



TITLE: IRB MEMBERSHIP REQUIREMENT AND RESPONSIBILITIES	SOP NO.: IRB 201
EFFECTIVE DATE: 2/24/2025	REVISION NO.: 01

1. PURPOSE

1.1. The purpose of this SOP is to describe the composition of the University of Maryland, Baltimore County (UMBC) IRB membership, as well as roles and responsibilities.

1.2. SCOPE

1.2.1. This SOP applies to the UMBC IRB.

1.2.2. The UMBC Institutional Review Board (IRB) is composed of members in accordance with federal regulations. This SOP outlines the composition of the IRB and the procedure to appoint members. Additionally, this SOP outlines the evaluation of IRB members and IRB resources.

1.2.3. UMBC Office of Research Protections and Compliance [ORPC] and its committee are responsible for the approval and implementation of this SOP.

2. DEFINITIONS

2.1. IRB – Institutional Review Board

2.2. HRPP – Human Research Protection Program



- 2.3. ORPC – Office of Research Protection and Compliance
- 2.4. Alternates - Board members appointed in any of the other UMBC IRB roles. These members may substitute for another member if their role (nonscientist or scientist) are comparable as determined by the IRB Administrator. For example, a Vice Chair may alternate for the IRB Chair.
- 2.5. Nonscientific - Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist.
- 2.6. Scientific - Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a social/behavioral or biomedical research discipline should be considered a scientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.
- 2.7. Unaffiliated - Members have no affiliation with UMBC or its Human Research Protection Program, either self or immediate family member. Immediate family members are a person's spouse, domestic partner, and dependent children. Unaffiliated members, who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which UMBC will draw its research subjects. The unaffiliated members should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.



- 2.8. Prisoner – Includes any individual who is involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

POLICY

- 2.9. The UMBC IRB evaluates the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The UMBC IRB strives to foster respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The UMBC IRB committee must consist of at least five regular, voting members. The institution will make every effort to have a diverse membership appointed to the UMBC IRB, within the scope of available expertise needed to conduct its functions. Composition of the UMBC IRB is to be adequate in light of the anticipated scope and complexity of UMBC's research activities, the types of subject populations likely to be involved, and the size and available resources of the institution.

The IRB committee includes at least one scientific member and at least one nonscientific member whose primary concerns are in nonscientific areas. The committee must include at least one unaffiliated member. A single member can be unaffiliated with the institution and have a primary concern in a non-scientific area. This individual would satisfy two of the regulatory membership requirements.

Officials in Research and Creative Achievement administration including, but not limited to the Vice President for Research and Creative



Achievement and the Administrative Officer for Research and Creative Achievement, do not serve as voting members of the IRB.

The UMBC IRB includes members who are knowledgeable about the concerns of participants who may be vulnerable (e.g., children, prisoners, and individuals with impaired decision-making capacity, etc.). Examples of such members might be nurses, social workers, chaplains, teachers, or previous prisoners. In general, a member representing a vulnerable group of participants should provide at least one of the following:

- A direct affiliation to the special group(s)
- Work or life experience with the special group(s)
- Research experience with special group(s)
- Hold certification or licensures that permits the treatment, counseling, or other direct relationship of the special group(s)

Individuals responsible for business development at UMBC or affiliated institutions will not serve as voting members of the IRB. This may include, but is not limited to, the following individuals:

- Employees of the institutions' granting or research contracting offices
- Employees of the institutions' Vice President for Research and Creative Achievement offices
- Employees of the institutions' Department of Information Technology offices

The management of the membership of the IRB panels and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the IRB Director or designee, in consultation with the IRB Chair.

The Vice President for Research and Creative Achievement and/or designee in consultation with the IRB Chair and IRB Manager have the authority to appoint members to the IRB. Members will be solicited from UMBC and greater Baltimore communities.



The IRB Chair will be a highly respected individual, from UMBC or its affiliated institutions, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

The UMBC Vice President for Research and Creative Achievement along with the UMBC Associate Vice President for Research and Creative Achievement, the IRB Manager, and IRB Chair review the resources allocated to the IRB and other components of the UMBC Human Research Protection Program (HRPP).

