TITLE: REVIEW OF AMENDMENTS TO RESEARCH STUDIES	SOP NO.: IRB 405
EFFECTIVE DATE: 10-6-2025	REVISION NO.: 01

1. **PURPOSE**

1.1. The UMBC Institutional Review Board (IRB) must approve changes in approved research.

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

2. **POLICY**

During the period for which approval has already been given, changes in approved research may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects. If an investigator makes changes that are necessary to eliminate apparent immediate hazards, a protocol deviation outlining the circumstances and any documents used must be submitted to the UMBC IRB. Please see IRB SOP 902: Protocol Deviations.

Investigators must submit requests for proposed changes to the IRB using an amendment application in the UMBC Kuali Protocols online system. Amendment applications should be submitted no later than 30 days upon receipt of changes from sponsors, collaborators, etc.

During amendment review, the IRB determines whether the research with the proposed changes still meets the regulatory approval criteria and any other applicable requirements.

Amendments to exempt studies are evaluated to determine whether changes alter the original exempt determination. Determinations are documented using the internal checklist. If the changes make the study ineligible for exemption, HRPI staff will

assign the amendment application to an expedited or convened board review. The amendment and study will be reviewed according to the requirements of initial review. Please see SOP 403: Initial Review – Criteria for IRB Approval.

Amendments to exempt studies that are minor changes and do not impact the study's eligibility for exempt determination, may be administratively reviewed and approved by HRPI staff.