

SHORT TERM STORAGE OF RESEARCH RECORDS

1. **OBJECTIVES:** Outline the procedures for storage and retention of research study records before the project has been completed and turned over for long term storage. **This storage is to alleviate the record storage problem for investigators who no longer need access to specific research records before the closing of the project. It is not intended as a file room and access will be limited.**

2. **RESPONSIBILITIES:**

- a) Research records are the property of the Atlanta VA Medical Center (AVAMC) and the responsibility of the Principal Investigator (PI).
- b) The PI is responsible for following the study records retention guidelines as required by federal regulations, the study sponsor and the AVAMC.
- c) The PI is responsible for properly 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 short term storage.
- d) Records will be stored in Lockable Cabinets using hanging folders. The PI should prepare the records for storage in that format.
 - i. Records will be purged of unneeded papers, removed from hard binders and arranged in folders in reverse chronological order. Folders will be labeled with the: PI name; Project name, IRB number and Point of contact.
- e) A Clinical Studies Center (CSC) staff member will assist a member of the research study team with specific instructions regarding preparing and organizing study records for storage.

3. **RETENTION GUIDELINES:**

- a) Records will be accessible for inspection and copying only by authorized personnel and/or an authorized federal regulatory entity after they are placed in short term storage.
- b) The PI is responsible for providing and keeping his/her contact information up to date with the AVAMC during the record retention period

4. **PROCEDURES:**

- a) The CSC requires a complete "Research Records Short Term Storage Request" form (available at <http://www.atlaref.org/aref/csc/policies.cfm>) to be filled out prior to delivering the records for storage.
- b) The completed short storage request form (See below) will be sent by email to the CSC Administrative Assistant (AA) for approval and processing. The AA will review the form for discrepancies and notify the submitter by return email of any discrepancies and arrange for delivery to the CSC.
- c) Upon completion of the research study, refer to the Long Term Storage of Research Records policy

ATLANTA VA CLINICAL STUDIES CENTER
 Research Records Short Term Storage Request

PI Name:			
Point of contact:	Phone:	email:	
Full project title:			
IRB Number:	Date Placed in storage:		
Number of Files Submitted :			
Note:			

Files include:			
1) Protocol and all Amendments through _____	YES	NO	Initials _____
2) IRB approvals, continuing reviews and supporting documentation	YES	NO	Initials _____
3) Reportable event documents	YES	NO	Initials _____
4) Pharmacy records	YES	NO	Initials _____
5) Correspondences	YES	NO	Initials _____
6 Informed Consent Forms: Number of Consents _____	YES	NO	Initials _____
7) Case Report Forms (paper) Number of consents _____	YES	NO	Initials _____
8) Other Items; photos, tapes, electronic storage devices	YES	NO	Initials _____
Notes:			

Date Received CSC:	CSC Staff Name:
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Date Returned to PI:	Individuals Name:
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