

LONG TERM STORAGE OF RESEARCH RECORDS

1. **OBJECTIVES:** Outline the procedures for storage and retention of research records after the project has been completed and the study has been closed.

2. **RESPONSIBILITIES:**

- a. Research records are the property of the Atlanta VA Medical Center (AVAMC), under the control and responsibility of the Principal Investigator (PI).
- b. The PI is responsible for following and implementing the study records retention guidelines as required by federal regulations, the study sponsor, and the AVAMC. All research study records must be kept indefinitely. Do not destroy research records, keys, or data.
- c. The PI is responsible for preparing the records for storage to include; properly securing all Patient Health information (PHI); properly storing all electronic records, and properly delivering all records to the Clinical Studies Center (CSC) for long term storage. Please follow directions on the "Procedures for Closing Human Research Studies" policy located on the AREF website.
- d. The PI is responsible for providing and keeping his/her contact information up to date with the AVAMC Research Office during the record retention period.

3. **RETENTION GUIDELINES**

- a. Federal regulations for the destruction of federal records indicate that all study records generated during the course of VA research must be retained *indefinitely*. Please follow directions on the "Procedures for Closing Human Research Studies" policy located on the AREF website.
- b. Store electronic research data on the secured research drive. Remove all research data from all other drives. Please follow directions on the "Procedures for Closing Human Research Studies" policy located on the AREF website.
- c. Research records will be shipped to and stored at: VA Records Center and Vault, 11693 Lime Kiln Drive, Neosho, MO, 64850.
- d. Records will be accessible for inspection and copying only by authorized personnel and/or an authorized federal regulatory entity after they are placed in long term storage.

4. PROCEDURES:

- a. Contact a Clinical Studies Center (CSC) staff member who will review with the research staff the specific instructions regarding preparing and organizing study records for storage.
- b. The CSC will provide new unmarked Special Purpose Shipping Boxes.
- c. Prepare all VA research records for storage. This includes but is not limited to:
 - i. All source documents and case report forms/data collection templates.
 - ii. All informed consent & HIPAA documents, demographic profiles, and data keys.
 - iii. All photographs, video/tape and audio recordings.
 - iv. All administered tests, assessments, questionnaires, etc.
 - v. All other study documents, including pharmacy records, X-rays, or other documents from other departments.
 - vi. Electronic data must be stored on the secured VA Research drive.
- d. The PI will organize and box study files in a chronological order. Please remove large paper clips, 3 ring binders and other hard folders. Bind papers together with large rubber bands.
- e. Complete all fields on the attached "Research Records Storage Request" form (attached - see page 3).
- f. Send the "Research Records Storage Request" form to the CSC Administrative Assistant (AA) for approval and processing. The AA will review the form and arrange for delivery of the research records to the CSC.
- g. The CSC AA will arrange for the shipment of labeled and boxed research records to the VA Records Center and Vault.
- h. Keep a copy of the completed Research Records Storage Request for your files.

Research Records Storage Request Form is attached. See next page.

ATLANTA VA CLINICAL STUDIES CENTER
Research Records Storage Request

PI Name:					
PI Address:	Atlanta VAMC, 1670 Clairmont Road, Decatur GA 30033				
Point of contact:	Phone:	email:			
Full project title:					
IRB Number		Date Activated		Date Term/Closed	
Number of Boxes Submitted :					
Notes:					

Boxes will include:	
1) IRB and R&D documents	Initials:
2) Protocol	Initials:
3) All approvals, modification, continue reviews and supporting documentation	Initials:
4) All reportable event documents	Initials:
5) Pharmacy records	Initials:
6) Other correspondences	Initials:
7) Patient records/consents: Number _____	Initials:
8) Other Items; photos, videos/tapes, audio recordings, electronic storage devices	Initials:
Notes:	

Electronic Study Documents MUST be saved to the Research Server and removed from all other drives and storage devices. A list of file names and location of electronically stored records MUST accompany this request for storage form. All electronic Patient Health Information (PHI) must be saved on the Research Server and separated from non-sensitive files. Contact Tony Laracuente for Electronic Storage.		
Date Accomplished :	/ /	Initials
List Attached:	Yes No	Initials
Note:		

The Research Compliance Officer (RCO) MUST be notified of project termination/closure.		
Date Study Activated:	Copy of Notification:	Initials _____
Date RCO Notified:		
Date Audited:	RCO Initials:	
Note:		

Send the AREF Clinical Trials Financial Analyst an e-mail regarding project closeout (if applicable)
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Date received CSC:	CSC Staff Name:
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Shipment number: VHA	Box Number:	Sequence number:
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