DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78229-4404

RESEARCH SERVICE
MEMORANDUM 07-37

May 2, 2007

POLICY AND PROCEDURES FOR COMMUNICATION WITH THE HUMAN SUBJECTS SUBCOMMITTEE (IRB)

1. PURPOSE: To outline the policy and procedures related to the lines of communication between the Institutional Review Board (IRB) and South Texas Veterans Health Care System (STVHCS).

2. POLICY: The IRB of the University of Texas Health Science Center at San Antonio (UTHSCSA; university affiliate) is the IRB of record for the STVHCS, as established by a Memorandum of Understanding. Effective communication between the UTHSCSA IRB and STVHCS research program is essential to the effective function of the human research protection program of the STVHCS. The Associate Chief of Staff (ACOS) for Research and Development, or the Administrative Officer (AO) for Research and Development should the ACOS for Research and Development be unavailable, is the point of contact for all communications from the IRB. The ACOS for Research and Development or AO for Research and Development is responsible to communicate with the appropriate STVHCS officials.

3. ACTION: There are a number of instances when the IRB and the STVHCS must communicate, either under routine or urgent circumstances.

   a. Protocol review. IRB staff will routinely provide the minutes of the IRB protocol review(s) meetings to the STVHCS research office staff. These minutes will be reviewed at the next Research and Development Committee meeting. If a concern related to the research protocol is raised in the Research and Development Committee review, information is discovered that the IRB should know about (e.g. issues related to human subject safety, protection of privacy, etc.) the Chair of the Research and Development Committee, or his/her designee, will notify the Director of the IRB promptly and provide the information necessary for the IRB to evaluate and take appropriate action.

   b. Unanticipated problems. VA Research investigators must report an Unanticipated Problem Involving Rick to Subjects or Others (UPIRSO) to the IRB. The timeline for reporting UPIRSO's is determined by the severity and significance of the unanticipated problem. UPIRSO's may include adverse events, breach of confidentiality or privacy, compromise of VA Information Security, serious or continuing research non-compliance, or research misconduct.

      1) Adverse events.

         a. Any adverse event (any untoward occurrence [physical, psychological, social, or economic] in a human subject), or an imminent threat of an adverse event, that results in substantive action by the IRB must be reported to the VA research office. The STVHCS Research Office must submit a written report of the event to the Office of Research oversight within 10 days of the IRB's determination to take such action. If the STVHCS Research Office or Compliance Office becomes aware of an adverse event UPIRSO that has not been reported to the IRB, the Principal Investigator will be informed of the requirement to notify the IRB in the appropriate timeframe, and will communicate with the IRB to ensure that this has been accomplished.

b. Any unexpected death of a research subject must be reported immediately to the STVHCS Research Office so that a written report can be submitted to the Office of Research oversight within 24 hours after the IRB's determination that the death was unexpected.

2) Breach of confidentiality or privacy. The IRB will report to the ACOS for Research and Development, or the AO for Research and Development should the ACOS for Research and Development be unavailable, any real or suspected unauthorized use, loss, or disclosure of individually-identifiable information related to a VA research protocol. The initial notification will be immediate upon receiving the report, either by phone call or receipt-verifiable email, to be followed by delivery of a full report when available. The ACOS for Research and Development or AO for Research and Development will then immediately notify the STVHCS Privacy Officer of the breach of confidentiality or privacy.

3) Compromise of VA information Security. The IRB will report to the ACOS for Research and Development, or the AO for Research and Development should the ACOS for Research and Development be unavailable, any real or suspected violation of Information Security requirements related to a VA research protocol. The ACOS for Research and Development or AO for Research and Development will then immediately notify the STVHCS Information Security Officer of the compromise of VA Information Security.

4) Research non-compliance or research misconduct. Any allegation, suspicion, or evidence of serious or recurring research non-compliance or research misconduct received by the IRB will be promptly reported to the STVHCS ACOS for Research and Development, who is also the STVHCS Research Integrity Officer. Similarly, any allegation, suspicion, or evidence of serious or recurring research non-compliance or research misconduct received by the STVHCS Research Integrity Officer will be reported promptly to the IRB if it involves a human subjects protocol.

c. IRB membership. The IRB will inform the STVHCS Research Office when any issues related to VA membership on the IRB arise (e.g. need for new members, absence of VA representation for a committee meeting, etc.). The STVHCS Research Office will work with the IRB to ensure that adequate VA representation is maintained on the IRB.

5. REFERENCES: Memorandum of Understanding Between South Texas Veterans Health Care System and the University of Texas Health Science Center at San Antonio Concerning Utilization of the University of Texas Health Science Center at San Antonio's Institutional Review Boards, (July 1, 2005).

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

7. RECISSION: None.

8. RECERTIFICATION: May, 2010.

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ACOS for Research and Development