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

Research Service Policy Memorandum 16-02

January 20, 2016

RESEARCH STANDARD OPERATING PROCEDURES (SOP)

Safety Program

1. **PURPOSE**: To outline the Research Service safety program established to ensure the safety of personnel engaged in research, and to define key roles, procedures, duties, and responsibilities of personnel involved in the safety program.

2. **POLICY**: The Research Service will maintain a service level program to ensure the safety of personnel engaged in research, and to meet and implement applicable safety directives.

a. Subcommittee for Research Safety (SRS), a subcommittee of the Research and Development Committee, will oversee and monitor the Research safety program. This oversight is inclusive of research laboratory and Veterinary Medical Unit (VMU) activities, and is independent of any specific research protocol. The SRS meets the requirements of the South Texas Veterans Health Care System (STVHCS) for a Service-level Safety Committee. In addition this committee will provide protocol- and investigator-focused review of all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines. The SRS meets the additional requirements of the VA Central Office consistent with VHA handbook 1200.08.

b. A Research Laboratory Safety Subcommittee (RLSS), which functions as a STVHCS Safety subcommittee, will be maintained to monitor safety practices of personnel involved in research at the STVHCS, research equipment, conduct laboratory inspections, and standard operating procedures for each hazardous chemical in laboratory use. The RLSS will also report to the SRS.

c. Institutional Biosafety Committee (IBC) is a subcommittee of the SRS responsible for approval of studies using recombinant or synthetic nucleic acid molecules. The STVHCS Director charges the IBC to review safety surveys characterized as the deliberate transfer of recombinant or synthetic nucleic acid molecules covered by NIH Guidelines. The IBC will risk assess and recommend biosafety containment level for recombinant or synthetic nucleic acid experiments.

3. **DEFINITIONS:**

a. **BIOHAZARDS**: Biohazards include, but are not limited to, the following:

(1) Pathogens and/or etiologic agents, human and non-human primate tissues including blood and body secretions, and human cell lines corresponding to Biosafety Level (BSL) 1-4 (Biosafety in Microbiological and Biomedical Laboratories 5th Edition, Center for Disease Control and Prevention-National Institutes of Health (CDC-NIH), Washington, DC, 1999). *Note that the STVHCS does not have the facilities for working with pathogens that require BSL3 or BSL4 handling, and therefore the STVHCS does not allow work with such organisms within the facility.*

(2) Toxins produced by microbial organisms (see CDC-NIH Biosafety in Microbiological and Biomedical Laboratories 5th Edition p. 379);

(3) Recombinant DNA molecules, The National Institutes of Health (US), Office of Biotechnology Activities; 2013, March.

(4) Select agents, as specified in Title 42 Code of Federal Regulations Part 72, Interstate Shipment of Etiologic Agents;

(5) Animals experimentally or naturally exposed to any of the above (see CDC-NIH Biosafety in Microbiological and Biomedical Laboratories 5th Edition pp. 67-75).

b. **CHEMICAL HAZARDS**: Chemical hazards include any substance or mixture of substances with properties capable of producing adverse effects on the health and/or safety of humans (see Title 29 CFR Part 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories).

c. **PHYSICAL HAZARDS**. Physical hazards include, but are not limited to (see Title 29 CFR Part 1910.269, Electric Power Generation, Transmission, and Distribution), ionizing and non-ionizing radiation (see VHA Handbook 1200.8, Appendix E), noise, vibration, extremes of temperature and pressure, explosive hazards, electrical hazards, mechanical hazards, and nanomaterials.

4. **ACTION:**

a. SUBCOMMITTEE FOR RESEARCH SAFETY (SRS) and Institutional Biosafety Committee (IBC). The SRS will monitor and review the entire Research Safety program. This committee will provide protocol- and investigator-focused reviews of all research activities involving biological, chemical, physical, and radiation hazards. The IBC will likewise review safety surveys characterized as the deliberate transfer of recombinant or synthetic nucleic acid molecules covered by NIH Guidelines. IBC will risk assess and recommend biosafety containment level for recombinant or synthetic nucleic acid experiments. The SRS review and approval includes VA research applications conducted at the VA facility or by VA personnel with VA funding located off-site, while the IBC review and approval includes research activities conducted at STVHCS VMU or other laboratories within the facility.

