1.0 **Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for human research studies approved under an expedited category of research, where there is no requirement for continuing review, and the Principal Investigator (PI) has not submitted a final report (FR) by the study’s expected end date.

2.0 **Research Protocols Affected:** Non-exempt human research activities reviewed and approved by the UMCIRB under an Expedited category of research under the revised Common Rule (as of January 21, 2019) where there is no requirement for continuing review.

3.0 **SOP:** For expedited studies with no continuing review requirement the PI is required to provide the UMCIRB with an “expected end date” in the IRB application. The UMCIRB uses this date to determine when a study will be completed and therefore, data retention periods commence. If the PI sees the study will not be completed by that date, they should amend the study to extend the end date. The amendment extending the expected end date should be submitted 30 days prior to the current expected end date approved by the UMCIRB. Otherwise, the PI should close the study by submitting a FR. If a PI has an expedited study that has passed the expected end date, and no amendment to revise the end date or FR has been submitted, the UMCIRB office will not release new study approvals for that PI until the requirements set forth in this SOP are met. This includes studies for which an amendment or final report has been submitted and is in the UMCIRB queue when the expected end dates passes.

4.0 **Definitions:**

4.1 **Expected End Date:** The date provided by the PI within the electronic IRB submission system documenting the anticipated date of study completion.

5.0 **Responsibilities:**

5.1 **Principal Investigator (PI) is responsible for the following:**

5.1.1 If the study passes the expected end date, the PI must 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. Continuing participation of already enrolled subjects in a study after the expected end date 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 already enrolled subjects to continue to participate in the research after the expected end date 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 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.

5.1.2 If the study will not be completed by the expected end date, submitting a study amendment, 30 days prior to the expected end date to extend the end date if human research activities need to continue.

5.1.3 If the study is complete, submitting a final report to the UMCIRB prior to the expected end date that was provided in the IRB application and approved by the UMCIRB.

5.1.4 If the UMCIRB requests more information or modifications to the amendment or final report application, the PI must respond in a timely fashion to ensure receipt of the response by the IRB prior to the expected end date.

5.1.5 Regardless of whether the study is to continue or be closed, submit a reportable event in the electronic IRB submission system for a protocol deviation/violation. The reportable event must contain the following information:

   5.1.5.1 The reason the study was allowed to pass the expected end date without submitting either a final report or an amendment to revise the expected end date,
   5.1.5.2 Whether there has been any research activity since the expected end date, and
   5.1.5.3 A robust and meaningful description of what corrective action will be taken to avoid this situation in the future.

5.1.6 A reportable event is not required for studies where an amendment or final report is submitted prior to the expected end date and the end date passes while in the UMCIRB queue.

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 at 75, 50, 30 and 15 days prior to the study’s expected end date and then generates a notification at the time the study passes the expected end date. These notifications are sent to the PI and all study team members approved to serve on the study team by the UMCIRB. 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 amendment and final report submissions in a timely manner.

   5.3.2 Reviewing the expired study list (which includes studies that have passed their expected end date) and ensuring that UMCIRB 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 an amendment to update the expected end date or a final report for the study(ies) and the amendment 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 acknowledged 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 the amendment or 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 the expected end date (when in the participants best interest) should be allowed while the study is being amended to extend the expected end date.

5.5 Post-IRB Approval Monitoring Staff is responsible for:
   5.5.1 Monitoring the electronic IRB submission system for studies that have passed their expected end date; this will be accomplished by running a report weekly;
   5.5.2 Posting the weekly report of studies which have passed their expected end date on the UMCIRB 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 passed the UMCIRB approved expected end date and informing them of both 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 a study passing the expected end date, 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, the PI believes it is in the best interest of the participants already enrolled in the study to continue to receive the research interventions or procedures the PI must immediately submit a written request to the UMCIRB.
   6.2.1 The written request must be submitted to the UMCIRB office by email. The email correspondence must include the following details:
      6.2.1.1 The UMCIRB study number,
      6.2.1.2 The number of participants currently enrolled,
      6.2.1.3 Which participants (all or certain individual participants) need to continue in the research, which procedures/interventions are being requested to continue and the rationale for the request.
   6.2.2 The emailed request must be forwarded by the UMCIRB staff member to the UMCIRB Chair or designee and the UMCIRB Administrative Director.
   6.2.3 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:
      6.2.3.1 In general, whether research procedures should be safely discontinued,
      6.2.3.2 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,
      6.2.3.3 In general, research procedures conducted to collect data with no direct benefit to the participant should not continue, and
      6.2.3.4 There may be cases where an ethical issue may be raised where the above general principles may not be followed.
   6.2.4 The UMCIRB staff will notify the PI and other key study personnel of the decision and will provide further instructions as applicable.
6.3 The post-IRB approval monitoring staff will monitor for studies that have passed the expected date by running a weekly report in the electronic IRB system and posting to the UMCIRB shared drive each week for review and reference by the UMCIRB staff.

6.4 A courtesy email will be sent by the post-IRB approval monitoring staff a to the PI, study coordinator (if there is one named on the study), faculty supervisor (if applicable) and the department chair as a reminder that the study has passed its expected end date. The email correspondence will outline the PI’s responsibilities as set forth in this SOP as well as the consequences of non-compliance with the SOP.

6.5 If, in monitoring studies that have been allowed to pass their expected end date, the post-IRB approval staff notes a pattern of non-compliance with the requirements for expedited studies (e.g., an investigator repeatedly or deliberately neglects to submit materials for 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.

Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
<th>Reference Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.2.19</td>
<td>New SOP</td>
<td>All</td>
</tr>
</tbody>
</table>

References:

UMCIRB SOP – Expedited Review Procedures Revised 01.21.19

How to Create an Amendment in ePIRATE (PPT)

How to Close a Study in ePIRATE (PPT)