TITLE: NON-FEDERALLY FUNDED RESEARCH	SOP NO.: IRB 105
EFFECTIVE DATE: 2/24/2025	REVISION NO.: 01

1. **PURPOSE**

1.1. The UMBC Institutional Review Board (IRB) applies applicable U.S. federal regulations for protecting research participants when research is sponsored or supported by a federal agency. Generally, those same regulations are followed by the UMBC IRB for non-federally funded research. Exceptions are outlined in this policy.

1.2. SCOPE: This policy applies to human subject research conducted at UMBC.

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.

3. **POLICIES**

The UMBC IRB follows the applicable U.S. federal regulations for protecting research participants when research is sponsored by a federal agency. UMBC generally applies the regulations in 45 CFR 46 subparts, A, B, C, and D to research

that is not federally funded except as outlined in this policy or other UMBC IRB SOPs, as indicated.

Specifically, non-federally funded research is not subject to the same requirements for the following:

Continuing Review (see IRB SOP 404: Continuing Review). For studies with no federal oversight or federal funding, unless the IRB determines otherwise, continuing review of research is still required for research eligible for expedited review, per UMBC standards.

Continuing review of research is not required for research eligible for exempt review, regardless of whether the research is federally funded or not.

Exemption from IRB Review (see IRB SOP 401b: Research Activities Exempt from IRB Review) For studies with no federal oversight or federal funding, the UMBC IRB designated additional exemption categories (A-E) allowing minimal risk research that fits into one or more of the additional exemption categories to be exempt from IRB review. Administrative and/or IRB Chair review will occur for research eligible for exempt review, regardless of whether the research is federally funded or not.

Informed Consent Requirements (see IRB SOP 701: General Requirements of Informed Consent) For studies with no federal oversight or federal funding, the pre-2018 Common Rule requirements for informed consent are required. The informed consent requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Final Common Rule are not required but may be included.

Institutional Reporting Procedures (see IRB SOP 905: Institutional Reporting Procedures) For studies with no federal oversight or federal funding, the IRB will still report to ORPC if the IRB takes any of the following actions:

• Determines that an event represents an unanticipated problem involving risks to participants or others.

• Determines that non-compliance was serious or continuing.

• Suspends or terminates approval of research.

Certification of Prisoner Research The IRB will apply the criteria and additional duties outlined in Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, with the exception that the IRB will not provide written certification to the Secretary that the duties of the Board have been fulfilled (outlined in §305(7)(c))**.**