



Procedure Name: Record Retention
Effective Date: February 26, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: QA-005, Rev 1
Application: Office of Clinical Trials
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OBJECTIVE:

Establish the requirements for maintaining and archiving records necessary to demonstrate compliance with regulatory requirements and to provide evidence of data integrity and subject safety.

REFERENCES:

21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator records and reports
21 CFR 812.140	Records
ICH E-6	Good Clinical Practice; 4.9 – Records and Reports
21 CFR 11	Electronic Records; Electronic Signatures
UNTHSC IR Standards & Policies 04.307 & 04.310	Protected Health Information Electronic Communications & Records and Information Management Program

SCOPE:

This procedure applies to clinical protocols, study documents, case histories and other documents (see Regulatory Binder procedure) associated with clinical research conducted by the UNTHSC Office of Clinical Trials (OCT). The procedure describes the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of documents and records. Documentation covered by this procedure can generally be described as “controlled or regulated documents” i.e. those documents subject to regulatory requirements. These are contrasted with non-regulated documentation such as business, human resource or personnel records.

The procedure has two sections. Section 1 defines general document and record requirements. Section 2 describes the requirements for electronic document management and electronic signatures.

The requirements described in this procedure apply to electronic or paper records that are created, modified, maintained, archived, retrieved, or transmitted.

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RESPONSIBILITY:

OCT management is responsible for following the requirements of this procedure for all applicable documents.

Principal Investigators are responsible for following the requirements of this procedure with respect to the study (ies) for which they serve as PIs.

PROCEDURE:

Section 1 – General Requirements:

- 1.0 Maintain written documentation as required for the compliant operation of clinical research (reference the Regulatory Binder procedure, CR-008).
- 2.0 Maintain Legibility. Records are created and maintained in such a manner as to be legible. Where records subject to the requirements of this procedure are handwritten, all entries will be made in permanent ink, corrections will be made with a single line through the incorrect entry with the correction entered adjacent and the correction initialed, dated, and explained (i.e., CE= clerical error).
- 3.0 Establish and Maintain Document Identity. Identification of the document, the author and any approvers will be maintained.
- 4.0 Securely stored:

Documents stored in physical form will be stored in secured, limited access cabinets. Appropriate measures will be taken to assure that documents are protected against fire, water or other natural disasters.

Records stored by electronic means must be backed up in accordance with the above-referenced approved procedures for electronic record security.

Documents considered to be confidential (such as subject identifiable Protected Health Information (PHI) documents) will be so marked and their distribution restricted.

- 5.0 Clinical documentation will be maintained for a period not less than two years from the date the NDA/PMA or equivalent (the application) is approved or the IND/IDE is formally discontinued by the sponsor. As international record retention requirements may be longer, the sponsor will indicate which jurisdictions and timing apply.
- 6.0 Study documents and records will not be destroyed without written authorization from the sponsor. Specific written authorization is required from the OCT management prior to destroying documentation subject to this procedure.

Documents approved for destruction according to the UNTHSC Records Retention Schedule will be destroyed according to the UNTHSC Records and Information Management Policy Records Disposition. Examples include a commercial shredding service or other means that renders the documents unrecoverable.

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- 7.0 Documents which are no longer required for day-to-day operations may be archived in a suitable location or facility (meeting the requirements defined above). Assure that any archived documents are retrievable within the requisite time window(s) so they may be provided during an audit or regulatory inspection.
- 8.0 When storing records, the first step is to call Office of Records Management @ ext. 0173 to order the number of boxes needed. Use OCT Records Storage account 64955. The second step is to complete Records Transmittal Form and Records Transmittal Log. These forms may be found on the UNTHSC intranet under departments. Click on the Information Technology Services (ITS)-internal link, then Forms. When completed, send records for retention to the Office of Records Management, Lib-122. Submit copies of completed forms to the Office of Clinical Trials Administration. To retrieve the records, call Office of Records Management personnel, and someone will pull them for you.

Section II – Electronic Records

1.0 Electronic Records

In lieu of paper records, UNTHSC OCT may utilize electronic records that are subject to review by regulatory agencies. This procedure is intended to assure that such electronic records are equivalent to paper records.

- 1.1 The electronic document system(s) utilized to create, maintain or store records specified in this procedure will meet the definition of closed systems: (*Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.*) [21CFR 11 - definitions]
- 1.2 If used, any electronic document system will be validated per the requirements of 21 CFR 11 and/or the applicable local regulations noted above.
- 1.3 If used, electronic records will utilize a secure, computer-generated, time-stamped audit trail to independently record the originator, date and time of original entries and any actions that modify or delete electronic records. Changes will not obscure previously recorded information. Such audit trail documentation will be retained for a period at least as long as that required for the subject records, and are subject to regulatory agency review.

2.0 Electronic Signatures

- 2.1 If used, UNTHSC OCT and its associated medical departments will hold individuals accountable and responsible for actions initiated under their electronic signatures to deter record or signature falsification.
- 2.2 Electronic signatures must contain the following information associated with the signature:
 - The printed name of the signer

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- The date and time (including time zone) when the signature was executed
 - The meaning of the signature. Such meanings could include performance, review, approval, authorship, etc.
- 2.3 Electronic signatures will be linked to their respective electronic records so that the signatures cannot be altered, copied or falsified by ordinary means.
- 2.4 Electronic signatures must be unique and will not be reassigned to anyone else.
- 2.5 Electronic signature security (system security) may be biometric or non-biometric. Non-biometric system security will require at least two distinct identifiers to permit system access.
- 2.6 A master list of signatures (handwritten), the printed name of the signer and whether electronic signatures are enabled will be maintained.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-005	Edited for clarity and cross-referenced to additional policies.	Michael V.W. Bergamini

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