

RESEARCH SERVICE

March 10, 2008

RESEARCH STANDARD OPERATING PROCEDURES

Document Management within the R&D Office

1. PURPOSE: This SOP states the requirements and procedures for document management, retention, and archiving within the STVHCS R&D Office.

2. POLICY: The R&D Office files must be maintained in a manner that contains a complete history of all R&D actions related to review and approval of a research protocol, including initial submission and review, continuing reviews, amendments, subcommittee reviews and communications, and adverse event reports. All records regarding a submitted study, regardless of approval status, must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy. All research personnel records, including documentation of VA appointment, training, degree verification, credentialing, licensing, and other relevant personnel actions must be maintained to ensure confidentiality.

3. ACTION

a. Responsibility:

- (1) The STVHCS Research Office staff is responsible for maintaining and complete files on all research reviewed by or submitted to the R&D and for all applicable regulatory compliance requirements.
- (2) Investigators are responsible for submitting pertinent and required documentation regarding their research projects to the R&D Office and to the UTHSCSA IRB.
- (3) The Director is responsible for the overall research operations of the STVHCS, and has delegated the management of the research program to the Associate Chief of Staff for R&D.
- (4) The Administrative Officer (AO) for R&D has been delegated the responsibility for the management of the R&D Office.

b. Procedures:

- (1) R&D Office Administrative Documents and Databases
 - (a) STVHCS Policies related to research activities and Research Service Standard Operating Procedures (SOPs) of the STVHCS HRPP will be maintained in the STVHCS Research Office.
 - (b) Personnel records: Records related to investigators and research staff, including information on the qualifications and VA appointment status of each principal investigator, shall be maintained by the STVHCS Research Office as part of the R&D

Personnel file. The Research Staff Credentialing Checklist (Appendix A) is used to ensure that the file is complete and current.

- (c) Training records: Copies of reports or certificates of human studies protection training or other relevant training will be maintained in the investigator's personnel file.
 - (d) Training database. An electronic database will be maintained to enable tracking of required training of research personnel. The database will be maintained on the STVHCS server, and have password-restricted access with regular backup by Office of Information and Technology staff. Individual R&D Office staff will be granted access approval as appropriate. The template for the training database is included as Appendix B.
 - (e) Protocol management database. An electronic database will be maintained to enable tracking of required documents and information submitted in support of the review and approval of a research protocol. The database will be maintained on the STVHCS server, and have password-restricted access with regular backup by Office of Information and Technology staff. Individual R&D Office staff will be granted access approval as appropriate. The template for the training database is included as Appendix C.
 - (f) ePROMISe database: The STVHCS Research Office reports all research protocols and investigators to the primary research database, ePROMISe. The [electronic] Project Management & Information System (ePROMISe) is linked to VA National Headquarters R&D Computer Center responsible for maintaining the VA Research and Development Information System (RDIS).
- (2) R&D Committee Records: R&D Committee records maintained by the STVHCS Research Office shall include the following categories:
- (a) Written operating procedures of the R&D Committee
 - (b) R&D Committee membership roster that includes qualifications of the members
 - (c) Copies of correspondence relating to membership appointments
 - (d) Training records (Reports or certificates of human studies protection training, other related training) of R&D members
 - (e) R&D Committee correspondence (other than protocol related documents)
 - (f) Minutes of convened R&D Committee meetings
 - (g) Minutes of and communications from the subcommittees of the R&D Committee
- (3) R&D Office records relating to research projects: For each approved project, the R&D administrative files shall contain the following items:
- (a) All materials submitted by the PI for initial review
 - (b) All materials from the PI related to protocol amendments, adverse events, continuing review, and termination of study.
 - (c) All protocol-related correspondence sent by the PI.

POLICY MEMORANDUM 08-46

- (d) All study related correspondence sent or received by the R&D Committee or any R&D subcommittee.
 - (e) All approved informed consent documents
 - (f) Any other related documentation regarding the study received by the research administration.
- (4) Access to R&D records
- (a) All R&D Office records are the property of the STVHCS.
 - (b) All research records are kept confidential and secure in locked filing cabinets in the Research Offices.
 - (c) Normal access is limited to the ACOS for R&D, Administrative Officer for R&D, research office staff, chair of the R&D Committee, authorized VA representatives, officials of federal or state regulatory agencies and appropriate accreditation organizations.
 - (d) All other access to R&D records is limited to those who have legitimate need, as determined by the STVHCS Director, the ACOS for R&D, R&D Committee, and VA Central Office.
- (5) Retention of R&D records
- (a) R&D records related to a study protocol are retained for at least 5 years after approval for a study is terminated. (This minimum requirement may be exceeded in accordance to applicable VA, FDA and DHHS regulations, or as required by outside sponsors of the study.)
 - (b) The R&D records relating to an investigator are retained for at least 5 years after the PI leaves the STVHCS.
- (6) Destruction of R&D Committee Review Records: All materials received by the R&D Committee, which are considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the R&D meeting and destroyed by cross-cut shredding.

4. REFERENCES: VHA Directive Handbook 1200.

5. RESPONSIBILITY: ACOS for Research and Development (151)

6. RECISSION: None.

7. RECERTIFICAION: March 2011.

//signed//
PETER C. MELBY, M.D.
ACOS for Research and Development

POLICY MEMORANDUM 08-46

HUMAN RESEARCH STAFF CREDENTIALING CHECKLIST

Date _____

EMPLOYEE: _____

ROLE: _____

TRAINING

- VA Human Protection/ GCP – CITI - Date of last training _____
- Security courses: VA Cyber Security Awareness - date: _____
VHA Privacy Policy – date: _____
Data Security – date: _____
Certificates received date: _____

VA APPOINTMENT

- VA Appointment, service: _____
- WOC appointment, service: _____ approval memo attached
Expiration date: _____
- Intellectual Property Agreement received, date: _____

DEGREES

- None
- Signed Written Release of Information received, date: _____
- Degree, type (e.g. MD, MSN...) _____
 - Degree verification attached
 - Degree verified by hospital through VETPRO process (e.g. MD, DDS)
 - Degree verified through Nursing Board/Residency

CREDENTIALING STATUS VERIFIED

- Clinicians (physician, dentist, psychologist), expiration date: _____
- Nurses (Boarded as Nurse/Research Nurse)
- N/A

LICENSES

- None
- Type (e.g. RN, MD...) _____
State: _____
Expiration: _____
Verified on: _____

EXCLUSIONARY LIST

- Exclusionary list check attached; date of last check _____

SCOPE OF PRACTICE/PD

- Scope completed and attached (research coordinators type positions) – within 2 years
 - Scope received _____
- PD in lieu of Scope if duties not applicable to scope attached
- MD scope = as privileged as staff physician
- Other privileged personnel: privileging scope attached

CONFLICT OF INTEREST

- N/A
- Received date: _____

Date file verified complete: _____ Date entered into database: _____ Date updated: _____