(1) **Membership**: The SRS will consist of at least five members, exclusive of ex-officio members. Members will include STVHCS Safety Officer (STVHCS Safety Committee member; occupational safety and health and environmental expertise), Chemical Hygiene Officer, Radiological Safety Officer, and research investigators with expertise in safety issues (i.e. infectious diseases, chemical carcinogens, recombinant DNA). Ex-officio members will include Deputy Associate Chief of Staff (DACOS) for R&D, Administrative Officer for R&D and Veterinary Medical Unit Supervisor, Local 3511 Union Safety Representative, and R&D Committee Liaison. All ex-officio representatives are non-voting members, with the exception of union representative. The IBC will at a minimum include, five members, who collectively have experience in general issues of laboratory biosafety, use of infectious materials, and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of such research and identify any potential risk to public health or the environment in addition to two members not affiliated with the institution (apart from their membership on the committee).

(2) **Meetings**: This subcommittee primarily will convene at a minimum quarterly to review protocol safety surveys in accordance with VHA Handbook 1200.08 and NIH Guidelines for recombinant or synthetic nucleic acid molecules.

(3) **Initial Review of research protocols**: The SRS and IBC must have a quorum to conduct meetings. The SRS and IBC will use the Research Protocol Safety Survey (VA Form 10-0398) as the tool for evaluating projects involving biological, chemical, physical, radiation hazards, and recombinant or synthetic nucleic acid molecules. Their review must include a risk assessment of the facilities, level of containment, laboratory procedures, environment (for recombinant or synthetic nucleic acid molecules) and training and expertise of personnel. SRS or IBC approval of safety survey(s) is required before Research and Development Committee approval of the protocol. SRS and/or IBC approvals will be submitted to Research and Development Committee for review and final approval by the chairperson. The safety survey will be

uploaded to Just-in-Time for potential VA funded studies to be approved by central office safety representative.

(4) **Continuing Review of research protocols**: The SRS with the IBC will annually review all protocols involving biological, chemical, physical, radiation hazards, and recombinant or synthetic nucleic acid molecules regardless of funding status or source. SRS and IBC reviews will be reported to Research and Development Committee for review. Any survey amendments must be documented on a new VA Form 10-0398 Safety Survey, and reviewed by the SRS and/or IBC prior to implementation of changes.

(5) **Reporting**: Written minutes from the convened SRS\IBC meeting will be forwarded for review by Research and Development Committee. In addition the committee will forward the following reports to the Research and Development Committee through the Research and Development Staff Assistant: Environment of Care (EOC) Rounds Deficiencies, Biological Safety Cabinet and Chemical Hood Certifications, Administrative Officer Laboratory Security Access Results, Law Enforcement Annual Multi-disciplinary Vulnerability Assessments, and Facility Safety Semi-annual Laboratory Hazardous Chemical Reports. The SRS\IBC Administrator will notify the principal investigators in writing of the committee's decision to approve, disapprove, or withhold approval pending non-substantive clarification of a protocol safety survey within 3 working days of a convened meeting.

(6) **Oversight Activities**:

a) Reviewing minutes of the Research Laboratory Safety Subcommittee and Radiation Safety Committee meetings and inspections, accident reporting reports, and laboratory safety issues.

(b) Ensuring a complete list of chemicals, designated or identified by OSHA and/or EPA as "hazardous", has been entered in the OEM computer based system for review by the appointed Facility Safety Officer for each identified safety survey involving chemical hazard use.

(c) Reporting operational problems or violations of directives to the Research Safety Office immediately unless a report had been previously filed by the principal investigator (PI).

(d) The Occupational Health representative in cooperation with the PI and veterinary medical unit supervisor identifies the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising Research and Development Committee and Employee Health Practitioner on the need for such surveillance. VA Occupational Health Clinic is the repository of completed health baseline questionnaires and returns the certification page to the research office for record keeping. UTHSCSA Employee Health is the repository for completed research health baseline questionnaires for all off-site studies, and they will notify the research office, by email, upon certification of their employee's enrollment.

(e) Ensuring Radiation Safety review and approval of protocol safety surveys involving the use of radiation equipment, except for use of such equipment as part of the standard of care for subjects enrolled in human protocols.