PROCEDURE

Appointing Members

- 2.10. It is the policy of UMBC that the IRB will include an appropriately diverse mixture of backgrounds and experiences in accordance with the Health and Human Services regulations under 45 CFR §46.107. The IRB will adhere to the following policy:
 - 2.10.1. The IRB will have at least five (5) members. Non-student members (e.g., faculty) will be appointed for revolving three-year terms. Student members (e.g., undergraduate, graduate students) will be appointed for one-year terms.
 - 2.10.2. Members will represent varying academic disciplines and have the necessary credentials to provide appropriate review of projects submitted for review. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity to provide appropriate review of research with a primary focus on protection of human participants.
 - 2.10.3. The IRB will include at least one member that is not affiliated with the Institution. The unaffiliated member must not: 1) have a professional



relationship with the Institution as an employee, consultant, volunteer faculty, or student, and 2) be a family member (first and second degree relative), which has a professional relationship with the Institution.

- 2.10.4. The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- 2.10.5. The IRB will include one or more members who are knowledgeable about, and experienced in, working with vulnerable participants, including: children, prisoners, people with disabilities or cognitively impaired individuals.
- 2.10.6. In situations where a prisoner is involved in research under IRB review, the Board must seek an ad-hoc prisoner representative to serve in that capacity. Among the primary goals in selecting a prisoner representative should be:
 - Adequate representation of the rights and interests of prisoners;
 - Particular knowledge of correctional settings, including some awareness of local conditions in which the study will be conducted; and
 - Ability to express views independent from the prison administration.
- 2.10.7. Where members have conflicts of interest pertaining to the research to be reviewed, members must be absent themselves from the meeting room before the final review discussion and vote, except where requested by the IRB to be present to provide information. IRB members with conflicts of interest must not participate in all types of reviews, including initial review, continuing review, review of modifications, review of unanticipated problems involving risks to participants or others, and review of non-compliance. IRB members also may not serve as reviewers for research in which they have a conflicting interest when asked to review using the expedited review process.



- 2.10.8. When review of a proposal requires expertise that is not available on the Board, at its discretion, the IRB will request assistance from an expert consultant. These individuals have access to all documents submitted to the IRB relevant to the specific project under review and may participate at the deliberations and make recommendations on the project, but will not vote (HRPP Policy#2.003).
- 2.10.9. Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the primary member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.
- 2.10.10. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

IRB Member Responsibilities

- 2.11. IRB members are expected to be fully engaged in the HRPP and will be involved in carrying out the following responsibilities (when requested by the IRB Chair or designee):
- 2.11.1.1. Serving as a primary or secondary reviewer for initial expedited applications.
 - 2.11.1.2. Serving as a primary or secondary reviewer for continuing review expedited applications.



- 2.11.1.3. Serving as a primary or secondary reviewer for internal unanticipated problems involving risk to participants or others.
- 2.11.1.4. Serving as a primary reviewer for external adverse events or serious problems.
- 2.11.1.5. Serving as a primary or secondary reviewer for amendments to expedited projects and/or consent documents.
- 2.11.1.6. Serving as a primary reviewer for incidents of non-compliance.
- 2.11.1.7. Serving as a primary or secondary reviewer for full board reviewed protocols.
- 2.11.1.8. Acknowledging protocol deviations.
- 2.11.1.9. Completing continuing education.

IRB Administrative Staff Responsibilities

- 2.12. When the IRB membership changes, the IRB Manager will prepare the notice that will be submitted to the ORPC within (30) business days.
 - 2.12.1. A membership list of IRB members must be maintained; it must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information about members:
 - 2.12.1.1. Name
 - 2.12.1.2. Earned degrees
 - 2.12.1.3. Affiliated or non-affiliated status
 - 2.12.1.4. Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist). For the purposes of this



roster, IRB members with research experience are designated as scientists (including graduate student members). Research experience includes training in research (e.g. doctoral degrees with a research-based thesis) and previous or current conduct of research. Graduate students being trained in research fields will be designated as scientists.

2.12.1.5. Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.

2.12.1.6. Representative capacities of each IRB member, which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are knowledgeable about or experienced with working with children, pregnant women, cognitively-impaired individuals, and other vulnerable populations locally involved in research.

2.12.1.7. Role on the IRB (Chair, Vice-Chair, etc.)

2.12.1.8. Voting status (any ex-officio members are non-voting members).

2.12.1.9. Alternate status, including the member they alternate with.

2.12.1.10. Relationship (e.g. employment) between the individual IRB member and the organization (UMBC).

2.12.2. The IRB roster is confidential. The names of IRB members who reviewed specific projects will not be released. One exception is the role of IRB Chair, whose appointment is made public under UMBC's Federalwide Assurance.

