

RESEARCH SERVICE

May 2, 2008

RESEARCH STANDARD OPERATING PROCEDURES (SOP)

Privacy Review of Research Protocols

1. PURPOSE: To outline the policy and procedures for review of research protocols to ensure that protected health information and other confidential information collected as part of a research protocol is protected.

2. POLICY:

a. The privacy of all individuals involved in human subjects research at the South Texas Veterans Health Care System (STVHCS) must be protected. All human subjects research protocols must be approved by the IRB and Research and Development (R & D) committees prior to activation of the protocol. As part of the approval process, the protocol must undergo privacy review as part of the administrative pre-review and must undergo final privacy review prior to activation of the research study.

b. A research protocol may not start until all the privacy review requirements are met, and the study is approved by the STVHCS Privacy Officer.

3. ACCOUNTABILITY:

a. Research Office. The Research Office will provide the forms requesting information related to privacy practices that are required to be submitted with the protocol for R & D Committee review, and will perform an administrative pre-review of the privacy procedures contained in the protocol.

b. Privacy Office. The STVHCS Privacy Officer, or his/her designee, will provide consultation as needed in the pre-review process, will attend the R & D Committee meeting, will perform a final privacy approval prior to activation of the research study, and will monitor the disclosures of private information.

c. Principal Investigator. The principal investigator (PI) must provide the necessary information to enable the Research Office staff and Privacy Officer to perform the privacy review. The PI, or his/her research staff, will maintain an accounting of disclosures of private information.

d. The ACOS for Research will oversee the privacy review process as part of the STVHCS Human Research Protection Program.

Policy Memorandum 07-34

4. PROCEDURES

a. An administrative pre-review will be performed by Research Office staff, and the Privacy Officer or his/her designee as needed, to ensure that all privacy information related to the protocol is submitted. When procedures in the proposed research protocol are identified as providing inadequate privacy protection, the Research Office staff will communicate this information to the Principal Investigator so that corrections can be made prior to R & D Committee review.

b. The R & D Committee will review and address any privacy issues identified in the protocol, and if deficiencies are identified, may only approve the protocol with the stipulation that the identified deficiencies must be corrected prior to approval.

c. The Privacy Officer, or his/her designee, will perform a final privacy review and document approval prior to activation of the research study.

d. 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.

e. The Privacy Officer, or his/her designee, will monitor the privacy disclosure database on at least a quarterly schedule.

5. RESPONSIBILITY: ACOS for Research and Development

6. RECISSION: Research Service Memorandum 07-34, dated March 29, 2007

7. RECERTIFICATION: May 2011

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PETER MELBY, M.D.

ACOS for Research and Development