

RESEARCH SERVICE MEMORANDUM
STANDARD OPERATING PROCEDURE (SOP)
Long Term Storage of Human Subjects Research Records

1. PURPOSE: To ensure all study records are stored in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by an outside sponsor.
2. POLICY: This SOP applies to all human subjects' research conducted at the South Texas Veterans Health Care System (STVHCS).
3. RESPONSIBILITY: The Principal Investigator, study staff, and the Research and Development (R&D) office will be responsible for implementing and following all procedures.
4. ACTION:
 - a. The Principal Investigator will identify on the Data Security Checklist where research records will be stored and for how long after completion of the study.
 - b. The Statement of Commitment and Understanding will list the responsibilities of the Principal Investigator with regards to record storage and retention.
 - c. The Principal Investigator or study staff must notify the R&D office when a research protocol has ended and all research records have been boxed for storage.
 - d. Storage media may be stored in the same boxes as paper documents.
 - e. Records are to be stored in a heavy duty storage box with multi-layered construction, with reinforced hand holes and lift-off lid.
 - f. The following information must be located on the outside of each box:
 - (1) Principal Investigator
 - (2) Other Responsible Official
 - (3) Contact number
 - (4) Protocol name
 - (5) Sponsor
 - (6) Sponsor contact name
 - (7) Dates research was conducted
 - (8) Destruction date for records
 - (9) Box # out of total number of boxes (i.e. box 1 of 2)
 - (10) Electronic Media (type and quantity)
 - (11) Description of Contents (i.e. CRFs, Binders, Tapes)
 - g. The Principal Investigator must notify the R&D office of any changes in the above listed items. If the Principal Investigator leaves the STVHCS, they must notify the R&D office of the name of the new Principal Investigator or Other Responsible Investigator. This is a requirement for out processing from the facility.

- h. Study records must be retained for a minimum of 5 years after the completion of the study as per VHA policy. Records may be stored longer if required by the study sponsor.
 - i. 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.
 - j. Records are the property and the responsibility of the local research office.
 - k. Investigators who require assistance with the long term storage of records will contact the R&D office at (210-617-5123) for a key and access to the R&D storage area.
 - l. The Principal Investigator and study staff will be responsible for transport of the boxed records to the R&D storage area to be determined by the Research Office.
 - m. The R&D office will maintain a log of all stored research records in the R&D storage area. The log will contain the following information:
 - (1) Principal Investigator
 - (2) Other Responsible Official
 - (3) Investigator contact number
 - (4) Protocol name
 - (5) Sponsor
 - (6) Sponsor contact number
 - (7) Dates of research
 - (8) Number of boxes
 - (9) Destruction date
 - n. Best efforts will be made to contact the Principal Investigator prior to destruction of the stored records based on the destruction date provided.
 - o. Principal Investigators should contact the R&D Office at least two (2) weeks in advance to ensure arrangements for storage are complete.
5. REFERENCES: VHA Handbook 1200.5.
6. RECISSION: None.
7. RECERTIFICATION: March 2011.
8. ATTACHMENTS: 2

//signed//

PETER C. MELBY, M.D.
Associate Chief of Staff,
Research and Development

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 Official)
(Contact information of PI or Responsible Official Address and phone
number)

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

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

John Villalpando
Administrative Officer