(f) SRS will oversee reports related to EOC Rounds Deficiencies, Biological Safety Cabinet and Chemical Hood Certifications, Administrative Officer Laboratory Security Access Results, Law Enforcement Annual Multi-disciplinary Vulnerability Assessments, and Facility Safety Semi-annual Laboratory Hazardous Chemical Reports provided by the RLSS.

b. RESEARCH LABORATORY SAFETY SUBCOMMITTEE (RLSS). This committee reports to the SRS and is responsible for the implementation and routine monitoring of all safety and occupational health directives within the Research Service.

(1) **Membership**: The RLSS will have a variety of members representing all laboratory and animal research activities. A Chair must be appointed. Although not a requirement, a Vice Chair may be appointed and will assist the chair and assume responsibilities during the incumbent's absence.

(2) **Meetings**: The RLSS will meet on a monthly basis, with no quorum required to hold a meeting. Each investigator/lab is encouraged to send a representative to each meeting. The purpose of the meetings is to provide a forum for the Research and Development administrative and STVHCS Safety Service staffs to provide research safety information to the research community, to get feedback from the research community related to safety issues and questions, and develop and implement plans to maintain and improve research safety.

(3) **Reporting**: The RLSS functions as a STVHCS Safety subcommittee. It also formally reports through submission of its meeting minutes and other verbal and written correspondence to SRS. The following reports will be provided to the SRS for review and monitoring: EOC Rounds Deficiencies, Biological Safety Cabinet and Chemical Hood Certifications, Administrative Officer Laboratory Security Access Results, Law Enforcement Annual Multi-disciplinary Vulnerability Assessments, and Facility Safety Semi-annual Laboratory Hazardous Chemical Reports.

(4) **Minutes**: will be prepared to document the meeting, including absent/present members, old and new business, inspection reports, accidents/incidents review, fire drill responses, disaster preparation, and training. Minutes are also provided to the SRS.

(5) **Inspections**: The RLSS will be responsible for monthly safety self-inspections or -assessments of all active, assigned research laboratory areas using a standardized checklist. NOTE: No one will inspect their own laboratory. Inspection findings and required corrective actions will be communicated with the appropriate principal investigator via email and documented in meeting minutes. Documentation of the inspection and results will be maintained by the administrative officer.

(6) **Safety Policies**: The committee will initiate and annually update service safety policies to ensure all employees have access to all current guidelines.

c. TRAINING: All employees involved in research, whether salaried or Without Compensation (WOC) are required to meet hospital safety training requirements. Training will include current hospital safety guidelines and Research specific issues. The Research Service will maintain a record of each employee's safety training compliance.

(1) **Supervisor Orientation**. After the hospital's new employee orientation is completed, supervisors must complete Research Site Specific Safety Training on specific job related hazards.

(2) **Annual training**: All employees are required to complete all mandatory hospital-wide Environmental Care Training (VA intranet or hard copies) and the Research Site Specific training. Individuals will maintain copies of completed training. Supervisors will retain annual certifications.

d. ASSOCIATE CHIEF OF STAFF FOR RESEARCH AND DEVELOPMENT (ACOS FOR R&D): The ACOS for Research and Development is the responsible official for providing safe working conditions within Research Service. This includes the responsibility to ensure the following:

(1) Maintenance of a commitment for safe practices culture, safety performance standards, and prevention of accidents and injuries within the Research Service,

(2) Active participation of research personnel in the safety program,

(3) Prompt investigation and reporting of all accidents and injuries and elimination of any identified or potential unsafe acts or conditions, and

(4) Strategic Quality Improvement planning and implementation related to service safety or occupational health activities.

e. RESEARCH AND DEVELOPMENT ADMINISTRATIVE OFFICER OR HIS/HER DESIGNEE IS DESIGNATED AS THE RESEARCH SERVICE SAFETY OFFICER. THE SAFETY OFFICER RESPONSIBILITIES INCLUDE THE FOLLOWING:

(1) Coordinating, maintaining, and continually improving the Research Safety program within the Service.

(2) Providing administrative support for safety program activities and coordinating the interaction and communication between the hospital Safety Office, SRS and Research and Development committees.

