UTHealth Houston

Title: Digital Storage of Clinical Research Documents	Version: 1.0	Effective Date: 1 Apr 2023	Page 1 of 4

1. Purpose

To outline the process for retention of clinical research records in digital format 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.

4. Policy

4.1 During the course of a study, clinical research records should be stored in a manner that is easily accessible for review by regulatory inspectors, sponsor monitors, sponsor auditors and IRB monitors. After the end of the study, records need to be retained for a duration specified in the Records Retention SOP.

4.2 FDA's current regulations and guidance permit the interchangeable use of electronic and paper records for the archiving and protection of records provided records are maintained in a manner such that all regulatory requirements are met and the copies of required records preserve their content and meaning.

4.3 Duplicate files, duplicate copies, library materials, and stocks of obsolete forms or pamphlets originally intended for distribution are not considered to be official records or record copies. Duplicates or non-record convenience copies should be destroyed when they cease to be useful and should never be kept longer than the official record copy.

4.4 When converting paper research records to electronic files for archiving, the electronic files should be certified. The person who converted a paper document into electronic format must certify that the electronic copy is an accurate and complete representation of the original, having all of the same attributes and information. Certification should be documented by the signing and dating the copy by using the Certification Template.

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. .

5.1 Electronic Records Best Practices:

5.1.1 Index the documents for ease of retrieval.

5.1.2 Label the file appropriately.

5.1.3 Review copied document and confirm that it is an EXACT copy of the original.

5.1.4 Confirm that each page is legible and facing in the appropriate direction.
5.1.5 Confirm that each consent is bookmarked and named appropriately.
5.1.6 Confirmed that the scanned document is password protected and saved in a secure location.
5.1.7 Complete certification statement and maintain in study files
5.1.8 Use appropriate security measures to protect files from unauthorized access
5.1.9 Once all of the research records are scanned and certified, the paper copies can be destroyed.

5.2 **Location of Electronic Files:** Electronic files of the scanned and certified study documents must be stored securely on UTHealth Houston servers in the department shared drive, UTHealth Houston Google Drive, UTHealth Houston OneDrive or UTHealth Houston REDCap. Study documents should ***not*** be stored on desktops, laptops, as these devices are not backed up by UTHealth Houston IT. If encrypted external hard drives are used, the hard drives must be encrypted and backed-up onto another encrypted hard drive. It is highly recommended that external hard drives be backed up at least once a month. Procedures for storing and backing up external hard drives should be outlined in a study SOP or workflow document.

5.3 **Timing of Conversion:** Study documents can be stored electronically anytime during the course of a study. For upcoming studies, study teams can decide to maintain documents electronically before the study starts. For studies that have been completed, study documents may be converted to electronic files at any time. Consider the duration of storage before making the decision to convert.

5.4 **Procedure for Conversion of Paper Research Documents to Electronic Files**.

5.4.1 **Regulatory Documents:**

(a) Check the Regulatory Binder for completeness. If there are missing documents, try to find them or write a 'Note to File' listing the missing documents.
(b) Scan the Regulatory Binder documents to a single PDF or as multiple PDF files that mirrors the paper files. E.g. Regulatory Binder 1 may be converted to Regulatory Binder 1 in PDF.
(c) Maintain the same formatting as the paper file – bookmark each separate document in the PDF document.
(d) Check the scanned PDF document carefully to ensure that it is exactly the same as the paper document. If one has scanned the documents have someone else verify that all the documents are scanned. Also, the quality of document is important. Make sure everything is legible.
(e) Use the Certify Study Documents template to certify the regulatory documents and maintain this as the first page of the PDF.

5.4.2 **Participant Documents:**

(a) Each participant research records should be stored as separate PDF file.
(b) Consider maintaining same filing structure as the paper participant binder.
(c) Bookmark each section of the PDF labeling the bookmark carefully to reflect the document that it refers to.
(d) Label the file with the IRB Number and Study ID of the participant. (22-0100-214-001)

(e) Remember to include pertinent e-mail correspondence in the scanned file (e.g., sponsor approval of an exception).
(f) Password protect the file. Please see the document titled *"How to Scan Study Documents to PDF for electronic storage'* for step by step instructions.

5.5 Studies with Few Documents: If there are no participant documents other than signed consent forms or there are only a few pages of participant study documents, you may store them together as one PDF file. You may wish to store them in one PDF or in multiple PDFs if there are many participants. (e.g. for a study with under 50 participants with 10 pages of consent + study documents, you may decide to store the entire study documentation in one PDF file. However for a study with 500 participants and 20 pages consent + study documents, you may decide to break them into 2 or 4 PDF documents.) Bookmark each participant using the participant ID.

5.6 **Electronic Documents**: Study documents that are in electronic format e.g. sponsor communication or source documents from electronic medical record may be converted to PDF and named according to the naming convention of the study and placed in the secure drive directly. The designated study staff member should certify that the PDF document is the exact copy of the original.

5.7 **Records Retention Duration:** Electronic files of research documents should be kept at a minimum of 7 years following end of study and in accordance with institutional policy. Sponsored and/or FDA-regulated studies may have additional requirements .

5.8 **Industry sponsored trials:** You may transfer industry sponsored trial documents into electronic format only with the prior written permission of the sponsor. This can be in the form of an email or letter that has the name and title of the person granting permission. This documentation of sponsor acceptance should be kept on file.

6. References

6.1 Records Retention Schedule - https://apps.uth.edu/rrss/
6.2 Investigational Devices - 21 CFR 812.140(d)
6.3 Investigational Drugs – 21 CFR 312.62(c)
6.4 IRB Records – 45 CFR 46.115(b
6.5 General Guidance on Good Clinical Practice - ICH E6
6.6 FDA Guidance on Computerized System in Clinical Investigations

7. Appendices

7.1 Certification Template

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