

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
STUDY CLOSURE AND RECORD RETENTION**

I. PURPOSE

This document outlines the University of Tennessee Health Science Center Institutional Review Board procedures for the termination of a research project and the amount of time research records are to be retained.

II. SCOPE

This SOP applies to all IRB administrative staff, board members, and investigators.

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

III. BACKGROUND

The completion or termination of a research study is considered a change in research activities that must be reported to the UTHSC IRB. Once all non-exempt research activities have ceased at the location(s) over which the UTHSC IRB has oversight, the investigator must submit a Study Closure form. However, research projects must remain open and a Form 3: Continuing Review Submission Form submitted for IRB review where the research activities are limited to data analysis or when the research involves the long-term follow-up of subjects, even if enrollment of new subjects has been completed.

Regulations require IRBs and investigators to retain research data not only while the research is being conducted but also after the research has been completed. However, there are several different regulations regarding retention of research data each of which has different requirements. Therefore, IRBs and investigators must retain their research records for as long as the applicable regulations require, or if more than one regulation applies, the longest applicable period.

In accord with:

45 CFR 46.110, 45 CFR 46.115(b), 45 CFR 46.117, 21 CFR 56.115, 21 CFR 312.62(c) and 21 CFR 812.140(d)

OHRP Guidance on Continuing Review

<http://www.hhs.gov/ohrp/policy/continuingreview2010.html>

OHRP Guidance on Written Procedures

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html>

Investigator Responsibilities: Frequently Asked Questions

<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/>

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules

<https://www.hhs.gov/sites/default/files/privacysummary.pdf>

Compliance with this policy also requires compliance with state or local laws and regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. Project Closure/Termination:

- a. Study completion requires the reporting of key information to the UTHSC IRB for review using the Form 7: Study Closure of an IRB-approved project.
- b. Once all research activities have ceased at the research location(s) over which the UTHSC IRB has oversight, the investigator must submit a Form 7: Study Closure form, including the appropriate signature via iMedRIS.
- c. To assist the investigators and research staff, the investigator will receive renewal/closure notices 45, 30, 20, 10, and 5 days in advance of the expiration date of the study via iMedRIS. However, it is the responsibility of the principal investigator to ensure that the continuing review of an on-going research study or project is approved prior to the expiration date or, if a project is completed, that a Form 7: Study Closure is submitted for IRB review.
- d. Projects that involve long-term follow-up of research subjects must remain open and a Form 3: Continuing Review Submission Form must be

- submitted for IRB review, even if enrollment of new subjects has been completed. See SOP: Continuing Review of Research.
- e. Projects must remain open and a Form 3: Continuing Review Submission Form must be submitted for IRB review even if the remaining research activities at the local site are limited to data analysis. See SOP: Continuing Review of Research.
 - f. Upon receipt of the Form 7: Study Closure, the IRB Director or designee review and acknowledge the study closure.
 - g. The IRB director or designee will change the status of the study in iMedRIS to Terminated/Closed-Study Completed and issue a correspondence to the investigator via iMedRIS acknowledging closure of the project.
 - h. If an investigator fails to submit a Form 7: Study Closure form by the expiration date of the study, then the investigator, faculty advisor (if applicable), and department head are issued a correspondence within iMedRIS indicating that the study was administratively closed due to the investigator's failure to submit a Form 3: Continuing Review Submission Form or a Form 7: Study Closure. In addition, the status of the study in iMedRIS is changed to Terminated/Administratively Closed.
 - i. Administrative study closures (i.e., those studies closed by the IRB) are included as informational items in the minutes of the meeting of the full Board.
 - j. All other study closures are placed on the electronic meeting agenda and sent electronically to Board members before the Board meeting each applicable week when the agenda is finalized.

2. Reporting Requirements once a Research Project is closed:

Once a research study is closed/terminated, the investigator's regulatory requirement for submitting documents to the IRB for review has been fulfilled. The IRB strongly suggests that the investigator consult the sponsor prior to closing a research study.

However, the IRB will accept regulatory documents for review if the material contains additional pertinent information that will be provided to the research subjects or if the sponsor's reporting requirements are different than that of the UTHSC IRB.

3. Investigator Record Retention:

If more than one of the conditions below applies, research records should be retained for the longest applicable period.

- a. **OHRP Requirements:** For all research that is regulated by HHS and reviewed under 45 CFR 46, records relating to the research must be retained for at least 3 years after completion of the research.

The UTHSC IRB voluntarily applies this minimum requirement of retaining research records for 3 years after completion of the research to **ALL** studies approved by the UTHSC IRB.

- b. **FDA Requirements:** An investigator conducting research that is regulated by the FDA and involves drugs or biologics being tested in humans must retain the research records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated or, if no application is being filed or the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified.

An investigator conducting research that involves a medical device shall maintain the research records for a period of 2 years after the later of the following two dates: (i) the date on which the investigation is terminated or completed; or (ii) 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.

- c. **HIPAA Requirements:** Research that involves collection of protected health information (PHI) is subject to the HIPAA regulations. Research records including signed consent forms that contain the HIPAA authorization must be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later.
- d. **Sponsor Requirements:** If a research project is sponsored, then the investigator must comply with the terms for record retention outlined in the contract with the sponsor.
- e. **Questions of data validity:** If there are questions or allegations about the validity of the data or appropriate conduct of the research, the investigator must retain all the original research data until such time as the questions or allegations have been completely resolved.

4. **IRB Record Retention**

The UTHSC IRB shall prepare and maintain appropriate written and/or electronic documentation of IRB activities and research studies subject to the

regulatory authority of the IRB. IRB records shall be retained for at least 6 years after the completion of the research.

- a. **Documentation Maintained:** The UTHSC IRB shall maintain documentation of all research protocols reviewed, scientific evaluations, if any that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects, records of continuing review activities, correspondence between the IRB and the investigators, statements of significant new findings provided to subjects, and IRB findings. In addition, the IRB shall maintain minutes of IRB meetings, lists of IRB members, and written procedures.
- b. **Access/Availability of Records:** Access to hardcopy and electronic documents maintained by the UTHSC IRB shall be limited to IRB personnel, Board members, officials, and staff who need such access in order to perform their job duties, to comply with regulatory requirements or to report any compliance issues. Records shall be accessible for inspection and copying by authorized representatives of OHRP, FDA, and/or other appropriate governmental entities.
- c. **Removal of Written Documents:** No written IRB records shall be removed from the IRB office except as approved by the IRB Director or in certain limited circumstances (e.g., for use in an UTHSC inquiry or investigation; for production in accordance with a subpoena or request for production of documents; or pursuant to an appropriate request from a governmental agency with regulatory authority over the UTHSC IRB).
- d. **Electronic Records:** The IRB electronic records shall be maintained in iMedRIS, which has implemented controls, including audits, system validations, audit trails, electronic signatures and documentation for the system that meet the requirements of 21 CFR 11.
- e. **Reporting of Security Breaches:** Persons who discover any security breaches or instances of missing or damaged documents or electronic information shall immediately report such event to the IRB Director or designee. The IRB Director will make further reports of such events as necessary (e.g., reporting to HIPAA Privacy Officer and/or HIPAA Security Officer), as well as inquire into any such events and implement appropriate corrective measures.
- f. **Destruction of Records:** At least once a year, the IRB staff or designated personnel shall review the IRB records and dispose of the records for which the retention period has expired. The IRB shall dispose of any

records that need no longer be maintained via shredding or other appropriate method of disposal. Appropriate documentation of destruction shall be maintained.