DEPARTMENT OF VETERANS AFFAIRS **Research Service Policy Memorandum 22-49**
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404 **December 9, 2022**

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.

Congruent with Federal Policy (Common Rule) for the protection of human subjects in research, W BT/F2 11.04 T

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 UTHealthSA IRB glossary at: https://www.uthscsa.edu/vpr/services/glossary

(2) Serious non-compliance: The STVHCS adheres to the definition of serious research non-compliance found in the UTHealthSA IRB glossary at: https://www.uthscsa.edu/vpr/services/glossary

(3) Continuing non-compliance: The STVHCS adheres to the definition of continuing research non-compliance found in the UTHealthSA IRB glossary at: https://www.uthscsa.edu/vpr/services/glossary

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 UTHEALTHSA

(3) The IRB will report serious or continuing non-compliances promptly, but no later than 48 hours via encrypted email or phone 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 UTHealthSA IRB according to the procedures and timelines outlined in the "Reporting Policy and Procedure" (https://www.uthscsa.edu/sites/default/files/Services/forms/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 agencies according to the same timelines outlined in the "Reporting 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:

iii. Title of the research project or grant proposal in which the problem occurred
iv. Name of the principal investigator on the protocol.

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

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

vii. Actions that the UTHealthSA IRB or STVHCS has taken or plans to take to address the problem.

viii. 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.

ix. The name of any agencies or organization external to VA that were notified or need