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

Research Service Policy Memorandum 16-19

February 1, 2016

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Handling of Research Non-Compliance and/or Reportable Incidents/ Unexpected Events Involving Research Safety and Laboratory Security

1. **PURPOSE:** To outline the procedures for handling of research non-compliance and/or reportable incidents/unexpected events involving research safety and laboratory security at STVHCS.

2. **POLICY:**

   a. The monitoring and reporting of research non-compliance and/or unexpected events are key components for the safety and security of VA research laboratories and are critical to the function of the Research Safety and Security Program (RSSP) at STVHCS.

   b. The Associate Chief of Staff (ACOS) for Research is responsible to ensure that all concerns or complaints related to research at STVHCS, received from any source, are promptly investigated.

   c. **Definitions**:

      (1) **Research Non-Compliance**: Conducting research in a manner that 1) disregards or violates federal regulations or institutional policies and procedures regarding research safety and laboratory security or 2) failure to follow the research practices listed in the Subcommittee for Research Safety (SRS) approved protocol. Noncompliance is characterized by severity of the event (i.e., serious or not serious) and the pattern of like or similar events (continuing or not continuing).

      (2) **Unanticipated or Unexpected Events.** The terms unanticipated and unexpected refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population. Examples presented in VHA Handbook 1058.01 include, but are not limited to: work-related or research-related injuries or exposures to any person requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.

3. **ACTION:**

   a. **SRS Review of Reportable Incidents/Unexpected Events**

      (1) Within 5 business days of becoming aware of any reportable incident/unexpected event, members of the VA research community are required to ensure that the incident has been reported in writing to the SRS.

      (2) The SRS will review any reportable incident/unexpected event at its next convened meeting.

      (3) Concerns of SRS members, staff, or investigators are presented to the SRS for review at the next scheduled meeting.

      (4) The SRS minutes will, in all cases, document action taken.

(5) Incidents that present a significant risk to the safety of research personnel or the environment may require immediate attention and result in the need to convene an emergency session of the SRS prior to the next scheduled meeting.

(6) Should the SRS determine that a reportable incident or event occurred, the SRS Chair, or designee will report the determination directly (without intermediaries) to the Medical Center Director, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research subcommittees, within 5 business days after the SRS's determination regardless of whether the determination is preliminary.

(7) The Medical Center Director will report the SRS's determination of a Research Event/Reportable Incident to the appropriate ORO review committee, with a simultaneous copy to the VISN Director, within 5 business days after receiving such notification.

(8) The SRS may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the PI and approved by the SRS, or if there are concerns regarding the safety of research personnel or the environment. The SRS may suspend an activity only after review of the matter at a properly convened meeting (quorum) of the SRS and with the suspension vote of a majority of members present.

(9) Should the SRS determine to terminate or suspend a protocol, the SRS Chair, or designee will report the determination directly (without intermediaries) to the Medical Center Director, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research subcommittees, within 5 business days after the SRS's determination.

(10) The Medical Center Director will report the SRS's determination of a protocol termination or suspension to the appropriate ORO review committee within 5 business days after receiving such notification.

b. <u>SRS Review of Laboratory Decommissions</u>

(1) The PI or Laboratory Director will obtain authorization (i.e., permission) from the SRS and the ACOS for Research prior to decommissioning (including vacating, reassigning, converting to non-laboratory use, or otherwise modifying) existing laboratory space that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses.

(2) The request for authorization to decommission laboratory space will be made in writing at least 1 month prior to implementation. Upon receiving such a request, the ACOS for Research will notify the VISN Safety Office to coordinate inventory and removal of hazardous materials, infectious agents, or equipment.

(3) Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any decommissioning implemented without the required authorization, the ACOS for Research will report the incident directly (without intermediaries) to the facility Director and the VISN Safety Office.