(3) Ensuring hospital safety policies, VA Central Office directives and training materials are communicated and available to research personnel.

f. SUPERVISORS HAVE A PRIMARY RESPONSIBILITY TO ENSURE PERSONNEL EMPLOY SAFE PRACTICES. The responsibilities of supervisors will vary according to the type of research that is being conducted, but may include:

(1) Ensuring a Safety Data Sheet (SDS) and Hazardous Chemical Standard Operating Procedure (SOP) are on file for each hazardous chemical used in work area,

(2) Ensuring employees complete all appropriate training in safety practices, employ proper procedures to eliminate safety, health, and fire hazards inherent in the work area, and maintain documentation of employee training. Supervisors are responsible for providing Research Site Specific Training, ensuring personnel complete web-based Environmental Care Training on the VA homepage, and maintaining records of completed training,

(3) Providing positive supervision over the manner in which the employee performs assigned duties,

(4) Taking positive action in eliminating any attitudes of carelessness toward safety and occupational health precautions,

(5) Ensuring all employees are cognizant of their responsibility to follow VA safety policy,

(6) Ensuring immediate accident reporting to Research Service, Research Service Safety Officer, and

(7) Ensuring attendance of research laboratory personnel at RLSS meetings.

g. EMPLOYEES: Employees involved in research are responsible for the following:

(1) Applying safe work practices with a positive attitude towards safety and occupational health,

(2) Recognizing the hazards of the job and taking precautions to assure safety of themselves and others,

(3) Informing their supervisor of on-the-job hazards and recommending methods to eliminate them and improve safety performance,

(4) Reviewing SDS and SOP for each hazardous chemical used in the work area,

(5) Actively participating in and cooperating with the overall hospital safety and occupational health program, completing annual occupational safety and health survey and sending it to Occupational Health Clinic for record keeping, and promptly reporting occupational illness and traumatic injuries to their supervisor, and

(6) Complying with safety and environmental rules and regulations for safe job performance and using and maintaining personal protective equipment when required.

h. OCCUPATIONAL SAFETY AND HEALTH: The Occupational Health Clinic is responsible for providing baseline Occupational Health Questionnaires and Certifications. The SRS\IBC Administrator will email periodic annual review requirements to researchers, VMU Husbandry staff and supervisors for Environmental Management Service (EMS) and Maintenance and Operations (M&O). The appropriate supervisor is responsible for ensuring the completion of occupational health certification and securing clearance for personnel to participate in research protocol activities.

(1) The VA Occupational Health Physician evaluates questionnaires and certifies participation of each on-site research personnel in the Research Service Occupational Health Program. Individuals will present completed certifications for all on site personnel to the SRS\IBC Administrator for retention.

(2) Principal investigators ensure enrollment and certification of UTHSCSA-employed, off-site, research assistants in the UTHSCSA Occupational Health Program.

(3) UTHSCSA Employee Health will email notifications of cleared off-site UTHSCSA research personnel to the SRS\IBC Administrator while retaining certifications.

i. VETERINARY MEDICAL UNIT (VMU): Anyone entering VMU animal rooms must be escorted, don appropriate personal protective equipment (PPE) provided by Husbandry Staff, and remove it upon departure of animal rooms. The VMU staff break area is in room U236. Husbandry staff must remove PPE before entering VMU supervisor's office or departing VMU.

5. REFERENCES: VHA Handbook 1200.08 *Laboratory Construction and Renovation,* 2005; 29 CFR Part 1910, *Occupational Safety and Health (OSHA) Standards.* OSHA Section 1910.1030, (*Bloodborne Pathogens* Section 1910.1200, *Hazard Communication and* Section 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories);* 29 CFR Part 1960, *Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matter;* OSHA *Biosafety in Microbiological and Biomedical Laboratories (5th Edition) CDC, NIH, 2007; NIH Guidelines for Research Involving Recombinant DNA Molecules,* NIH, 2013; VHA Directive 1105.1, *Management of Radioactive Materials*, 2004; and VHA Directive 2005-003, *Requirements for Submittal and Approval of Biosafety Level-3 (BSL-3) Research*

6. RESPONSIBILITY: ACOS for Research and Development (151)

7. RESCISSIONS: Research Service Memorandum 13-02, September 3, 2013

8. RECERTIFICATION: September 2019

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