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 failure by the PI to submit either a continuing review or final report (and all required supporting documents) to the UMCIRB. This SOP also applies when the information is not submitted in enough time for the UMCIRB to review and approve the research study by the expiration date last assigned by the UMCIRB. If the continuing review for a study is in any of the following states “Changes Required by IRB Staff”, “Changes Required by Expedited Reviewer”, “Changes Required by IRB”, or “Modifications Pending” and the study expires before the PI provides a response, this SOP applies.

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)** is responsible for the following:
5.1.1 Ensuring that IRB approval for their study(ies) does not expire. For research where the PI is a student, the Faculty Supervisor named on the study is responsible for ensuring the student PI meets the regulatory requirements for the conduct of the study. If the student PI leaves the University before transferring or closing the study the Faculty Supervisor is responsible for closing the study. If a faculty member separates from the University before transferring or closing their study their Department Chair is responsible for seeing to it that the study is either transferred to another PI or closed.
5.1.2 If the study is to continue, the PI must create and submit a continuing review application at least 30 days prior to the date of expiration to allow time for appropriate IRB review before the study approval expires (see UMCIRB SOP titled “Continuing Review” for recommended time frames for submission);
5.1.3 If the study meets the criteria for closure the PI must create and submit a final report application 30 days prior to the date of expiration to allow time for appropriate IRB review before the study approval expires.
5.1.4 If, in either case above, the UMCIRB requests more information or modifications of the continuing review or final report application the PI must respond in a timely fashion to ensure
receipt of the response by the IRB prior to the study expiration date.

5.1.5 If the study is allowed to expire the PI must cease all research activities involving human subjects immediately, unless it is determined to be in the best interest of those already enrolled to continue participating in the research. Continuing participation of already enrolled subjects in a study during the period when IRB approval has lapsed may be appropriate, 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.

5.1.5.1 The determination regarding whether it is in the best interest of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made by the PI possibly in consultation with the subjects’ treating physicians (if the investigator is not the subjects treating physician), but the investigator, as soon as possible, must submit a request for confirmation that the IRB agrees with this determination.

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

5.1.5.3 If the PI or IRB determines that it is not in the best interests of already 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.

5.1.6 Notifying the Sponsor, if any, of the lapse in approval immediately.

5.1.7 Creating and submitting a Reportable Event in the electronic IRB submission system for a Protocol Deviation/Violation informing the IRB of why the study was allowed to expire, whether there has been any research activity since the expiration date, and what corrective action will be taken to avoid study expiration in the future.

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 programmed 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 maintained on the UMCIRB shared drive and ensuring that IRB approval letters for new studies are not released to the PI and the new study may not begin until:

5.3.2.1 The PI has submitted either a continuing review or final report for his/her expired study(ies) and the CR or FR has been reviewed and approved by the IRB, IRB Chairperson or designee, and

5.3.2.2 The PI has submitted a Reportable Event (Protocol Deviation/Violation) as required above, and the reportable event 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,
5.4.2 Reviewing, requesting modifications to (if required) and acknowledging the Reportable Event (Protocol Deviation/Violation), and
5.4.3 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 Director** is responsible for:

5.5.1 Continuously 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 UMCIRB shared drive for review by the UMCIRB staff; and
5.5.3 Administratively closing the expired studies, where no continuing review or final report has been received by the UMCIRB, by revising the project state from “Expired” to “Withdrawn” immediately upon discovery of expiration.

6.0 **Procedures:**

6.1 Upon expiration of a study the PI must cease all research activities (including recruitment, enrollment, treatments, follow-up, and data collection/analysis) involving human subjects immediately.

6.2 If, as described above, the PI believes it is in the best interest of the participants already enrolled in the study to continue to receive the research interventions he/she 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 number of the study,
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 director will continuously monitor for expired studies by running a weekly expired study report in the electronic IRB system.

6.8 Any expired study appearing in this report, where a continuing review or final report application has not been submitted to the UMCIRB, will be administratively moved from the state of “Expired” to “Withdrawn”.

6.9 An email will be generated by the post-IRB approval monitoring director and sent to the PI, study coordinator (if there is one named on the study), faculty supervisor (if there is one named on the study) and the department chair notifying them of this action.

6.10 If, within thirty (30) calendar days of receipt of the email notification described in 6.9 above, the PI contacts the UMCIRB to state that he/she wishes to continue their study, the study will be moved back into the original state of “Expired” and the PI may create and submit a continuing review for continuation of the study. The PI will have seven (7) calendar days to submit the continuing review to the UMCIRB. If after seven days a continuing review has not been submitted the study will be administratively moved from “Expired” to “Withdrawn” again. At this time, the PI will need to create and submit a new study submission if he/she wishes to continue to conduct the study.

6.11 If it is greater than thirty (30) days after the email notification described in 6.9 above, and the PI contacts the UMCIRB about continuing his/her study they will be informed that they must create and submit a new study submission to open the study again.

6.12 A copy of the “Expired Study” report will be posted to the UMCIRB shared drive each week for review and reference by the UMCIRB staff.

6.13 If, in monitoring for expired studies, the post-IRB approval director 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 supported the research, and OHRP.

Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
<th>Reference Section(s)</th>
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</thead>
<tbody>
<tr>
<td>05.17.19</td>
<td>New SOP</td>
<td>All</td>
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<tr>
<td>05.31.19</td>
<td>Grammar/spelling corrections; “process” clarified in 5.3.2</td>
<td>5.1.6, 5.1.7, 5.3.2</td>
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References:


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)