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 records are submitted 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. 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 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 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.
   d. Records should be removed from hard binders and then arranged in manila 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 Atlanta VAMC research website.
**ATLANTA VA CLINICAL STUDIES CENTER**

**Short Term Storage** of Research Records Request

<table>
<thead>
<tr>
<th>PI Name:</th>
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<tbody>
<tr>
<td>Point of contact:</td>
<td>Phone: email:</td>
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<tr>
<td>Full project title:</td>
<td></td>
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<tr>
<td>IRB Number:</td>
<td>Date Placed in storage:</td>
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<tr>
<td>Number of Files Submitted (each subject should have at least 1 file):</td>
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<td>Notes:</td>
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**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:

Date Returned to PI: Individuals Name:

04/11/2017