


Standard Operating Procedures for Clinical Research at USF Health CRC			
	ARCHIVING STUDY RECORDS		
	SOP#: 504	Effective Date:01/01/2015	Version: 1.0 Page: Page 1 of 5

PURPOSE: The purpose of this SOP is to describe the procedures for archiving all study documents related to clinical research at the CRC.

SCOPE: This SOP applies the Investigator and research personnel who conduct clinical research studies at the CRC.

RESPONSIBILITIES: The PI and designated study coordinator are responsible for archiving trial related documents.

DEFINITIONS:


Archive: A way of sorting and organizing older documents, whether it be digitally (photographs online, e-mails, etc.) or manually (putting it in folders, photo albums, etc.).

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).


PROCEDURE:

1. The PI will ensure that his/her records are available for review by the IRB within a reasonable period of time upon request.
2. The PI must maintain all research records (e.g. signed informed consent documents, source documents, case report forms, laboratory results, and regulatory binder documents) for a minimum of five (5) years after the study is closed by the IRB.
3. The PI will retain study records containing HIPAA Authorization language and Personal Health Information (PHI) for a minimum of six (6) years from the date of study closure or later as outlined in the HIPAA Authorization language.
4. If the sponsor requires records to be maintained for an alternative period of time, the PI and study personnel will maintain all research records for the period of time that meets the requirements of all parties but no less than the five years as required by the IRB
5. The PI should review all written agreements with sponsor to ensure that any additional specific contractual obligations associated with record retention and accessibility are met.

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PROCEDURE (cont.):


6. The PI and/ or research designee is responsible for the following:
 - 6.1. Ensure that research study documents should be archived in a legible condition and prompt retrieval should be possible when required.
 - 6.2. Ensure adequate and suitable space should be provided for the secure storage of all study documents upon completion of the trial with appropriate environmental controls and adequate protection from fire, flood and unauthorized access.
 - 6.3. Follow the Sponsor's archiving procedures. The study Sponsor should provide the Principal Investigator (PI) with details of exactly what is to be archived off site. The Sponsor may also provide details of what documents are to be archived locally (e.g. Iron Mountain).
7. The documents to be archived should include:
 - Site Files
 - Case Report Forms (CRFs)
 - Pharmacy Site File (if applicable)
 - Sponsor File
 - Any other documents that may be required to show a clear audit trail of a process performed in relation to the clinical trial
 - Any source data documents that are not part of a participant's medical notes
8. Preparing Documents for Archiving:
 - 8.1. The Site File(s) should be organized in suitable binders and/or box files and clearly labeled with the following information:
 - Sponsor's name
 - Sponsor's ID number
 - Short study title
 - Name of the PI
 - Brief summary of the contents
 - 8.2. All dividers, paper clips, duplicate documents and irrelevant correspondence should be removed. Only correspondence relating to any agreements or significant discussions relating to the study should be included.
 - 8.3. All CRFs should be removed from their binder, if applicable, and filed with individual patient packs.
 - 8.4. Documents relating to study visits should be bound in chronological order, with the earliest visit on top. These can then be filed directly into the Archive box, put

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PROCEDURE (cont.):

into individually labeled envelopes or filed in a box file. One unused copy of the latest version of the CRF should also be retained if possible.

- 8.5. Source Data Documents that form part of current medical records (such as ECGs, test results etc) should remain with the medical records and a note detailing the location of these source data documents included in the archived documents. ECG printed results should be photocopied and the copy retained with the original in the patient notes (this is because original ECG results fade quickly). Duplicate copies of source data documents should not be archived with study documents.
- 8.6. Only original copies of pharmacy prescriptions are to be included as part of the archived pharmacy file. Duplicate copies should not be archived with site file essential documents and should be destroyed at the time of archiving.
9. For each archived study, the research designee will maintain a list detailing what has been included in the archived study documents. Refer to *Appendix GG: Archiving Log*
10. Prior to archiving, the research designee will label each Archive Box with:
 - The protocol number
 - The box number and how many boxes there are (e.g. 1 of 5)
 - The name and address of the Sponsor(s)
 - The short title(s)
 - The name and contact information of the PI
 - List of content for that particular Archive Box (e.g. Regulatory File, CRFs for subjects 001-023)
 - Date of archiving
 - Expected end date of archiving for each study
 - A copy of the outer label will also be placed within the box in case the outer label fades over time. The outer label should be secured to the box in a waterproof plastic sleeve (Appendix FF: Archiving Label Template).
11. Once documents have been archived, the research designee will document a statement detailing document preparation for archiving that includes:
 - Archive box numbers
 - Where the documents have been archived
 - Number of actual archive boxes

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PROCEDURE (cont.):

- Date of archiving
- Length of time of archiving
- Expected end date of archiving

12. Destruction of archived documents after storage:

- 12.1 The research designee should be contacted prior to destruction
- 12.2 When the agreed date of destruction is known, the research designee will contact the study Sponsor for written authorization for the destruction. Destruction must not take place without written authorization from the Sponsor. If there is no longer an identifiable Sponsor the research designee will authorize destruction on the agreed date.
- 12.3 A certificate of destruction must be issued and the reasons for destruction documented.
- 12.4 A copy of the record of destruction together with any written authorization for destruction will be retained by USF for an additional 5 years from the date that the study documents were destroyed.

13. Archiving trial data on computers:

- 13.1. The PI will inform the research designee as soon as it is known that electronic study data will need to be archived.
- 13.2. Electronic study data should be encrypted and copied onto a read-only media device for archiving with the study documents as described above.
- 13.3. The PI will ensure that all study data held on computer servers are permanently deleted as soon as the study has been reported and the participants notified of the results.

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REFERENCES:

ICH GCP Section 5.5.12
USF HRPP Policy and Procedures Manual: Records Retention and Accessibility

RELATED POLICIES:

SOP 103: Responsibilities of the Clinical Research Team

APPENDICES:

Appendix FF: Archiving Label Template
Appendix GG: Archiving Log

REVISION HISTORY: Keep a running history of all revision dates.

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	