TITLE: CONTINUING REVIEW	SOP NO.: IRB 404
EFFECTIVE DATE: 10-6-2025	REVISION NO.: 01

1. **PURPOSE**

1.1. The UMBC Institutional Review Board (IRB) must conduct continuing review of approved protocols to ensure human subject protections remain appropriate and to determine if it is appropriate for the study to continue as is, or with modifications. This SOP outlines the standards the IRB must follow in considering continuing review.

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

2. **POLICY**

When considering whether to renew a study, the IRB revisits the same criteria used to grant initial approval. The IRB will not approve protocols submitted for continuing review, if, due to interim changes in IRB policies and procedures, the IRB would not approve that same protocol as a new proposal.

During continuing review, the IRB determines whether the study can be renewed at the same risk level, or if new information has changed that determination. As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. Additionally, the IRB may need to impose new precautions or revise those it had previously imposed on the research protocol. The IRB will reassess the approval period for each continuing review application.

Investigators are required to submit a continuing review application in the UMBC Kuali Protocol online system prior to the expiration of the study. Please see SOP 307: Expiration of IRB Approval for the policy regarding the expiration of a study.

The continuing review application must describe the progress of the study; enrollment and withdrawals; adverse events, complaints, and other problems that have occurred; and safety monitoring results. Submission requirements are outlined on the IRB or HRPI websites.

Continuing review must occur at intervals appropriate to the degree of risk. Continuing review is not required for studies determined to be exempt. Documentation of the length of the approval period is made in the board member checklist and, if applicable, the minutes of the convened board meeting. The determination of the length of the approval period is made by the IRB considering the degree of risk, and according to the following standards.

3. **NOTES**

3.1. Continuing review for research not subject to FDA regulation (routine for UMBC, a nonclinical site)

- For studies reviewed at a convened meeting, the continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.

- Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review [2] .

- Unless the IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following [3], which are part of the IRB-approved study:

    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3.2. Continuing review for research subject to FDA regulation [1] or Grandfathered studies (not routine at UMBC, a nonclinical site)

For studies that are subject to FDA or pre-2018 Common Rule requirements, the following standards of continuing review apply:

- For studies reviewed at a convened meeting, continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.

- For studies approved using expedited review procedures, continuing review must occur within one (1) year from the date the IRB Chair or designated expedited reviewer gives final approval to the protocol.

3.3. Extended Approval Periods

For minimal risk studies not subject to federal oversight and not federally funded, the UMBC IRB may have permitted continuing review to occur within two (2) or more years from the date of the convened meeting at which the IRB approved the research or from the date the IRB Chair or designated expedited reviewer gave final approval. For studies that were granted two-year (or longer) approval, the ongoing use of the same-length approval for studies undergoing continuing review is acceptable.