

## SHORT TERM STORAGE OF RESEARCH RECORDS

1. **OBJECTIVES:** Outline the procedures for storage and retention of research records before the project has been completed and before it is 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. Access will be limited.**
  
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.
  - c. The PI is responsible for preparing the records for storage to include; properly securing all Patient Health information (PHI); properly storing of all electronic records, and properly delivering all records to the Clinical Studies Center (CSC) for short term storage.
  - d. The PI is responsible for providing and keeping his/her contact information up to date with the AVAMC during the short-term record retention period.
  
3. **PROCEDURES:**
  - a. 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.
  - b. Complete the **attached** "Short Term Storage of Research Records Request" form and email 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.
  - c. Records will be stored in lockable cabinets using hanging folders. The PI should prepare the records for storage in that format.
  - d. Records will be reviewed and papers removed from hard binders, then arranged in folders in reverse chronological order. Folders will be labeled with the: PI name; project name, IRB number, and point of contact.
  - e. 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.
  - f. Upon completion of the research study, prepare for long term storage by referring to the "Procedures for Closing Human Research Studies" and "Long Term Storage of Research Records" policy. These are located on the AREF website.

ATLANTA VA CLINICAL STUDIES CENTER  
Short Term Storage of Research Records Request

PI Name:			
Point of contact:	Phone:	email:	
Full project title:			
IRB Number:	Date Placed in storage:		
Number of Files Submitted (each subject should have at least 1 file):			
Notes:			

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	YES	NO	Initials:
7) Case Report Forms	YES	NO	Initials:
8) Other Items; photos, audio recordings, video/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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