DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio. Texas 78229-4404

Research Service Policy Memorandum 11-51

March 2, 2011

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Research Data Security and Privacy Subcommittee

1. **PURPOSE:** To outline the structure and function of the South Texas Veterans Health Care System (STVHCS) Research Data Security and Privacy Subcommittee.

2. **POLICY:** The Research Data Security and Privacy Subcommittee is responsible as a subcommittee of the Research and Development (R&D) Committee to provide oversight to the data security and privacy aspects of the R&D program. The subcommittee is responsible to evaluate the data security and privacy practices and procedures related to each research protocol that is submitted to the R&D Committee for approval, and to evaluate and make recommendations to the R&D Committee concerning any data security and privacy issue that arises in the course of conduct of research at the STVHCS. The subcommittee provides the venue for review and approval of all research protocols by the STVHCS Privacy Officer and Information Security Officer. The subcommittee is operationally assisted by the administrative staff of the R&D office to fulfill its responsibilities. No research at STVHCS, whether funded or unfunded, may be undertaken without review by the Data Security and Privacy Subcommittee and concurrence by the STVHCS Privacy Officer and Information Security Officer.

3. **ACTIONS**

a. **Responsibilities and functions:**

(1) **Program oversight:** The subcommittee is responsible to provide oversight of data security and privacy policies and procedures to ensure compliance with VHA and other applicable regulations. Any regulatory issues related to data security and/or privacy that arise in the course of conduct of research at the STVHCS will be reviewed by the subcommittee and the results of the subcommittee's evaluation and its recommendations will be communicated to the R&D Committee. Issues of potential noncompliance will be forwarded to the Research Compliance Officer, Privacy Officer, and Information Security Officer as appropriate, and will be brought to the R&D Committee for evaluation and action.

(2) **Review of research protocols:** All research to be conducted at the STVHCS (IRB full board reviews, expedited IRB reviews, exempt protocols, and non-human subjects protocols) must be reviewed as part of the initial protocol submission to ensure that data security and privacy practices and procedures protect human subjects and VA research data, and comply with VHA and other applicable regulations. Review of the data security and privacy practices and procedures will be facilitated by review of the research protocol, IRB submission documents, Informed Consent Document including the HIPPA authorization, HIPAA and informed consent waiver requests and approvals, and the "*Requirements and Guidelines for Collection, Storage and use of VA-sensitive Research Data*" form http://www.southtexas.va.gov/Research/Documents/VADataSecurityChecklist.doc. Changes or amendments to a research protocol, which alter the previously approved data security and privacy procedures, will be submitted to the Subcommittee for review and approval as a modification of the "*Requirements and Guidelines for Collection, Storage and use of VA-sensitive Research Data*" form. The results of the subcommittee review and the Subcommittee's recommendations and approvals will be communicated to the R&D Committee.

(3) **Review of research data disclosures or transfers:** Any proposed disclosure or transfer of research data, or storage of research data outside the VA protected environment, must be reviewed by the subcommittee and approved by the Privacy and Information Security Officers prior to disclosure or transfer.

(4) **Accounting of Disclosures:** The PI or his/her research staff will maintain an accounting of disclosures of private information by entering the necessary information into a web-based database. The Privacy Officer, or his/her designee, will monitor the privacy disclosure database on at least a quarterly schedule. A summary of the disclosures will be reported to the subcommittee for review and monitoring.

(5) **Subcommittee records:** The subcommittee will maintain adequate records until expiration of the authorized retention period, a minimum of 5 years. Research records may be electronic or paper. When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature must be used. If an electronic signature is used, it must meet all of the requirements of VA, the Office of Human Research Protection, the Food and Drug Administration (FDA), and any other Federal requirements. A scanned electronic copy of the original signed document may be maintained in lieu of the original paper document.

(6) **Subcommittee communication with the R&D Committee:** The subcommittee will make available to the R&D Committee a complete, unredacted set of minutes (draft or final) prior to the R&D Committee meeting at which the protocols listed and other information contained within the minutes are to be discussed. If draft minutes are submitted, formally approved minutes must be sent to the R&D Committee prior to the following R&D Committee meeting. If the approved minutes differ substantially from the draft minutes, the subcommittee must ensure the R&D Committee considers whether the difference would alter any R&D Committee decisions that were based on the draft minutes. Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.

(7) **Meeting schedule:** The subcommittee will meet at least monthly, but may hold unscheduled meetings in response to emergent issues.

