RESEARCH COMPLIANCE PROGRAM STANDARDING OPERATING PROCEDURE (SOP) REPORTING APPARENT SERIOUS AND/OR CONTINUING NONCOMPLIANCE

1. **PURPOSE:** To establish policy and procedure for reporting apparent serious and/or continuing noncompliance within the South Texas Veterans Health Care System (STVHCS) Human Subject Research Program.

2. **POLICY:** It is the policy of the STVHCS to ensure prompt reporting of all apparent serious and/or continuing noncompliance to appropriate institutional and federal officials in order to protect the safety, welfare, and confidentiality of human subjects involved in the Human Research Program. ***Note:*** *The determination that noncompliance is "serious" or "continuing" rests with the IRB; hence, individuals are required to report apparent serious or continuing noncompliance. Decision charts related to such reporting are provided on the Office of Research Oversight Web site at: http://www1.va.gov/oro/*

3. **ACTION:**

(1) All occurrences of apparent serious and/or continuing noncompliance discovered during the auditing process or reported to the Research Compliance Officer (RCO) will be investigated and reported.

(2) **Responsibilities:**

(1) The RCO will report all incidents of apparent serious and/or continuing noncompliance within 5 business days of identifying apparent serious and/or continuing noncompliance based on an informed consent audit, regulatory audit, or other systematic audit of VA research. An RCO must report the apparent noncompliance directly (without intermediaries) to the Medical Center Director (MCD).

(2) The report must be made in writing, with a simultaneous copy to the ACOS for Research, the Research & Development Committee (R&DC), the University of Texas Health Science Center at San Antonio Institutional Review Board (UTHSCSA IRB), and any other relevant research review committee.

(3) An initial report of apparent serious and/or continuing noncompliance based on an RCO informed consent audit, RCO regulatory audit, or other systematic RCO audit is required regardless of whether disposition of the matter has been resolved at the time of the report.

(4) Once the apparent serious and/or continuing noncompliance is reported to the MCD, he/she must report the apparent serious and/or continuing noncompliance to the appropriate Office of Research Oversight Regional Office (ORO RO), with a simultaneous copy to the Veterans Integrated Service Network (VISN) Director and the Office of Research and Development (ORD), within 5 business days after receiving such notification.

c. Contents of initial reports to ORO of reportable research events must (as applicable) include:

(1) The name and any relevant Assurance number of the reporting VA facility.

(2) The title of the research project(s).

(3) The number(s) used by the facility's Research Service or relevant research review committee(s) to identify the project(s).

(4) The name of any external sponsor(s) of the project(s).

(5) The funding source(s) for the project(s).

(6) The name of any agencies or organizations external to VA that were notified, or need to be notified, of the event.

(7) A description of the event being reported.

(8) A description of any immediate actions taken to address or investigate the reported event.

d. Contents of Follow-Up Reports to ORO should contain additional investigation and review information needed to obtain a complete understanding of the facts associated with the case. Interim and final reports must be provided as directed by ORO to incorporate the full scope of relevant determinations and remedial actions, including programmatic actions as warranted.

e. The relevant research review committee is responsible for determining the appropriate remedial action(s) in response to identified noncompliance and for verifying that the remediation is implemented as required. The RCO will also verify that remedial actions for the identified noncompliance are implemented and completed.

(1) Except in extraordinary circumstances, remedial actions related to specific research projects must be completed within 90-120 days of the research review committee's determination of noncompliance (or of such a determination by ORO).

(2) Except where remediation requires substantial renovation, fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions related to programmatic noncompliance must be completed within 120-180 days of the noncompliance determination.

(3) Where completion of remedial actions extends beyond the periods described in the preceding subparagraphs, the facility must provide ORO with a written justification for the delay and an acceptable timeline for completion.

f. The reporting facility will ensure secure transmission of all reports of apparent serious and/or continuing noncompliance as these reports are likely to include VA sensitive information as defined in VA Directive 6500. Electronic transmissions of such reports must be encrypted, and hard copies of such reports must be sent by secure carrier in accordance with VA requirements in VA Directive and Handbook 6500 and VA Directive 6609.

g. The RCO will ensure that all documentation relevant to the reported event is maintained in a study specific file in the Research Compliance Office.

4. **REFERENCES:** VHA Handbook 1200.05, VHA Handbook 1058.1

5. **RESPONSIBILITY:** Research Compliance Officer (003C)

6. **RESCISSIONS:** Research Compliance Program Standard Operating Procedures (SOP), dated January 12, 2011

7. **RECERTIFICATION:** July 2018

Celeste Burton, MSA
Research Compliance Officer