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

Research Service Policy Memorandum 12-50

March 27, 2012

RESEARCH STANDING OPERATING PROCEDURES (SOP)
Handling of Research Suspensions and Terminations

1. **PURPOSE:** To outline the procedures for handling of suspensions and terminations related to human subject research studies at the STVHCS.

2. **POLICY:**

a. The procedures for and reporting of research suspensions and terminations is a key component of the Human Research Protection Program (HRPP) at the STVHCS. The STVHCS follows the UTHSCSA Suspension or Termination of Research Policy (http://research.uthscsa.edu/irb/policy/Suspension or Termination Policy and Procedure.doc) for determining and reporting of suspensions and terminations.

b. In addition to the procedures outlined in the UTHSCSA Suspension or Termination of Research Policy, the STVHCS will maintain procedures for reporting of suspensions or termination to the IRB, other appropriate internal institutional officials, and VA external oversight agencies.

c. In addition to the entities identified in the UTHSCSA policy, the STVHCS Institutional Official (Medical Center Director), R&D Committee Chair, and/or the ACOS for R&D as designated representatives of the STVHCS Director, have the independent authority to suspend a research protocol at the STVHCS that is not being conducted in accordance with IRB or R&D Committee requirements, or is associated with unexpected harm to subjects. Authority to terminate the research is limited to the convened IRB or the Institutional Official.

d. **Definitions**:

(1) **Suspension**: The STVHCS adheres to the definition of suspension found in the UTHSCSA IRB glossary at: http://research.uthscsa.edu/irb/GLOSSARY OF OIRB TERMS.doc

(2) **Termination**: The STVHCS adheres to the definition of termination found in the UTHSCSA IRB glossary at: http://research.uthscsa.edu/irb/GLOSSARY OF OIRB TERMS.doc

3. **ACTION:**

a. The PI is responsible to comply with the determinations and requirements of the IRB related to suspensions or terminations of research according to the UTHSCSA Suspension and Termination Policy (http://research.uthscsa.edu/irb/policy/Suspension or Termination Policy and Procedure.doc).

b. If the event leading to a suspension or termination also involves an unanticipated problem involving risk to subjects or others (UPIRSO) or Unanticipated Adverse Device Effect (UADE) the investigators and research staff are responsible for taking appropriate action to protect the safety and welfare of the subject(s) and following the UTHSCSA UPIRSO and UADE Policy (http://research.uthscsa.edu/irb/policy/UPIRSO Policy and Procedure.doc) .

c. When a study is suspended or terminated, continuation of research interventions or interactions in already enrolled subjects should only continue when the IRB Chair or designee, in consultation with the Chief of Staff, finds that it is in the best interest of individual subjects to do so.

d. The IRB will make determination of suspensions and terminations, as outlined in the UTHSCSA Suspension and Termination Policy and Procedure http://research.uthscsa.edu/irb/policy/Suspension or Termination Policy and Procedure.doc When the suspension or termination is initiated by the STVHCS IO, ACOS for R&D, or R&D Chair, the UTHSCSA IRB will be notified promptly and the IRB will follow its procedures for suspension or termination of research as described in the above policy.

e. The IRB will report suspensions and terminations promptly, but no later than 48 hours via encrypted email or phone, with follow-up paper copy, to the ACOS for R&D, or his/her designee.

f. Reporting of suspensions and terminations to non-VA regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA) if the protocol involves a FDA regulated activity, and/or any other federal agencies overseeing research that require separate reports from OHRP will be accomplished by the UTHSCSA IRB according to the procedures and timelines outlined in "IRB Reporting to Internal and External Entities Policy and Procedure" (http://research.uthscsa.edu/irb/policy/Reporting Policy and Procedure.doc). In addition to the UTHSCSA IRB reporting to the above agencies, the STVHCS Medical Center Director will also forward the report, prepared by the UTHSCSA IRB, with a cover letter to the non-VA federal agencies according to the same timelines outlined in the IRB's policy "IRB Reporting to Internal and External Entities Policy and Procedure".

g. Reports of suspensions or terminations received from the IRB by the ACOS for R&D, or his/her designee, will be reported to appropriate internal institutional officials as described below:

(1) Reports of suspensions or terminations will be reported to the Medical Center Director within 5 business days after the termination or suspension occurs.

(2) If the suspension or termination involves unauthorized use, loss, or disclosure of individually-identifiable information related to a VA research protocol, the ACOS for R&D or designee will then promptly notify the STVHCS Privacy Officer of the breach of confidentiality or privacy.

(3) If the suspension or termination involves compromise of VA information Security, or violation of Information Security requirements related to a VA research protocol, the ACOS for R&D, or designee, will then promptly notify the STVHCS Information Security Officer.

(4) Reports of suspensions or terminations received from the IRB by the ACOS for R&D, or his/her designee, will be reported promptly to the STVHCS Compliance Office.

(5) Reports of suspensions or terminations received from the IRB by the ACOS for R&D, or his/her designee, will be reported promptly to the Chair of the R&D Committee and presented to the R&D Committee at the next convened meeting.

h. The ACOS for R&D will ensure that external VA regulatory and oversight agencies are notified of suspensions or terminations as required.

(1) Suspensions or terminations will be reported by the STVHCS Director to Office of Research Oversight (ORO) within 5 business days after receiving such notification. Notification to ORO will include any official correspondence from the IRB, and will include the following information when not included in any IRB correspondence:

(a) The nature of the event (suspension or termination)

(b) Name of the institution conducting the research.

(c) Title of the research project or grant proposal in which the problem occurred.

(d) Name of the principal investigator on the protocol.

(e) Identification numbers of the research project as assigned by the UTHSCSA IRB and the STVHCS R&D Office and the identification number of any applicable federal award(s), grant, contract, or cooperative agreement.

(f) A detailed description of the problem including the findings of the organization and the reasons for the decision of the R&D Committee Chair, ACOS for R&D, STVHCS Institutional Official, and/or IRB.

(g) Actions that the UTHSCSA IRB or STVHCS has taken or plans to take to address the problem.

(h) Plans, including a timetable for completion of the investigation and/or corrective action if appropriate, for the UTHCSA IRB or STVHCS to send a follow-up or final report.

(2) Reports of suspensions or terminations involving a violation of information security requirements will also be reported promptly by the STVHCS ISO to the VHA ISO.

(3) Reports of suspensions or terminations involving real or suspected unauthorized use, loss, or disclosure of individually-identifiable information related to a VA research protocol will be reported promptly by the STVHCS Privacy Officer to the VHA Privacy Officer as appropriate.

(4) Reports of suspensions or terminations will also be reported by the STVHCS Director to the sponsor, including VA Office of Research and Development (ORD), when ORD is the sponsor.

(5) Reports to external regulatory agencies by the STVHCS or the UTHSCSA IRB will be communicated to the reciprocal office.

4. **REFERENCES:** VHA Handbook 1200.5; What to Report to ORO; 45 CFR 46; 21 CFR 50, 56; 38 CFR 16

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

6. **RECISSIONS:** Research Service Policy Memorandum 10-50, dated January 20, 2010

7. **RECISSION:** This policy will expire March 2015

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