TITLE: EXPIRATION OF APPROVAL	SOP NO.: IRB 307
EFFECTIVE DATE: 4/2/2025	REVISION NO.: 01

1. **PURPOSE**

1.1. The approval period of a study, whether during initial or continuing review is determined by the UMBC Institutional Review Board (IRB). This SOP outlines how the expiration date is calculated. This SOP also outlines the expiration of IRB approval.

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

2. **DEFINITIONS**

2.1. Approval Date - The approval date is the date the convened board voted to approve, the date the convened board voted to approve with modifications, or the date the designated expedited reviewer approved the research in conjunction with IRB Admin. staff.

2.2. Effective Date - The approval effective date is the date the approval letter is sent to the investigator through the UMBC Kuali system.

2.3. Expiration Date - The expiration date is the last day of approval and the date by which continuing review must occur.

POLICY

The length of the approval period for a study is determined by the UMBC IRB considering the degree of risk, and according to the standards outlined in SOP 404:

Continuing Review. When an approval period is determined, an expiration date is calculated to indicate the date by which continuing review must occur and approval ends.

Kuali populates the expiration date based on the determined approval period. For example, a study approved for one year would receive an expiration date that is one day earlier in the following year than the date the convened board approved the research. If the IRB determines the study requires continuing review more or less frequently than annually, the expiration date is manually adjusted in Kuali according to the IRB's determination.

For research that is approved with modifications by the convened board, the approval period is not effective and does not begin until the changes are accepted by the IRB Chair and the approval letter is sent.

Review of a change in a protocol (i.e., modification or amendment) does not alter the expiration date because continuing review is review of the full protocol, not simply a change to it.

Investigators are sent three automatic notifications (30, 15, and 7 days before the due date) regarding the need to apply for continuing review prior to the expiration date. There is no grace period extending the conduct of non-exempt research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted for non-exempt protocols. A continuing review application must be submitted in Kuali to be reviewed by the IRB even if the continuing review cannot be conducted before the expiration date. For research which is expired and is reviewed after the expiration date, a new expiration date will be calculated as described above. The lapse in approval due to the expiration of the study and the dates of the lapsed approval are documented in Kuali. If required by the IRB, the investigator will provide the IRB with an action plan to prevent any future lapses in approval.

There is an exception for exempt student protocols. While exempt protocols technically do not expire, IRB Admin. place an expiration date on students' exempt protocols to encourage protocol closure prior to the student PI graduating or otherwise moving on from the UMBC research community. Upon the student PI's request, IRB Admin. may administratively extend the expiration date on exempt protocols. A student PI may request an administrative extension of their exempt protocol by submitting an amendment within their Kuali protocol, to extend the approval period of the study.

If the investigator fails to submit a continuing review application by the expiration date, the study will be administratively closed by an IRB staff member. Once the study is closed, the investigator must submit a new study application for initial review and approval to continue with the study.

All research activities must cease upon expiration of IRB approval or study closure.

Expiration of IRB approval does not require IRB Admin. to report as a suspension or termination of IRB approval according to IRB SOP 904: Administrative Hold, Suspension and Termination of Approved Research, and IRB SOP 905: Institutional Reporting Procedures. However, an expired protocol is out of compliance and the PI must provide justification for why the protocol was allowed to expire (opposed to the PI taking action to either renew or close the protocol).

PROCEDURES

1. Assignment of Expiration Dates

1.1 During the initial and continuing review application review, the assigned board reviewer selects the approval period in the board reviewer checklist in Kuali. For expedited review, the board reviewer checklist documents the determined approval period. For convened board review, the minutes document the determined approval period.

1.2 The IRB administrator or coordinator selects the appropriate approval period based on the determined approval period (e.g., one year, no further continuing review, etc.) in Kuali. The IRB administrator or coordinator is responsible for verifying the correct expiration date when processing the study.

2. Expiration of Approved Studies

2.1 Once IRB approval for a study expires, an expiration notice is automatically generated and sent from Kuali to the investigator. The expiration notice informs the investigator the research is expired and no research activity may continue until the application for continuing review is approved by the IRB. The notice also informs the investigator that no new participants may be enrolled.

2.2 In order to conduct any study-related procedures after IRB approval expires, investigators must renew the study and provide a justification for the expiration in writing to the IRB Chair for review and approval. If the IRB Chair determines that subjects participating in an expired study would suffer a hardship because research procedures must be discontinued, appropriate research procedures may continue beyond the expiration date for a reasonable amount of time. The IRB Chair will address on a case-by-case basis those rare instances where failure to enroll new subjects would seriously jeopardize the safety or well-being of an individual. Prospective research data cannot be collected until a continuing review application or other progress report is reviewed and approved. The IRB Chair will notify the Investigator of the decision by way of written documentation and this documentation will be attached permanently to the continuing review form, accessible by all IRB members. Documentation will be retained in Kuali.