

Study Completion and Closure	Effective Date	4.25.2016
	Revision Date	2.8.2022

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to describe when and how to close a research study with the UMCIRB.
- 2.0 Research Protocols Affected:**
- 2.1 Human research activities reviewed and approved by the UMCIRB (does not include Exempt categories of research).
- 3.0 SOP:** Once a research study is complete, the IRB will conduct a review of what has occurred since the last time the study was approved (or renewed) and acknowledge the study will be considered completed in the IRB records. The IRB will receive and approve the application via a Final Report within the electronic submission system.
- 4.0 Definitions:**
- 4.1 **Final Report** is the activity within the electronic IRB Submission system that creates an application to close the specified study. This application is generated, completed and Submitted by the PI (or other study team members) and reviewed by the IRB.
- 4.2 **Closure** is the act of submitting a Final Report to the IRB to indicate a study is complete. A study can be closed under the following conditions:
- 4.2.1 Non-FDA regulated human research that was approved on or after the effective date (1/21/2019) for the revised human research regulations (or amended to comply with these new revised regulations) may be closed with the IRB when the research is permanently closed to the enrollment of new subjects and the research is:
- 4.2.1.1 At the point where data analysis (of identifiable or de-identified data) only is occurring,
- 4.2.1.2 Only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, or
- 4.2.1.3 Completed.
- 4.2.2 Non-FDA regulated human research that was approved prior to the effective date (1/21/2019) for the revised human research regulations (and not amended to comply with these new revised regulations) may be closed with the IRB when the research is permanently closed to the enrollment of new subjects and the research is:
- 4.2.2.1 At the point where data analysis of de-identified data only is occurring, or
- 4.2.2.2 Completed.
- 4.2.3 FDA regulated human research may be closed with the IRB when it is closed to enrollment of new subjects and;
- 4.2.3.1 There are no further research-related intervention or activities,
- 4.2.3.2 There is no further follow-up required,
- 4.2.3.3 There is no further data collection or data analysis of identifiable data planned, and
- 4.2.3.4 The sponsor/funding agency has verified the study can be closed.
- 4.3 **IRB Records** include

Study Completion and Closure	East Carolina University University & Medical Center Institutional Review Board	Page 1 of 4
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- Research plan and all other documents submitted as part of a new study application.
- Research plan and all other documents submitted as part of a request for continuing review or closure of research application.
- For devices, documentation of determination by IRB of significant risk/non- significant risk.
- All other IRB correspondence related to the research.
- IRB correspondence to and from research investigators.
- Notification of Continuing Noncompliance and Serious Noncompliance.
- Notification of Unanticipated Problem Involving Risk to Subjects or Others.
- Notification of Suspension or Termination of research.
- Notification of expiration of IRB approval to the investigator and requirements related to the expiration.
- Documentation of all IRB review actions.
- Approval letters that include any requirements that the investigator must satisfy before beginning the study.
- Documentation of complaints and any related findings and/or resolution.
- Documentation of reliance agreements.
- Documentation of review by another institution’s IRB when appropriate.
- For expedited review, documentation of the risk determination and period of approval. For research reviewed by the convened board these determinations are recorded in the minutes.
- For expedited review, documentation of any findings and determinations required by the regulations and study-specific findings supporting those determinations, including, but not limited to, waiver or alteration of consent, waiver of documentation of consent, research involving pregnant women, fetuses, and neonates, research involving prisoners, and research involving children. For research reviewed by the convened board these findings and determinations are recorded in the minutes.
- Documentation of type of IRB review. For exempt determinations and expedited review, this will include the category under which the review is allowed.
- Documentation of scientific or scholarly review (if applicable).
- DHHS-approved sample consent form document and research plan, when they exist.
- Copy of IRB-approved Consent/Assent/Parental Permission Documents.
- Documents submitted and reviewed after the study has been approved, including modification requests, protocol/research plan exception requests, proposed advertisements, data and safety monitoring reports, and reports of new safety information.
- Documentation of audits, investigations, reports of external site visits.

5.0 Responsibilities:

5.1 Principal Investigator (PI) will

5.1.1 Ensure research studies eligible to be closed are closed prior to the study’s IRB expiration date or prior to the Expected End Date (for non-FDA regulated expedited studies).

5.1.1.1 If the study is funded or sponsored by an outside agency, the PI should verify with the agency that the study can be closed locally.

