



TITLE: IRB AUTHORITY AND SIGNATORY AUTHORITY	SOP NO.: IRB 104
EFFECTIVE DATE: 2/24/2025	REVISION NO.: 01

1. PURPOSE

- 1.1. This SOP outlines the specific authority granted to the UMBC Institutional Review Board (IRB) to review, approve, and monitor research involving human subjects as a component of the Office of Research Protection and Compliance (ORPC) at UMBC.
- 1.2. SCOPE: This SOP applies to the UMBC IRB and those with signatory authority for the IRB.

2. DEFINITIONS

- 2.1. IRB – Institutional Review Board
- 2.2. ORPC – Office of Research Protection and Compliance
- 2.3. FWA – The Federalwide Assurance is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research.
- 2.4. Institutional Official – The UMBC designee who is ultimately responsible for the oversight and conduct of the ORPC of which the IRB is a component.



3. POLICIES

The Vice President for Research and Creative Achievement has been designated by the Board of Trustees and the UMBC President to serve as the Institutional Official on UMBC's Federalwide Assurance with the Office of Human Research Protection (OHRP) which also serves as the Food and Drug Administration (FDA) registration for IRBs.

The UMBC Administration through the Vice President for Research and Creative Achievement grants the UMBC IRB authority to approve research activity, specify modifications required to secure IRB approval of the research activity, or disapprove any research activity overseen and conducted by UMBC and its affiliates. The UMBC IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB's policies, is not in compliance with federal regulations, or that is associated with unexpected, serious harm to participants. The UMBC IRB also has the authority to observe or have a third party observe the consent process, and the conduct of the research.

Research that has been approved by the UMBC IRB may be subject to further review and approval or disapproval by officials of UMBC, as appropriate. However, UMBC officials may not approve the research if it has not been approved by the UMBC IRB.

The IRB Manager, IRB Chair(s), and IRB Vice Chair(s) are authorized to sign any documents in connection with the review and approval of research projects involving human subjects, which have been reviewed and approved pursuant to UMBC IRB policies and procedures. The IRB Chair may designate signatory authority to qualified IRB members and IRB staff members, as appropriate. In all cases, individuals must sign their own name and indicate their title under their signature.

Electronic signatures via the online system DocuSign, are considered valid. Individuals must electronically approve items using their secure login. DocuSign is password protected and limited to only those individuals directly connected with the



respective document and the appropriate regulatory staff. DocuSign records the individual by name and their electronic approval (i.e., electronic signature), and all actions taken by that individual. In addition, the results of IRB review, actions, and decisions are issued through the online IRB Management system, Quali, and is further described in IRB SOP 305: Documentation.

Any action or correspondence between the IRB, and/or members of the faculty/staff of UMBC that provides information concerning the review of research protocols by the IRB/IRB staff related to approval status of the research protocol, may be signed by designated IRB staff members.

Any letters or memos sent to agencies of the federal government, funding agencies (whether private or public) or their agents on behalf of the UMBC IRB are signed by the Institutional Official, ORCA Director, IRB Manager, IRB Chair or designee. Letters or memos may be signed with an electronic signature.

Any letters, memos or email sent representing the decision or opinions of the IRB Chair or designee, may be signed by the IRB Chair or designee, as long as such correspondence does not imply review and approval of research projects.