

Expedited Studies Where Continuing Review Does Not Apply, the Expected End Date Has Passed and A Final Report Has Not Been Submitted	Effective Date	08.02.19
	Revision Date	07.22.21

- 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 date 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 should 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.).
- 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.

5.2 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 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 list of studies where the expected end date has passed and there has been no amendment or final report submitted and ensuring that UMCIRB approval letters for new studies are not released to the PI and the new study may not begin until the PI has met their obligations as outlined in this SOP.

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.

5.5 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 On a weekly basis, providing the UMCIRB staff with an updated list of the studies where the expected end date has passed.; 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 should cease all research activities (including recruitment, enrollment, treatments, follow-up, and data collection/analysis) involving human subjects. In order for the study to continue the PI must submit an amendment to the UMCIRB. If the study is complete the PI must submit a FR. The PI should take the appropriate action as soon as they become aware that the study has passed the expected end date.

6.3 The post 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 approval monitoring staff 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 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:

Date	Change	Reference Section(s)
08.02.19	New SOP	All
07.22.21	Revisions throughout to more accurately reflect the evolution of the requirements related to studies that have reached their UMCIRB approved end date and have not been amended or closed. Specifically, removal of the requirement to submit a reportable event and removal of language related to whether or not participants should continue in the study, for safety reasons, after the end date.	

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 \(PPT\)](#)