TITLE: RESEARCH SUBMISSION REQUIREMENTS	SOP NO.: IRB 301
EFFECTIVE DATE: 3/24/2025	REVISION NO.: 01

1. **PURPOSE**

    1.1. The UMBC Institutional Review Board (IRB) members rely on the documentation submitted by investigators for new study, continuing review, and amendment applications to provide enough information to assess if a study adequately meets or continues to meet the IRB's criteria for approval.

    1.2. SCOPE: This SOP applies to research submissions to the UMBC IRB.

2. **DEFINITIONS**

    2.1. IRB – Institutional Review Board

    2.2. ORPC – Office of Research Protection and Compliance

POLICY

The UMBC Kuali system uses a smart form application which requires specific information based upon the responses of the applicant (e.g., if an investigator indicates that the study will request a waiver for consent documentation, additional fields will generate in the application to justify the request). Applications which are incomplete cannot be submitted electronically. The application may require additional documents such as consent forms and recruitment materials. In some cases, ancillary approval may be required, and additional information will be requested in the Kuali application. A comprehensive list of required documents and ancillary approvals essential for new study, continuing review, and amendment applications is found on the IRB website.

A research proposal (with associated documents) is submitted via Kuali. The submission by the responsible investigator in Kuali is considered an electronic signature, legally valid as if the research proposal was submitted in paper format with a printed signature. A submitted proposal is scheduled for IRB review once the IRB staff determines that the application and required documents present an adequate description of the proposed research.

All study personnel who play a role and hold responsibilities in the design, conduct, and/or reporting of the research, as outlined in the research proposal, must be included in the Kuali application.

If the IRB or IRB staff determines that the submitted information is not adequate, investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. Incomplete submissions will not be reviewed by the IRB.

Complete submissions as outlined in this policy are made available to IRB members for expedited and convened full review via Kuali.