Study Completion and Closure	East Carolina University University & Medical Center Institutional Review Board	Page 2 of 4
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- 5.1.1.2 If funded, expenditures for the study should be completed and the account is to be closed.
- 5.1.1.3 If an expedited study (with no expiration date) is not yet done by the time of the Expected End Date (provided by the PI in the original IRB application), an Amendment must be submitted to modify that date.
- 5.1.2 Complete and submit the Final Report application within the electronic IRB system.
- 5.1.3 Maintain the IRB letter acknowledging the study has been closed.
- 5.1.4 Retain and dispose of IRB records as per The University of North Carolina System Records Retention and Disposition Schedule. However, some records may have additional retention periods depending on their funding or sponsoring agency. In these cases, the longer retention period should be followed:
 - 5.1.4.1 DHHS regulations require that, “records relating to research which is conducted shall be retained for at least 3 years after completion of the research.” If a protocol is cancelled without subject enrollment, IRB records are maintained for at least three years after cancellation.
 - 5.1.4.2 FDA regulations require that sponsors and investigators of an Investigational New Drug (IND) retain “records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified.”
 - 5.1.4.3 FDA regulations require that the investigator or sponsor of an Investigational Device Exemption (IDE) maintain the records “for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.”
 - 5.1.4.4 HIPAA regulatory documentation (including signed consent/assent form(s), signed stand-alone HIPAA Authorization(s), documentation of verbal consent/authorization(s), research records documenting that a request for waiver of HIPAA Authorization was approved) must be retained for 6 years following completion of the research.
 - 5.1.4.5 For clinical trials, the contract should be reviewed and followed for specific sponsor requirements related to retention and disposition.
- 5.2 UMCIRB Office staff will
 - 5.2.1 Provide assistance and guidance in training research team members about when it is appropriate and how to submit Final Reports, and IRB members in the proper method of conducting reviews of Final Reports.
 - 5.2.2 Pre-review Final Reports for completeness prior to IRB review.
 - 5.2.3 Process letter to acknowledge closure and send to study team.
 - 5.2.4 Report study closures to UMCIRB members and other appropriate officials within the UMCIRB minutes.
 - 5.2.5 Retain and dispose of IRB records as per the federal regulations and University of North Carolina System Records Retention and Disposition Schedule. Some records may have additional retention periods. In these cases, the longer retention period should be followed:

- 5.2.5.1 DHHS regulations require that, “records relating to research which is conducted shall be retained for at least 3 years after completion of the research.” If a protocol is cancelled without subject enrollment, IRB records are maintained for at least three years after cancellation.
- 5.2.5.2 HIPAA regulatory documentation (including signed consent/assent form(s), signed stand-alone HIPAA Authorization(s), documentation of verbal consent/authorization(s), research records documenting that a request for waiver of HIPAA Authorization was approved) must be retained for 6 years following completion of the research.
- 5.2.5.3 IRB records within the ePIRATE electronic IRB submission system are currently kept indefinitely.

5.3 UMCIRB Chairperson or designee will

- 5.3.1 Review final information for research studies submitted for closure and request any information that may be needed to confirm research activities since the last review of the research.
 - 5.3.1.1 Final Reports can be reviewed and approved utilizing expedited review (i.e., review by the Chairperson or designee), however the study team will be notified if review by the convened UMCIRB is required.

6.0 Procedures:

- 6.1 Investigator ensures that the study is eligible to be closed.
- 6.2 Investigator/study team member completes and submits a Final Report within the electronic IRB submission system.
- 6.3 A researcher may not collect data or perform any protocol required activities under a research study that has been closed; the researcher would need to re-open the study as a new study in order to conduct any further human research. Additional research projects using data acquired in the approved study may constitute new human research subject to separate IRB review.

Revision History:

Date	Change	Reference Section(s)
4.25.2016	Pulled information to a stand-alone document.	All
1.21.2019	Updated to reflect revised regulations surrounding continuing review and subsequent process changes.	Sections 2.0-6.0
2.8.2022	Addition of data retention and disposition information.	Section 4.3, 5.1.4, 5.2.5

References:

FDA. Code of Federal Regulations:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.109>

DHHS, OHRP. Code of Federal Regulations:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109>

The University of North Carolina System Records Retention and Disposition Schedule:
https://files.nc.gov/dncr-archives/documents/files/university_gs_amendments_2020.pdf