(8) **Meeting agenda:** The subcommittee administrator in conjunction with the chairperson, ACOS for R&D, and Deputy ACOS for R&D will prepare the meeting agenda for the Research Data Security and Privacy Subcommittee meeting. Copies of the agenda and materials needed for review will be distributed to the Committee members by the Subcommittee administrator.

(9) **Attendance requirements, quorum and voting:** Members or their designated alternates are encouraged to attend all regularly scheduled meetings. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In that case, the member must have had opportunity to review all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions. There must be a quorum present in person, by teleconference, or video conference for any meeting (scheduled or unscheduled). A quorum, i.e. a majority of voting members, must be present to conduct business and must be present for each vote. If a quorum is lost during the meeting, further Subcommittee business must be suspended. Whenever a Committee member recuses him- or herself or leaves the meeting, the number of remaining Committee members must still constitute a quorum (recused members and members not in the room are not counted towards a quorum). Each voting member has one vote with no proxy voting allowed.

(10) **Conflict of Interest for Subcommittee Members:** Members are considered to have a conflict of interest if they are participating in a proposed study as a principal or collaborating investigator, or if they

have a financial or other relational interest in the study. Members with a conflict of interest relating to a study under review may not participate in the review, whether the initial, continuing, final deliberations, or in the vote on such studies.

(11) **Minutes:** Minutes for each meeting must be recorded and include the following information:

(a) A list of all members in attendance.

(b) The presence of a quorum.

(c) Findings of the subcommittee and any actions taken to include the type of action, vote on the action including the number voting for, against, and abstaining. In addition, any recused member from the vote should be named, and whether the person was present during the discussion and the vote should be noted. Actions also include the basis for requiring changes to a research protocol to obtain approval, any required follow-up and which committee, subcommittee, or person is responsible for the follow-up, and the basis for recommending disapproval of a research project when this occurs.

(12) **Notification of Committee findings:** The PI must be notified in writing or at a scheduled face-to-face administrative pre-review meeting of the Subcommittee's review and any stipulations that must be met to gain approval. Responses and clarifications to all stipulations must be approved by the Privacy Officer and the Information Security Officer prior to the protocol being presented to the R&D Committee. The signed and approved "Requirements and Guidelines for Collection, Storage, and Use of VA-sensitive Research Data" will be forwarded to the PI for the protocol regulatory file at the time of R&D committee approval.

b. **Membership:** Members of the Research Data Security and Privacy Subcommittee are appointed by the Medical Center Director. Nominations for membership may be from current R&D Committee members, subcommittee members, and the facility's staff. The types and requirements of membership are as follows:

(1) Members may be compensated Federal Employees, WOC or be affiliated through an IPAA. Members of the subcommittees may serve as members of the R&D Committee. The Privacy Officer is the subcommittee member designated to serve as a liaison with the R&D Committee.

(2) Voting members will include at least one STVHCS investigator actively engaged in research (serves as the Chairperson of the Subcommittee), one individual involved in research at the STVHCS as a Research Coordinator or in Research Regulatory Affairs, the Research Compliance Officer, the Privacy Officer or alternate Privacy Officer, and the Information Security Officer or alternate Information Security Officer.

(3) Ex officio, non-voting members will include the ACOS for R&D, the Deputy ACOS for R&D, The AO for R&D, and at least one administrative staff person from the R&D office who has primary responsibility for human subject protocol reviews (serves as the Subcommittee administrator),

(4) Alternate members may be appointed to substitute for the primary members if their qualifications are comparable to the primary members they are to replace. They must meet all the same eligibility criteria as the primary member. Terms of appointment, length of service, and duties are the same as for the regular member. If both the alternate and primary member attends the Subcommittee meeting, only the primary member may vote and only the primary member counts toward the quorum.

(5) All Committee members are required to complete training related to human subjects protection, privacy, and information security as specified by VHA's ORD and other applicable Federal regulations found on the ORD website at: www.research.va.gov.

4. **REFERENCES:** VHA Handbook 1200.05, VA Directive 6500, VHA Handbook 1605.1, VHA Handbook 1200.12

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

6. **RECISSIONS:** Research Service Policy Memorandum, 10-51, dated February 8, 2010

7. **RECISSION:** March 2016

Kimberly K Summers, PharmD

KIMBERLY K. SUMMERS, PHARM.D.
Acting ACOS for Research and Development