TITLE: SOP REVIEW AND APPROVAL OF AN SOP	SOP NO.: IRB 101
EFFECTIVE DATE: 2/24/2025	REVISION NO.: 01

1. **PURPOSE**

1.1. UMBC Institutional Review Board (IRB) standard operating procedures (SOPs) provide a framework for the ethical and scientifically sound conduct of human research. This SOP outlines UMBC's IRB practice for creating, publishing, and routine review of its policies, procedures, and guidance documents. Supported by institutional policies and written procedures, the IRB SOPs ensure that the rights and welfare of human research subjects are overseen and protected uniformly, regardless of personnel changes.

1.2. SCOPE: This SOP applies to the UMBC Institutional Review Board and staff.

2. **DEFINITIONS**

2.1. IRB – Institutional Review Board

2.2. SOP – Standard Operating Procedure

2.3. FWA - Federal Wide Assurance

2.4. ORPC – Office of Research Protection and Compliance

3. **POLICIES**

The UMBC Institutional Review Board functions independently. Federal regulations governing human subjects research, and the UMBC Administration, through the Vice President for Research and Creative Achievement, grant the IRB this authority as part of the Human Research Protection Program. The IRB maintains an active Federal Wide Assurance (FWA) and agrees to apply 45 CFR 46 whenever UMBC is engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) of the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. Research that is not federally funded, supported or otherwise subject to federal oversight, and that is outside of the FWA is subject to commensurate protections by the UMBC IRB except where otherwise described in UMBC IRB policy (see IRB SOP 105: Non-Federally Funded Research). The UMBC IRB does not have the capacity to oversee clinical investigations regulated by the Food and Drug Administration (FDA). The UMBC IRB applies the standards of the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) to research that involves the use of protected health information.

4. PROCEDURE

4.1. Review, Approval, and Revision of IRB SOPs

4.1.1. If the creation of a new SOP is necessary, the SOP will be sent to the full IRB Membership Committee for review and approval.

4.1.2. Each SOP that has been approved and published on the IRB website will be reviewed every three years from the date of approval as described in this policy. The review date is determined as three years from the last date of approval. The IRB Manager, in consultation with the IRB Chair, may extend the review date as deemed necessary.

4.1.3. For the review of an approved SOP, an IRB Administrator initially reviews the SOP for consistency with state or federal guidelines, current practices or institutional polices. If minor clarifications and changes are necessary, the IRB Administrator provides the revised SOP to a designated member(s) of the IRB Membership Committee for approval. If the IRB Administrator determines that significant changes to a policy must be made, the revised SOP may be sent to the full IRB Membership Committee for approval.

4.1.4. Review and approval of the SOP is documented by an IRB Administrator who records the date approved, and the IRB Committee member(s) responsible for approval. The approval date is the effective date.

4.2. SOP Dissemination

4.2.1. Any new or revised SOP is disseminated to IRB members and IRB staff by an IRB Administrator. Record of dissemination and any applicable training is documented by the IRB Administrator.

4.2.2. Approved SOPs are posted on the IRB website by an IRB Administrator or designee.

4.3. Creating and Using IRB Forms

4.3.1. Forms are used to ensure that policies are integrated into the daily research and review operations and enable the IRB to manage review, tracking, and notification functions consistently. Forms are not subject to the same standards of control cited in sections 4.1 and 4.2. Forms include checklists, applications, and automated notifications sent by the UMBC electronic IRB managing system, Kuali.

4.3.2. Forms are created and revised by IRB administrators or designee under the direction of the IRB Manager, in consultation with the IRB Chair.

4.3.3. As applicable, forms are implemented in the Kuali online system by the Kuali programmer(s).