

Expiration of IRB Approval	Effective Date	05.17.19
	Revision Date	07.22.21

1.0 Purpose: Federal regulations governing human subject research and University & Medical Center Institutional Review Board (UMCIRB) policy require non-exempt human subject research be conducted only during the period approved by the IRB. HHS regulations at 45 CFR 46 make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. This SOP establishes the procedures followed when non-exempt human research which has been approved by the UMCIRB and assigned an expiration date is allowed to expire.

2.0 Research Protocols Affected: Non-exempt human research activities reviewed and approved by the UMCIRB which have been assigned an expiration date.

3.0 SOP: This SOP applies to studies approved by the UMCIRB and assigned an expiration date where the study is allowed to expire due to:

- 3.1** Failure of the PI to submit either a continuing review or final report (and all required supporting documents) to the UMCIRB before the expiration date;
- 3.2** Submission, by the PI, of the continuing review or final report just prior to the expiration date where there is not enough time for the UMCIRB review process to be completed before the study expires while in the UMCIRB queue; or
- 3.3** Failure of the PI to provide a timely response to a UMCIRB request for modifications, clarification and/or more information for a continuing review or final report that is in the UMCIRB queue at the time of expiration.

If an investigator has an expired study(ies) (including those studies which expire while in the UMCIRB queue), the UMCIRB office will not release new study approvals for that PI until the requirements set forth in this SOP are met.

4.0 Definitions:

4.1 Expired Study: A human research study is considered expired (1) if the UMCIRB has not reviewed and approved the study for continuation by its expiration date or (2) if the study meets the criteria for closure (see UMCIRB SOP titled “Study Completion and Closure”) and the UMCIRB has not received and acknowledged a final report by its expiration date.

5.0 Responsibilities:

5.1 Principal Investigator (PI) must take the following actions if they allow their IRB approval to lapse:

5.1.1 Immediately cease all research activities involving human subjects (inclusive of recruitment, consent, enrollment, interventions and/or interactions with participants, data collection, data analysis of identifiable data, etc.), *unless* it is determined to be in the best interest of those already enrolled to continue participating in the research. Continued participation of enrolled subjects in a study during the period when IRB approval has lapsed may be appropriate in *limited* situations, for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects.

5.1.1.1 The determination regarding whether it is in the best interest of enrolled subjects to continue to participate in the research after IRB approval has expired shall be made by the

PI in consultation with the UMCIRB.

5.1.1.2 This determination may be made for all enrolled subjects as a group or for each individual subject.

5.1.1.3 If the PI or UMCIRB determines that it is not in the best interest of enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects.

5.1.2 Submit a continuing review application immediately if the study is to continue. The continuing review application must contain the following information:

5.1.2.1 The reason the study was allowed to expire,

5.1.2.2 Whether there has been any research activity (inclusive of recruitment, consent, enrollment, interventions and/or interactions with participants, data collection, analysis of identifiable data, etc.) since the expiration date, and

5.1.2.3 A thorough and meaningful description of the corrective action that will be taken to avoid expiration of this and other studies in the future.

5.1.3 Submit a final report immediately if the study is complete and all research activities have ended.

5.1.4 Notify the Sponsor, if any, of the lapse in approval immediately.

5.2 University & Medical Center Institutional Review Board (UMCIRB) Office is

responsible for maintaining records of the status of all approved studies. As a courtesy, the UMCIRB office ensures the electronic IRB submission system is programed to generate reminders of pending study expiration at 75, 50, 30 and 15 days prior to the study expiration date and then generates an expiration notification at the time the study expires. These notifications are sent to the PI and all study team members approved to serve on the study team by the IRB. The notifications are sent to the email address provided by the PI and study team when they register to use the electronic IRB submission system.

5.3 UMCIRB Staff is responsible for:

5.3.1 Reviewing, requesting modifications (if required) and processing continuing review and final report submissions in a timely manner.

5.3.2 Reviewing the expired study list in ePIRATE and ensuring that IRB approval letters for new studies are not released to the PI and the new study may not begin until; the PI has submitted either a continuing review (CR) or final report (FR) for their expired study(ies) and the CR or FR has been reviewed and approved by the IRB, IRB Chairperson or designee.

5.4 UMCIRB Chairperson or designee is responsible for:

5.4.1 Reviewing, requesting modifications to (if required) and making an approval determination for continuing review and final report submission in a timely manner, and

5.4.2 Reviewing, requesting modifications to (if required) and deciding if the PI's request to allow continued participation in the research of participants after IRB approval has expired should be allowed.

