

February 8, 2010

RESEARCH STANDING OPERATING PROCEDURES (SOP)
Long Term Storage of Records Associated With VA Approved Research Projects

1. **PURPOSE:** To outline the policy and procedures related to the long term storage of records associated with VA approved research projects. All records will be stored off site at a National Archives and Records Administration certified Records Storage facility.

2. **POLICY:** All research study records must be stored in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by an outside research sponsor.

3. **ACTION:**

a. **The Principal Investigator:**

(1) Will identify on the Data Security Checklist and the Request for Inactivation of a Research Protocol where research records will be stored and for how long after completion of the study.

(2) Will budget \$25.00 per month for record storage during budget negotiations if possible (i.e. pharmaceutical company sponsored trials).

(3) If assistance in long-term storage is required, the Principal Investigator or study staff should contact the R&D office at (210) 617-5123. Contact should be initiated at least two (2) weeks in advance to ensure arrangements for storage are complete.

(4) Records are to be stored in bankers boxes, size(s) 12x10x15, 12x11x24, or 15x10x24 storage boxes with multi-layered construction, reinforced hand holes and lift-off lids.

(5) Storage media cannot be stored in the same boxes as paper documents.

(6) The Principal Investigator and study staff will be responsible for packaging and labeling (see para 7.) the short side of the storage boxes.

(7) The following information must be located on the outside short end of each box:

- (a) Responsible Investigator
- (b) Investigator contact number
- (c) Protocol name
- (d) Sponsor
- (e) Sponsor contact number
- (f) Dates research was conducted
- (g) Destruction date for records as identified by protocol or sponsor (Note: VA regulations may require records be stored for a longer duration)
- (h) Box # out of total number of boxes (i.e. box 1 of 2)
- (i) Electronic Media type and quantity, if applicable

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(j) Description of Contents (i.e. CRFs, Binders, Tapes)

(8) The Responsible Investigator must notify the R&D office of any changes in the above listed items. If the Responsible Investigator leaves the STVHCS, they must notify the R&D office of the name of the new Responsible Investigator. This is a requirement for out processing from the facility.

b. Research Service:

(1) When records are ready for storage, the R&D office will arrange transfer of records to off-site storage location.

(2) The R&D office will maintain a register of all off-site stored research records (see attachment 2). The register will contain the following information:

- (a) Responsible Investigator
- (b) Investigator contact number
- (c) Protocol name
- (d) Sponsor
- (e) Sponsor contact number
- (f) Dates research was conducted
- (g) Number of boxes
- (h) Destruction date as identified by protocol or sponsor

(3) Prior to transfer the R&D office will upload registry information, provided by principal investigator or designee, into the off-site records storage database and will barcode each box on the short end.

(4) Once records are transferred to off-site storage, Research Service will maintain custody of those records until they are destroyed. Transfer of records will be documented in writing through a transfer memo (see attachment 1).

(5) All records must be accessible for inspection and copying by authorized representatives of VA, OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.

(6) The Responsible Investigator and/or study staff will be contacted for destruction of the stored records based on the destruction date provided and VHA regulations.

4. **REFERENCES:** VHA Handbook 1200.05

5. **RESPONSIBILITY:** Associate Chief of Staff for Research (151)

6. **RECISSIONS:** None

7. **RECISSION:** This policy will expire on February 2015



PETER MELBY, M.D.
ACOS for Research and Development

Attachments: (2)

Attachment: 1

**Department of
Veterans Affairs**

Memorandum

Date: (date)

From: ACOS Research and Development (151)

Subj: Administrative Transfer of Research Records
(NAME OF STUDY)
(NAME OF PI)

To: (NAME of Responsible Investigator)
(Contact information of Responsible Investigator: address and phone number)

- 1) The Research and Development Office hereby accepts custody of the Research Study records for the protocol entitled: (enter research protocol title) (the number of boxes).
- 2) For questions regarding the disposition of these records, please contact the Research and Development Office at (210) 617-5123 or you may write to :

South Texas Veterans Health Care System
Audie L. Murphy Division
Research & Development Service (671/151)
7400 Merton Minter Boulevard
San Antonio Texas 78229-5700
Attention: Administrative Officer