Appointment of the IRB Chair(s)

2.13. The IRB Manager publishes notice of IRB Chair vacancy on the IRB website if a candidate is not available among current, experienced IRB



committee members. Further the IRB Manager disseminates this vacancy notice to research leaders at UMBC and its affiliates. The written notification will request that any nominations or persons who wish to volunteer be submitted to the IRB Chair, IRB Manager, or designee. The IRB Manager will review the nominations and volunteers with the Associate Vice President for Research and Creative Achievement and the current or outgoing IRB Chair(s) for qualified candidates.

- 2.14. Qualified candidates will be selected based on (but not limited to) their current standing with UMBC, IRB experience (if any), research experience with human subjects (if any), education and professional background, professional and personal interests.
- 2.15. Once qualified candidates have been determined, the Associate Vice President for Research and Creative Achievement, the IRB Manager and current IRB Chair(s) will conduct interviews with each individual. In a collaborative effort, the three most qualified candidates will be selected from the interview process and will be re-interviewed with the Vice President of Research and Creative Achievement, the Associate Vice President for Research and Creative Achievement, the IRB Manager and current IRB Chair. The Vice President for Research will make the final appointment of the qualified candidate for IRB Chair.

Evaluation of IRB Members

- 2.16. IRB members are evaluated at the conclusion of the first year of service and at the end of each term by the IRB Manager or assigned IRB staff member using an evaluation tool. Interim evaluations of the IRB members may occur more frequently, as determined by the IRB Manager or assigned IRB staff member.
- 2.17. A member may be removed at the discretion of the IRB Chair, in conjunction with the IRB Manager. Further consultation with the VP for Research and Creative Achievement may clarify next-steps, if necessary, before the conclusion of the member's current term. A member may resign



before the conclusion of their term. Vacancies are filled as quickly as possible.

- 2.18. The IRB Chair(s) is evaluated by the Vice President for Research and Creative Achievement (and may include the Associate Vice President for Research and Creative Achievement and IRB Manager) at the conclusion of the first year of service and at the end of each term as chair. Interim evaluations of the IRB Chair(s) may occur more frequently, as determined by ORCA administrative staff.
- 2.19. A summary of the evaluation will be provided by the IRB Manager to the IRB Chairs and IRB members via email or in-person. The evaluation tool may be retained as part of the member's profile in UMBC's online IRB management system Kualii.

Maintaining Roster and Board Member Information

- 2.20. To ensure that board members meet the needs of the IRB in its review of research, board member information forms and current CV's/résumés are completed or updated at the beginning of each three-year term of service by IRB members in Kualii. A Confidentiality and Conflict of Interest Agreement are electronically submitted through DocuSign by each board member at the beginning of their initial term of service; a copy of the signed agreement is stored in the UMBC IRB Box folder.
- 2.21. In order to maintain rosters of IRB membership, the following information is collected and maintained in UMBC's ORPC Box folder: member names; earned degrees; scientific status; representative capacity; indications of experience sufficient to describe each member's chief anticipated contribution to the IRB's deliberations; employment or other relationship between each member and the IRB and/or UMBC (e.g., full-time employee, etc.); affiliation status; and office/membership status (e.g., vice-chair, etc.).



Maintaining Sufficient IRB Resources

- 2.22. UMBC provides meeting space and sufficient staff to support the IRB's review and recordkeeping duties. UMBC will provide the IRB staff with resources sufficient to conduct IRB duties.
- 2.23. The adequacy of the existing IRB(s) is evaluated at least annually by the Associate Vice President for Research and Creative Achievement, the Director of ORPC, and the IRB Manager to meet the anticipated scope of research activities and the types of participant populations likely to be involved and the appropriateness of the proposed and initial and continuing review procedures in light of probable risks, and the size and complexity of UMBC.
- 2.24. The IRB Manager, in conjunction with the IRB Chair, requests a report from the Compliance Specialist, Sr. Compliance Specialist, or designee, consisting of but not limited to the following:
- Number of new studies submitted;
 - Review process (i.e., expedited, convened board) for initial studies, amendments, continuing review, and unanticipated problems, if applicable;
 - Time required for approval of each type of application;
 - Number of studies from each Department; from each College;
- 2.25. The Associate Vice President for Research and Creative Achievement, the ORPC Director and the IRB Manager discuss the findings of the report to evaluate whether the number of IRB panels is appropriate for the volume and types of human subject research being reviewed, and whether the review process is being accomplished in a thorough and timely manner.