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

Research Service Policy Memorandum 13-49

March 22, 2013

RESEARCH STANDING OPERATING PROCEDURES (SOP)

Handling of Research Non-Compliance Involving Human Subjects

1. **PURPOSE:** To outline the procedures for handling of research non-compliance related to human subject research studies at the STVHCS.

2. **POLICY:**

   a. The monitoring and reporting of research non-compliance is a key component of the protection of human subjects in research and is critical to the function of the Human Research Protection Program (HRPP) at the STVHCS.

   b. Congruent with Federal Policy (Common Rule) for the protection of human subjects in research, VA regulations require written procedures for the reporting of research non-compliance to the IRB.

   c. The Associate Chief of Staff (ACOS) for Research is responsible to ensure that all concerns or complaints related to research at the STVHCS, received from any source, are promptly investigated according to the procedures outlined in Research Service SOP 10-26. Any concern or complaint that is identified as possible research non-compliance will be handled as described in this SOP.

   d. Research non-compliance may be identified through any number of ways, including but not limited to:

      (1) A report by any individual to the IRB, R&D Committee, or R&D Office

      (2) Continuing review of ongoing research by the IRB or R&D Committee

      (3) Compliance audits conducted by the UTHSCSA or STVHCS compliance offices

      (4) A report by another committee, subcommittee of the R&D Committee, department, or official

      (5) A report from the study sponsor or sponsor's monitoring entity

   e. Possible research non-compliance identified by any component of the STVHCS HRPP (e.g. the STVHCS compliance office, R&D office) must be promptly reported to the UTHSCSA IRB.

   f. The STVHCS follows the procedures for evaluation and determination of research noncompliance as detailed in the UTHSCSA Noncompliance Policy and Procedure (http://research.uthscsa.edu/irb/policy/Noncompliance Policy and Procedure.doc).

g. The STVHCS will maintain procedures for the reporting of possible non-compliance to the IRB and reporting of any serious or continuing research non-compliance, as determined by the IRB, to the appropriate internal institutional officials and external oversight agencies.

h. Definitions:

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

(2) Serious non-compliance: The STVHCS adheres to the definition of serious research non-compliance found in the UTHSCSA IRB glossary at: http://research.uthscsa.edu/irb/GLOSSARY OF OIRB TERMS.doc

(3) Continuing non-compliance: The STVHCS adheres to the definition of continuing research non-compliance found in the UTHSCSA IRB glossary at: http://research.uthscsa.edu/irb/GLOSSARY OF OIRB TERMS.doc

3. ACTION:

a. Responsibilities of the Principal Investigator:

(1) The Principal Investigator is responsible to promptly report any incident of possible non-compliance of which he/she becomes aware, regardless of the source, to the IRB according to the UTHSCSA Noncompliance Policy and Procedure (http://research.uthscsa.edu/irb/policy/Noncompliance Policy and Procedure.doc).

(2) The PI is responsible to comply with the determinations and requirements of the IRB related to the report of possible non-compliance according to the UTHSCSA Noncompliance Policy and Procedure (http://research.uthscsa.edu/irb/policy/Noncompliance Policy and Procedure.doc).

(3) If research non-compliance 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) .

b. Procedures for handling noncompliance:

(1) If the ACOS for R&D becomes aware of an incident that is possible non-compliance, either directly through the PI or through any other component of the STVHCS HRPP, that has not been previously reported to the IRB, the Principal Investigator will be informed of the requirement to promptly notify the IRB. The ACOS for R&D will also promptly report the possible non-compliance to the IRB.

(2) A report of possible research non-compliance will be received and reviewed by the IRB to make a determination whether it is substantiated as research non-compliance, as outlined in the UTHSCSA Noncompliance Policy and Procedure (http://research.uthscsa.edu/irb/policy/Noncompliance Policy and Procedure.doc).

(3) The IRB will report determinations of serious or continuing non-compliance 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. The IRB will submit a report to the STVHCS within 30 days from the date of determination of resolution of the non-compliance.

(4) Reporting of determinations of serious and/or continuing non-compliance to non-VA regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA) if the protocol involves FDA regulated research, 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 the "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 Reporting to Internal and External Entities Policy and Procedure".

(5) Reports of determinations of non-compliance received from the IRB by the ACOS for R&D, or his/her designee, will be reported to the appropriate internal institutional officials as described below:

(a) Reports of serious and/or continuing non-compliance will be reported promptly to the Medical Center Director.

(b) If the report of non-compliance involves any real or suspected violation or compromise of VA Information Security related to a VA research protocol, the ACOS/Research will report within 5 business days, to the facility director, R&D committee, and any relevant research review committee upon discovering receiving, or otherwise becoming aware of a credible report. The ACOS/Research will also ensure the facility ISO has been notified. Communication in writing will follow as appropriate.

(c) If the report of non-compliance involves any real or suspected unauthorized use, loss, or disclosure of individually-identifiable information related to a VA research protocol, the ACOS/Research will report within 5 business days, to the facility director, R&D committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report. The ACOS/Research will also ensure the facility Privacy Officer has been notified. Communication in writing will follow as appropriate.

(6) The ACOS for R&D will ensure that external VA regulatory and oversight agencies are notified of determinations of serious and/or continuing non-compliance as required.

(a) Determinations of serious and/or continuing non-compliance involving VA research will be reported by the STVHCS Director to the Office of Research Oversight (ORO) within 5 days of the IRB's determination of serious and/or continuing non-compliance. Notification to ORO will include any official correspondence from the IRB, and will include the following information when not included in any IRB correspondence:

1. The nature of the event (serious and/or continuing non-compliance)

2. Name of the institution conducting the research.

3. Title of the research project or grant proposal in which the problem occurred.

4. Name of the principal investigator on the protocol.

5. 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.

6. A detailed description of the problem including the findings of the organization and the reasons for the decision of the IRB.

7. Actions that the UTHSCSA IRB or STVHCS has taken or plans to take to address the problem.

8. 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.

9. The name of any agencies or organization external to VA that were notified or need to be notified, of the event.

(b) Reports of determinations of non-compliance involving a violation of information security requirements will also be reported promptly by the STVHCS ISO to the VHA ISO.

(c) Reports of determinations of non-compliance 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.

(d) Reports of determinations of serious and/or continuing non-compliance involving a VA-funded research protocol will also be reported by the STVHCS Director to the VA Office of Research and Development (in addition to the report to ORO) within 5 days of the IRB's determination that a report of possible non-compliance was determined to be serious and/or continuing non-compliance.

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

4. **REFERENCES:** VHA Handbook 1200.05; VHA Handbook 1058.01; 45 CFR 46; 21 CFR 50, 56; 38 CFR 16

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

6. **RECISSION:** Research SOP for Handling of Research Non-Compliance 12-49, dated March 27, 2012

7. **RECERTIFICATION:** March 2018

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