment procedures are described above in the Membership section of this document. Acceptance of the IO's Letter of Appointment carries with it the acknowledgement of the primacy of human subject protections. As a representative of the institution, and the IRB, each member must exhibit high standards of moral integrity and ethical conduct.

All IRB members (voting and non-voting) are instructed that activities related to research protocol review or other IRB-related activities performed during the time of an IRB member's appointment will be conducted in strict confidence and not discussed outside of the context of these duties.

IRB members are requested to serve a minimum three-year term.

IRB members are expected to participate in an initial education program, conduct reviews of research protocols in a timely manner, attend and contribute to the IRB review and discussion of protocols during full board meetings, and attend any required continuing education for IRB members.

The IO may remove an IRB member at any time.

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3.6. Alternate Voting Members: The IRB may recruit alternate members to substitute for any of the primary voting members of the IRB. Alternate members have voting rights, except that they may not vote at meetings attended by their respective primary members. Alternate members are included in determining or establishing quorum at IRB meetings, when the respective primary members are absent. Alternate members are approved by the IO.


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. Alternate voting members are appointed to three-year, renewable terms.

3.7. Ad Hoc Consultant Reviewers: The IRB may invite scientists or non-scientists who have special expertise to assist the IRB in its review of research protocols. These *ad hoc* reviewers may be from within MU or outside the MU community. *Ad hoc* reviewers have access to all documents submitted to the IRB relevant to the specific research protocol under review, may participate in the IRB meeting during discussion, and make recommendations on the research protocol, but they may not vote with the IRB. *Ad hoc* reviewers may also be asked to provide written comments in addition to, or in place of, attending the IRB meeting. The *ad hoc* reviewer's identity and any documents they create may be kept confidential at their request.

3.8. Member Liability Protection: Marquette University maintains an "Educational Organization Errors and Omissions Policy," under which "Individual Insureds" include "members of an Institutional Review Board (as recognized by the U.S. Food and Drug Administration and U.S. Department of Health and Human Services." The policy provides defense and indemnity with respect to claims for damages arising from a "Wrongful Act," which is "any actual or alleged error, omission, act, misstatement, neglect or breach of duty in the discharge of duties" by an Individual Insured. This includes both affiliated and unaffiliated IRB members.

3.9. Resignation from the IRB: IRB members are expected to serve a minimum of three years on the IRB. Members who wish to resign from the IRB are requested to do so in writing to the RCO or IO. A member will be expected to attend all meetings and conduct all protocol reviews assigned up until the date their resignation takes effect.

3.10. IRB Member Education: IRB members participate in both initial and continuing education. These programs focus on the ethical principles and regulatory requirements underpinning human subject protections and how to apply those

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principles and requirements to the initial and continuing review of research protocols.

3.11. Initial Education Program: The initial education program consists of in-person training provided by the ORC and on-line training found at: <http://www.marquette.edu/orc/irb/training-education.shtml>. All IRB Chairs and Vice-Chairs, members, and alternates must participate in the training (or its equivalent) before actively participating in the IRB. The initial education program includes information about the following areas:

- (1) Ethical Principles and *The Belmont Report*
- (2) Regulatory Requirements
- (3) MU Federal Wide Assurance (FWA)
- (4) MU Institutional Policies and Procedures
- (5) IRB's Role and Responsibilities
- (6) Research Protocol Review Criteria and Review Process
- (7) Informed Consent Process and Document
- (8) Vulnerable Populations: Pregnant Women, Fetuses, Prisoners, Children and Others
- (9) Investigator Responsibilities
- (10) HIPAA Policies and Procedures

New primary voting IRB members are provided resources, which may include a copy of the Bankert and Amdur's *Institutional Review Board Management and Function*, Second Edition.

3.12. Continuing Education Program: Continuing education programs may include scheduled short current topics (case studies and current events) and Just-in-Time (JIT) training that flows from issues raised in the course of the review of research protocols. IRB members are encouraged to attend local, regional, and national educational conferences as appropriate. Continuing education modules are included in the agenda for every convened meeting.