(4) The facility Director will report any unauthorized decommissioning to ORO CO within 5 business days after being notified.

c. SRS Review of Research Non-Compliance

(1) Review of Research non-compliance may be identified through any number of ways, including but not limited to:

(a) A report by any individual to the SRS, R&D Committee, or R&D Office
(b) Continuing review of ongoing research by the SRS or R&D Committee
(c) Compliance audits conducted by the UTHSCSA or STVHCS compliance offices
(d) A report by another committee, department, or official.
(e) A report from the study sponsor or sponsor's monitoring entity

(2) Noncompliance identified as deviation from an approved protocol may be reported in a number of ways including but not limited to:

(a) Self-reporting by the Principal Investigator.
(b) Reporting by other committees, departments or officials.
(c) Reporting by other faculty/staff.
(d) The SRS may learn of noncompliance as a result of continuing review of ongoing research.
(e) Reporting by the study sponsor or a monitoring entity.
(f) As a result of Semi-Annual Inspection findings.

(3) SRS may determine the following:

(a) Not noncompliance
(b) Noncompliance that is neither Serious nor Continuing
(c) Noncompliance that is Serious and/or Continuing
(d) Not enough information available to make a determination (Deferred)
(e) If a possible noncompliance is Deferred, additional information may be requested from the investigator or the issue may be sent to a subcommittee to further investigate the allegation. The subcommittee will report the findings of the investigation to the SRS for determination.

(4) Issues or events that are reported are possible noncompliance until a final determination is made by the SRS.

(5) Should the SRS determine serious and/or continuing noncompliance, the SRS Chair, or designee will report the determination directly (without intermediaries) to the Medical Center Director, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research subcommittees, within 5 business days after the SRS's determination.

(6) The Medical Center Director will report the SRS's determination of serious and/or continuing noncompliance to the appropriate ORO review committee, with a simultaneous copy to the VISN Director, within 5 business days after receiving such notification.

(7) Final determination is sent to the PI with a corrective action plan if appropriate.

d. Reporting to ORO

(1) Notification to ORO will include any official correspondence from the SRS, and will include the following information when not included in any SRS correspondence:

(a) The nature of the event (serious or continuing non-compliance) including when and how the SRS became aware of the problem.
(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 SRS 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 SRS.
(g) Actions that SRS 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 SRS or STVHCS to send a follow-up or final report.
(i) The name of any agencies or organization external to VA that were notified or need to be notified, of the event.

(2) Interim and final reports will be provided as directed by ORO.

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

e. **Research Laboratory Security Incident Reports.**

(1) **Physical Security Problems.** Any break-in, physical security breach, or other physical security problem affecting VA research that involves (a) injury or harm to an individual; (b) Loss of any quantity of a select agent or toxin; (c) Substantial damage to the facility; or (d) Substantial loss of equipment or physical resources will report the situation in writing to the ACOS for Research within 5 business days.

(2) Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any physical security problems identified above, the ACOS for Research will report the incident directly (without intermediaries) to the facility Director in writing with simultaneous copies to the R&D Committee, any relevant research review committee, and the VA Police Service.

(3) Within 5 business days of being notified, the facility Director will report the incident to ORO CO.

(4) **Findings of Noncompliance.** Any findings of noncompliance related to research laboratory security by any VA office (other than ORO) or any Federal or state entity (e.g., Department of Homeland Security) will be reported in writing to the ACOS for Research within 5 business days. Reports to ORO based on findings made by entities external to the facility will include a copy of the official findings.

(5) **Other Deficiencies.** Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program will be reported in writing to the ACOS for Research within 5 business days.

(6) **Suspensions or Terminations**. Any suspension or termination of research (e.g., by the ACOS for Research or other facility official) related to concerns about research laboratory security will be reported in writing to the ACOS for Research within 5 business days.

f. **Substantive Changes in MOUs.** Within 5 business days after being informed of any substantive change in an MOU with an affiliate institution or other entity regarding research laboratory security arrangements, the facility Director will report the change to ORO CO.

4. **REFERENCES:** VHA Handbook 1058.01

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

6. **RECISSION:** Research Service Policy Memorandum 13-19, April 24, 2013

7. **RECERTIFICATION:** January 2021

JACQUELINE A. PUGH, M.D.
ACOS Research and Development