

March 30, 2018

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 UTHealthSA Suspension or Termination of Research Policy (http://research.uthscsa.edu/irb/Policy/Suspension_or_Termination_Policy.pdf) for determining and

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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 Associate Chief of Staff for Research, 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 UTHealthSA Suspension and Termination Policy and Procedure (http://research.uthscsa.edu/irb/Policy/Suspension_or_Termination_Policy.pdf). When the suspension or termination is initiated by the STVHCS IO, ACOS for R&D, or R&D Chair, the UTHealthSA 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 UTHealthSA IRB according to the procedures and timelines out Policy http://research.uthscsa.edu/irb/Policy/Reporting_Policy.pdf. In addition to the UTHealthSA IRB reporting to the above agencies, the STVHCS Medical Center Director will also forward the report, prepared by the UTHealthSA IRB, with a cover letter to the non-VA federal

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:

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- (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 UTHealthSA 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 UTHealthSA 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 to the VHA ISO.