**GUIDANCE: Records Retention**

**Policy:** It is the policy of UTHSC-H that all essential research records be maintained in a secure location for the duration required by this policy and procedure.

**Key Terms**

**Essential Documents:** Essential documents are those documents which individually and collectively permit evaluation of the conduct of research and the quality of data produced.

**Period of Retention**: Depends on the type of research being conducted and the source of funding for the research:

1. For industry sponsored research, essential study documents should be retained for as long as specified in the study contract.
2. For investigator initiated research under FDA oversight, i.e. research involving drugs or devices, essential study documents should be retained for at least 15 years after the completion of the study at this site.
3. For all other research, essential study documents should be retained for at least 15 years after completion of the research study at this site.

**Essential Documents:** Essential documents are those documents which individually and collectively permit evaluation of the conduct of research and the quality of data produced. These documents serve to demonstrate the compliance during the conduct of research to applicable regulatory requirements and institutional policies. Essential documents must be retained for the specified duration. Essential documents include, but are not limited to:

* 1. Approved Protocol and all Amendments
	2. Approved Consent Form
	3. Investigator Brochure (if available)
	4. IRB Approval Letters (initial, continuing, amendments)
	5. Signed Consent Forms
	6. Source Documents
	7. Case Report Forms
	8. Unanticipated Problem Reports and Adverse Event Reports
	9. Drug / Device Accountability Logs
	10. Reports to IRB, Federal Agencies, Sponsor
	11. Records of Monitoring, Audits and Inspections
	12. Study Participants Master Contact Log

**Storage:** After study closeout, the Principal Investigator and/or Study Coordinator should organize essential research records for storage. Records should be stored in a manner that is easily accessible for review by regulatory inspectors, sponsor monitors, sponsor auditors and IRB monitors.

Records may be stored within the institution or arrangements may be made to archive research records in an offsite secure location. It is good practice to check if the offsite location has protection against fire, theft and other disasters. <is there a process for this? Who is notified? >

**Change in Study Personnel** – if the Principal Investigator were to leave the institution during the records retention period, the responsibility of maintaining research records should be transferred to another individual at the institution who is willing to accept responsibility for maintaining the records for the required time period. The sponsor should be notified in writing of the name and address of the individual assuming responsibility.

**Applicable Regulations and Guidelines**

* **Investigational Devices** - 21 CFR 812.140(d) - *Retention period.* An investigator or sponsor shall maintain the records required by this subpart during the investigation and 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.
* **Investigational Drugs** – 21 CFR 312.62(c) *Record retention.* An investigator shall retain records required to be maintained under this part 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 to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.
* **IRB Records** – 45 CFR 46.115(b) IRB records shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

**Applicable Institutional Policies and Procedures**

* Records Retention Schedule - <http://records.uth.tmc.edu/retention_schedule.htm>

**Attachments**

* Study Archival Checklist
* Labels for Boxes
* List of Study Participants for Source Document Retention

**If you find errors in this document, contact** **clinicaltrials@uth.tmc.edu**

|  |  |
| --- | --- |
| **Document Number:** | 402-023 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | June 1, 2011 |
| **Revision History:** | None |
|  |  |
|  |  |