

August 1, 2016

RESEARCH COMPLIANCE PROGRAM

1. PURPOSE: To establish policy pertaining to the activities of the Research Compliance Program at South Texas Veterans Health Care System (STVHCS).

The Research Compliance Program adds value to the organization through improvement of research processes. Compliance monitoring will provide internal oversight on quality and compliance issues related to the performance of clinical and laboratory research studies involving human subjects, laboratory animals, and laboratory safety. Through the auditing process, data will be collected that will allow observation of trends and provide opportunities for improvement.

2. POLICY:

a. **The Research Compliance Officer's primary responsibility is** oversight of research projects for compliance to applicable regulations, including but not limited to VHA Handbooks 1200.05, 1200.7, 1200.08, 6500, 1605.1, 1058.01, ICH Good Clinical Practices, and applicable CFR (45 CFR 46; 21 CFR 50; 38 CFR 16).

b. **The Research Compliance Officer (RCO) is responsible for** providing Medical Center Leadership with reasonable assurances the Facility Research Program complies with VA and Federal Regulations, and is effectively auditing research studies for conduct within the guidelines set forth by the Office of Research Oversight (ORO), Office of Research Development (ORD), Office of Human Research Protection (OHRP), Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Public Health Service (PHS), Association for Assessment and Accreditation of Lab Animal Care (AAALAC), Office of Laboratory Animal Welfare (OLAW), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Center for Disease Control (CDC), National Institutes of Health (NIH), and Department of Health and Human Services (DHHS).

c. **This policy is inclusive of research activities related to the conduct of research,** which may include requirements in one or more of the following areas: The protection of human research subjects, laboratory animal welfare, and research safety and data privacy and security. This policy and its procedures apply to all individuals engaged in research which has been approved or should have been approved by all appropriate boards and committees as set forth in VHA guidance. This would include but is not limited to: The Institutional Review Board (IRB), Research and Development Committee (R&DC), Institutional Animal Care and Use Committee (IACUC), and Subcommittee for Research Safety (SRS)

3. ACTION:

a. **Responsibility**

(1) **Medical Center Director.** The Medical Center Director (MCD) is responsible for appointing one or more RCOs to conduct annual research informed consent audits and triennial regulatory audits, to assist in facility assessments of regulatory compliance, and provide prompt reporting to all appropriate committees and research oversight bodies. The MCD must report

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any appointment, resignation, or change in status of the facility RCO to ORO VHA Central Office, with a copy to the relevant ORO RO, within 5 business days after the appointment, resignation, or change takes effect.

(2) **Associate Chief of Staff Research & Development (ACOS/R).** The ACOS/R is responsible for the implementation, conceptual oversight, and administrative leadership with regard to ensuring compliance and quality improvement for the Human Research Protection Program (HRPP), Institutional Animal Care and Use Committee (IACUC), Research and Development Committee (R&DC) and Subcommittee for Research Safety (SRS)

(3) **Research Compliance Officer.** The RCO is responsible for the development and implementation of a Research Compliance Program to provide oversight on the day to day activities of human, animal, and scientific research. The RCO provides programmatic oversight of the HRPP, animal use, and appropriate committees and subcommittees.

(4) **Investigators.** The Principal Investigator (PI), Lead Site Investigator (LSI), and investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including the local VA facility's SOPs, regarding the conduct of research and the protection of human subjects. **NOTE: The responsibilities for the PI, LSI, and Investigator are further defined in VHA Handbook 1200.05.**

b. Scope

(1) **The RCO will report directly to the Medical Center Director.**

(2) **The RCO will conduct audits and investigate complaints regarding** all research conducted at STVHCS. On a monthly basis the RCO will provide a report on all audits and investigational activities to the MCD, ACOS/R, the R&D Committee and subcommittees (IRB, SRS, IACUC). Reporting of apparent serious or continuing noncompliance found during RCO auditing activities will be done in accordance with VHA Handbook 1058.01.

(3) **The RCO will conduct audits and reviews to ensure compliance with** all VHA, federal and local affiliate IRB regulations and guidance. The research compliance auditing plan will be structured to fulfill the auditing requirements set forth by the Office of Research Oversight (ORO) and Office of Research and Development (ORD).

c. Audit Cycle Requirements

(1) **The RCO or designee will conduct annual audits of** all active protocols recruiting human subjects for compliance with the applicable regulations and policies related to research informed consents. All informed consent documents (ICD) executed since study initiation or since last annual informed consent audit will be reviewed.

Annual informed consent audits can include but will not be limited to: Completion of all required signature blocks, use of the most current version of the ICD, presence of IRB stamp, appropriate documentation of the informed consent process and scanned copy of the properly executed ICD along with properly executed Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization in the Computerized Patient Record System (CPRS), the VA electronic medical record.

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(2) **The RCO or designee will conduct Triennial Regulatory audits** for every active human subject, animal, and laboratory protocol every three years or at least one time during the life of the study if it is less than three years in duration. .

(3) **The RCO or designee will conduct Close-Out audits** on selected protocols which are inactivated during the audit cycle. Eligibility for a Close-Out audit will be determined on a case by case basis based on such factors as subject enrollment, protocol changes since last audit, and time elapsed since last regulatory audit.

