UTHealth Houston

Title: Clinical Research Records Retention	Version Number: 1.0	Effective Date: 1 Apr 2023	Page 1 of 2

1. Purpose

To outline the process for retention of clinical research records at UTHealth Houston.

2. Scope and Responsibility

This SOP applies to all individuals participating in the conduct of clinical research at UTHealth. All staff to whom an investigator assigns a study task are required to follow this SOP.

3. Definitions

3.1 **Essential Documents:** Essential documents are those documents which individually and collectively permit evaluation of the conduct of research and 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

4. Policy

4.1 Essential research records must be maintained in a secure location for the duration required by this policy and procedure.

4.2 The records retention requirements depend on the type of research being conducted and the source of funding for the research:

4.2.1 For industry sponsored research, essential study documents should be retained for as long as specified in the study contract.

4.2.2 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.

4.2.3 UTHealth Houston School of Public Health research documents including but it is not limited to consent / assent forms used for behavioral health interviews / surveys, demographic information and behavioral questions, observations, and medical procedures that are considered low-risk (e.g.: height and weight measurements) should be retained for ***10 years*** after completion of the research study.

4.2.4 For all other research, essential study documents should be retained for at least ***7 years*** after completion of the research study at this site.

4.2.5 For research involving minors, consent documents should be retained until the youngest participant's 21st birthday or 10 years following end of calendar year in which consent form was signed, whichever is later.

5. **Procedures -** 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.

5.1 After study closeout, the Principal Investigator and/or Study Coordinator should organize essential research records for storage. Study documents that are determined to not be 'essential documents' may be disposed by shredding.

5.2 **Paper Records**:

5.2.1 Label storage boxes clearly and completely.

5.2.2 If files are in cabinets each cabinet will need to be labeled clearly and completely

5.2.3 Document inventory of storage boxes.

5.2.4 Store in a secure location for the required period of time in a manner to facilitate ease of retrieval.

5.2.5 Maintain an inventory of all stored study documents and save this on department shared drive for ease of retrieval and the maintenance.

5.3 **Electronic Records**:

5.3.1 Create an inventory of all the documents that are being stored.

5.3.2 Organize electronic records into folders.

5.3.3 Save the electronic files in the department common drive with access control.

5.3.4 Clearly indicate how long the files need to be stored.

5.3.5 Ensure that the files are deleted after the storage period.

5.4 **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.

6. References

6.1 Any references – include links if available

6.2 Records Retention Schedule - https://apps.uth.edu/rrss

6.3 Investigational Devices - 21 CFR 812.140(d)

6.4 Investigational Drugs – 21 CFR 312.62(c)

6.5 IRB Records – 45 CFR 46.115(b

7. Appendices

7.1 Study Archival Checklist

7.2 Labels for Boxes

7.3 List of Study Participants for Source Document Retention

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

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