UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
STUDY CLOSURE AND RECORD RETENTION

I. PURPOSE

This document outlines the University of Tennessee Graduate School of Medicine 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 activity that must be reported to the UTGSM IRB. Once all non-exempt research activities have ceased at the location(s) over which the UTGSM IRB has oversight, the investigator must submit a Study Closure form. However, research projects must remain open where the research activity is limited to data analysis or when the research involves long-term follow-up of subjects, even if enrollment of new subjects has been completed. A Form 3: Continuing Review Submission Form must be submitted for IRB review.

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 accordance 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/continuingreview 2010.html

OHRP Guidance on Written Procedures
http://www.hhs.gov/ohrp/policy/irbgd107.html

Investigator Responsibilities: Frequently Asked Questions
http://www.hhs.gov/ohrp/regulations-and-policyguidance/faq/investigator-responsibilities/

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules
http://www.hhs.gov.ocr/privacy/

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 UTGSM IRB for review using the Termination form of an IRB approved project.
   - **b.** Once all research activities have ceased at the research location(s) over which the UTGSM IRB has oversight, the investigator must submit a Termination form including the appropriate departmental signatures.
   - **c.** To assist the investigators and research staff, the investigator will receive renewal/closure notice 60 days in advance of the expiration date of the study. 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 Termination form is submitted for IRB review.
   - **d.** Projects that involve long-term follow-up of research subjects must remain open and a 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 Continuing Review Submission From must be submitted for IRB review even if the remaining research activities are limited to data analysis. See SOP: Continuing Review of Research.
   - **f.** Upon receipt of the Termination form, the IRB staff will forward the submission to the IRB Chair or IRB Director for review and acknowledgement of study closure.

g. The IRB staff will change the status of the study to Terminated/Closed-Study Completed and issue a correspondence to the investigator acknowledging closure of the project.

h. If an investigator fails to submit a Termination form by the expiration date of the study, then the investigator, faculty advisor (if applicable), and department head are issued a correspondence indicating that the study was administratively closed due to the investigator's failure to submit a Termination form. In addition, the status of the study is changed to Terminated/Administratively Closed.

i. The study closure is included as an informational item in the minutes of the meeting of the full Board.

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 UTGSM IRB.

3. Investigator Record Retention:

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.

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 UTGSM 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 3 years after the completion of the research.

a. **Documentation Maintained:** The UTGSM IRB shall maintain documentation of all research protocols reviewed, scientific evaluation, 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 UTGSM 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 Chair or in certain limited circumstances (e.g., for use in an UTGSM 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 UTGSM 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. Electronic Data Storage: Electronic study data should be stored on FIPS 140-2 compliant storage media. Compliance to this standard can be maintained either through appropriate software tools or specialized storage media. Hardware protected FIPS 140-2 compliant storage media are the preferred method of long term storage for electronic study data as these devices offer the greatest protection against accidental loss of data. If this standard cannot be met, details regarding secure storage protocol should be outlined to the IRB as part of the study protocol.

http://csrc.nist.gov/groups/STM/cmvp/standards.html

f. 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 Assistant Director or Chair. The IRB Chair or Assistant 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.

g. Destruction of Records: At least once a year, the IRB staff shall review the IRB records and dispose of the records for which the retention period has expired (3 years after termination) 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. Destruction of records should use HIPAA recommended procedures that follow the NIST guidelines for media sanitization under NIST Special Publication 800-88.

http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf