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. 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 Atlanta VAMC research 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. All study records generated during the course of VA research must be retained for at least 6 years and longer if required by other Federal regulations (FDA) or the sponsor. Please follow directions on the “Procedures for Closing Human Research Studies” policy located on the Atlanta VAMC research website.
   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 approval 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 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. IRB and R&D documents
   iii. Protocols
   iv. All approvals, modifications, continuing reviews and supporting documentation
   v. All reportable events
   vi. Pharmacy records
   vii. Other correspondences
   viii. Patient records/consents
   ix. Other items: photos, tapes, electronic storage devices, etc.
   x. Electronic study documents and data must be saved to the Research server and removed from all other drives and storage devices. Email antonio.laracuente03@va.gov to notify him 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 AVAMC Research website.

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 storage of labeled and boxed research records.

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