Triennial Regulatory and Close-Out audits can include but will not be limited to: Review of regulatory documents, adverse event reporting, review of subject files, review inclusion and exclusion criteria, timely reporting of Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO), progress reports/continuing reviews along with adverse events and study deviation logs, study staff training/qualifications, subject enrollment logs, safety concerns, and compliance with all privacy and confidentiality requirements. Individual protocols will be assessed for safety concerns including biological, chemical, and/or radioactive agents. Study specific documentation maintained by other Services supporting the research activity can be included.

(4) **Triennial Regulatory Audits will also be conducted to** review animal and laboratory research study activities. Audits in these areas can include but will not be limited to: Review of protocols, regulatory documents, animal care and use, study personnel training/qualifications, and safety concerns including biological, chemical, and/or radioactive agents.

(5) **Occurrence of audits can vary**, the IRB, the study sponsor, the PI, VHA administration (ORO, ORD), Facility Director, the ACOS/R, or the RCO can require more frequent audits. They can also require focused audits of one or more aspects of the study. The requirement to increase the frequency of audits or to audit specific aspects of the study can be based on such considerations as: Involvement of vulnerable populations, level of risk, involvement of FDA approved drugs for which there has been a safety warning or change in the labeling that indicates increased risks, previous issues of noncompliance, data breaches, Phase I or Phase II studies.

d. Reporting

(1) **The RCO is responsible for the prompt reporting of** all auditing and monitoring reports in which apparent serious and/or continuing noncompliance is identified to the MCD, with simultaneous copies to IRB Director, ACOS/R, R&D Committee Chair, and any other appropriate subcommittees, adhering to the 5 day reporting requirement.

(2) **The RCO, through timely reporting to the MCD, will facilitate** submission of audit reports identifying apparent serious and/or continuing noncompliance to SRO/ORO, with simultaneous copies to the VISN Director, VISN Research Compliance Officer, VISN Chief Medical Officer, ACOS/R, R&D Committee Chair, Director IRB, and ORD within the 5 day reporting requirement.

(3) **The RCO will maintain oversight to ensure adequacy of** the STVHCS Research Program processes, such as, the effectiveness of communication with all applicable committees, persons, and officials. The RCO will also ensure documentation and reporting requirements of the auditing program are met to include: Content of the reports; persons, officials or committees that must receive and review reports (e.g., the Principal Investigator,

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MCD, IRB Director, R&D Committee, ACOS/R), and other administrative persons or entities as appropriate. Ensure adherence to time frames for reporting and timelines for corrective actions required by the IRB, R&DC, IACUC, SRS, or other appropriate entities to be taken based on the findings. The RCO should also be cognizant of who should implement and review the corrective actions; and how to evaluate the results of any corrective actions.

e. Additional Program Responsibilities

(1) **The RCO will provide education to investigators and research staff regarding regulatory and policy requirements;** the RCO is a local resource for regulations, policies, memoranda, alerts and other VA and federal requirements related to research compliance.

(2) **The RCO will implement a strategy to collect pertinent data from** all audits performed. That data will be used to complete selected portions of the Facility Director's Certification of Research Oversight. This annual reporting requirement will be completed in conjunction with the local Research and Development Office. Additionally, data compiled from auditing will be used to identify opportunities for improvement within the STVHCS research program.

(3) **The RCO may serve as a nonvoting consultant to the following facility committees:** R&D, IRB, IACUC, SRS, and other research review committees. The RCO will attend committee meetings to provide information and serve as a subject matter expert on research compliance issues. The RCO may not contribute to quorum or deliberate or vote with the committee. The Committee Chair may elect to exclude the RCO from any or all proceedings of the committee meeting if it is felt, by the Committee Chair, that a conflict of interest exists. The RCO will also evaluate his/her presence at a committee meeting for potential conflict of interest and act accordingly.

(4) **The AO/R, ACOS/R, R&DC, IACUC, SRS, and IRB will notify the RCO of suspected research noncompliance.** The AO/R and the IRB will make available all VA research records necessary for conducting audits, reviews, or reports to the RCO.

(5) **It is the responsibility of employees who suspect that** another employee, or an employee of the affiliate, are functioning in a manner that does not comply with federal, state or local laws and regulations, or internal policies and procedures governing research report these suspicions of research noncompliance to the RCO. An open line of communication between the RCO and medical center personnel is equally important to the successful implementation of a research compliance program and the willingness to report suspected research noncompliance. Confidentiality of those who report noncompliance will be kept as strict as possible. Communications to the RCO will be confidential in nature; however, in the event that higher authorities become involved, an individual's identity may need to be disclosed. Employees who report possible compliance issues will not be subjected to retaliation or harassment as a result of the report. Concerns about possible retaliation or harassment should be reported to the RCO. Please remember this is a serious issue. Knowingly making a false report will result in disciplinary action.

4. REFERENCES:

- a. VHA Handbooks 1200.05, 1058.01, 1200.7, 1200.08
- b. VHA Directives

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c. STVHSC Policy Memorandum 151-11-03

5. RESPONSIBILITY: Research Compliance Officer (003C)

6. RESCISSION: STVHCS Policy Memorandum 003-11-02 dated May 23, 2011

7. RECERTIFICATION: August 2021

(Signature on File)

ROBERT M. WALTON
Director

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