

STORAGE OF RESEARCH RECORDS (Long Term)**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 Ralph H. Johnson VA Medical Center (RHJVAMC), 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 RHJVAMC. Research records, data, or keys should not be destroyed.
- 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 storing all hardcopies in a secured storage room for long term storage. Please follow directions on the Ralph H. Johnson VAMC research website regarding the procedures for Closing Human Research Studies. **[SOP 14]**
- d. The PI is responsible for providing and keeping his/her contact information up to date with the RHJVAMC Research Office during the record retention period.

3. RETENTION GUIDELINES:

- a. All study records generated during the course of VA research must be retained for at least 6 years after the study is completed and longer if required by other Federal regulations (FDA) or the sponsor.
- b. Store electronic research data on the secured research drive. Remove all research data from all other drives.
- c. Research records will be shipped to and stored at an approved VA facility.
- 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 Records Control staff member who will review with the research staff the specific instructions regarding preparing and organizing study records for storage.
- b. The Records Control staff member will provide new unmarked Special Purpose Shipping Boxes.
- c. Prepare all VA research records for storage. This includes but is not limited to:
 - Patient records/consents/HIPAAAs
 - Photos, tapes, electronic storage devices, etc.
 - Pharmacy records
 - IRB and R&D documents
 - Protocols

- All approvals, modifications, continuing reviews and supporting documentation
- All source documents and case report forms/data collection templates
- All reportable events
- Other correspondences
- Electronic study documents and data must be saved to the Research server and removed from all other drives and storage devices. Email the RC POC for Research Service to notify him/her of final location of electronic research data.

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 located on the RHJVAMC Research website.

f. Send the "Research Records Storage Request" form to the Records Control Manager for approval and processing. The RC POC will review the form and will coordinate long-term storage with the facility RCM.

g. The RHJ VAMC Records Manager will arrange for the storage of labeled and boxed research records.

h. Keep a copy of the completed "Research Records Storage Request" form for your files.



R. Amanda C. LaRue, Ph.D.
Associate Chief of Staff for Research