5.5 Post-IRB Approval Monitoring (PAM) Staff is responsible for:

5.5.1 Monitoring the electronic IRB submission system for expired studies; this will be accomplished by running an "Expired Study" report weekly;

5.5.2 Posting the "Expired Study" report on the PAM shared drive for tracking and monitoring

purposes; and

5.5.3 Preparing and sending a courtesy reminder email to the PI that their study has expired and informing them of their responsibilities as outlined in section 5.1 above as well as the consequences for non-compliance with this SOP which includes withholding of the IRB approval letter for any new study submission by the PI.

6.0 Procedures:

- 6.1** Upon expiration of a study the PI must immediately cease all research activities (including recruitment, enrollment, treatments, follow-up, and data collection/analysis) involving human subjects.
- 6.2** If, as described above in 5.1, the PI believes it is in the best interest of the participants already enrolled in the study to continue to receive the research interventions the PI must immediately submit a written request to the UMCIRB to continue interventions for any research subjects for whom discontinuation of the research could cause harm and continuation in the research would be in the best interest of the participants.
- 6.3** The written request must be submitted to the UMCIRB by email at umcirb@ecu.edu. The email correspondence must include the following details:
 - 6.3.1** The UMCIRB study number,
 - 6.3.2** The number of participants currently enrolled,
 - 6.3.3** Which participants (all or certain individual participants) need to continue in the expired research, which procedures/interventions are being requested to continue and the rationale for the request.
- 6.4** The emailed request must be forwarded by the UMCIRB staff member to the UMCIRB Chair or designee and the UMCIRB Administrative Director.
- 6.5** The UMCIRB Chair or designee will determine if the participant(s) may continue in the research. This determination may be made by expedited review unless the UMCIRB Chair or designee determines it should be reviewed by the full committee. Determination of which subjects can continue in the research will include:
 - 6.5.1** In general, whether research procedures should be safely discontinued,
 - 6.5.2** In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such,
 - 6.5.3** In general, research procedures conducted to collect data with no direct benefit to the participant should not continue, and
 - 6.5.4** There may be cases where an ethical issue may be raised where the above general principles may not be followed.
- 6.6** The UMCIRB staff will notify the PI and other key study personnel of the decision and will provide further instructions as applicable.
- 6.7** The post-IRB approval monitoring staff will monitor for expired studies by running a weekly expired study report in the electronic IRB system.
- 6.8** The expired study report will be posted to the PAM shared drive each week for tracking and reference by the PAM staff.
- 6.9** A courtesy email will be sent by the post-IRB approval monitoring staff to the PI, study coordinator (if applicable), faculty supervisor (if applicable), the associate dean of research and the department chair as a reminder that the study has expired. The email correspondence will outline the PI's responsibilities as set forth in this SOP as well as the consequence of non-compliance with the SOP.

6.10 If, in monitoring expired studies, the PAM staff notes a pattern of non-compliance with the requirements for continuing review (e.g., an investigator repeatedly or deliberately neglects to submit materials for continuing review in a timely fashion) such patterns will be reported to the UMCIRB for determination whether such a pattern represents serious or continuing non-compliance that needs to be reported to appropriate institutional officials, the HHS agency that supports the research, and OHRP.

Revision History:

Date	Change	Reference Section(s)
05.17.19	New SOP	All
05.31.19	Grammar/spelling corrections; “process” clarified in 5.3.2	5.1.6, 5.1.7, 5.3.2
08.22.19	Document revised throughout to improve clarity and accurately reflect changes to the process as it has evolved since inception; corrected effective date	3.0, 5.0, 5.3, 5.5, 6.0
04.03.20	Omitted requirement to close study and re-open as a new submission if no response to PAM email within 30 days, revised requirement for submission of reportable event (protocol deviation) and made other minor changes related to format, readability and grammar. Updated links to References	5.0, 6.0, References
07.22.21	Omitted requirement to submit a separate reportable event, rather the PI must provide the details of expiration in the CR if the study is to continue. Updated links to references	5.1, 5.3, 5.4

References:

[U.S. DHHS, OHRP. Continuing Review Guidance \(2010\) Section H. Lapses in IRB Approval](#)

[U.S. DHHS, OHRP. 45 CFR 46](#)

[UMCIRB SOP – Continuing Review Revised 01.21.19](#)

[UMCIRB SOP – Study Completion and Closure Revised 01.21.19](#)

[How to Create a Continuing Review in ePIRATE \(PPT\)](#)

[How to Close a Study in ePIRATE \(PPT\)](#)