

RESEARCH SERVICE MEMORANDUM  
STANDARD OPERATING PROCEDURE  
Research 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. A Research Service Safety Committee (RSSC) will be maintained to oversee, monitor, and enhance the safety practices of personnel involved in research at the STVHCS. This oversight is inclusive of research laboratory and Veterinary Medical Unit activities, and is independent of any specific research protocol. This committee meets the requirements of the South Texas Veterans Health Care System for a Service-level Safety Committee.

b. A Subcommittee for Research Safety (SRS), will be maintained to 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. This Research and Development Subcommittee meets the additional requirements of the VA Central Office consistent with VHA handbook 1200.8

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 BSL 1-4 (Biosafety in Microbiological and Biomedical Laboratories 4<sup>th</sup> Edition, Center for Disease Control and Prevention-National Institute 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 CDC-NIH. Biosafety in Microbiological and Biomedical Laboratories 4<sup>th</sup> Edition p. 237);

(3) Recombinant DNA molecules (see subparagraph 6g of above fourth edition.);

(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 4<sup>th</sup> Edition pp. 53-75).

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, and mechanical hazards.

4. ACTION:

a. Research Service Safety Committee (RSSC). This committee overall responsibility is to implement all safety and occupational health directives within the Research Service. This committee will oversee, monitor, and enhance the safety practices of personnel involved in research at the STVHCS.

(1) Membership: The Subcommittee will have a variety of members representing all 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 RSSC 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 R&D administrative staff and Safety Service staff 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 Research Service Safety committee functions as a STVHCS Safety subcommittee. It also formally reports, through submission of its meeting minutes and other verbal and written correspondence as needed, to the Subcommittee for Research Safety, a subcommittee of the Research and Development Committee. 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. Provide minutes to the STVHCS Safety Committee, Subcommittee for Research Safety, and the Research and Development Committee.

(4) Inspections: The RSSC will be responsible for monthly safety inspections of all research areas. The unannounced inspections of the Research area will be conducted monthly by two members of the Committee using a standardized checklist. Communicate inspection findings and required corrective actions with the appropriate principal investigator and document in meeting minutes.

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

b. Subcommittee for Research Safety (SRS). The SRS provides protocol- and investigator-focused review of all research activities involving biological, chemical, physical, and radiation hazards. This review includes VA research applications and conducted at the VA facility or by VA personnel with VA funding located off-site.

(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, environmental expertise), Chemical Hygiene Officer, Radiological Safety Assistant, infectious control specialist, and expert in chemical carcinogens and hazards. Ex-officio member will include Administrative Officer for R&D and Veterinary Medical Unit Supervisor, both (non-voting).

(2) Meetings: This subcommittee will convene at a minimum quarterly to review protocol safety surveys in accordance with VHA Handbook 1200.8.

(3) Initial Review of research protocols: The committee must have a quorum to conduct meetings. The subcommittee will use the Research Protocol Safety Survey (VA Form 10-0398) as the tool for

evaluating projects involving biological, chemical, physical, and radiation hazards, and their review must include a risk assessment of the facilities, level of containment, laboratory procedures, training and expertise of personnel. SRS approval is required before Research and Development Committee approval of the protocol. Submit approvals to VA Central Office for all approved potential funding protocols.

(4) Continuing Review of research protocols: The SRS will annually review all protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. Submit review report to R&D Committee through the Staff Assistant. Any survey changes not in original application must be documented on VA Form 10-0398 Safety Survey, and reviewed by the Subcommittee prior to implementation of changes.

(5) Reporting: The SRS Administrative Coordinator will provide written minutes from the convened SRS meeting to the Staff Assistant for inclusion or review by R&D Committee. The coordinator will notify principal investigators of committee decision to approve, approved pending clarification, deferred or disapproved protocols safety survey.

(6) Oversight Activities:

(a) Reviewing minutes Research Service Safety and Radiation Safety meeting minutes 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 submitted to Facility Safety Officer for review and approval prior to the submission of a protocol for local review.

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

(d) The Occupational Health representative in cooperation with the principal investigator and veterinary medical unit supervisor identifies the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising R&D Committee and Employee Health Practitioner on the need for such surveillance. Employee Health is the repository for completed research health surveys and will notify administrative officer, by email, of survey receipt.

(e) Ensuring Radiation Safety review and approval of protocol safety surveys involving the use of radiation equipment, except for studies involving normal care of human patients.

c. Training: All employees involved in research, whether salaried or Without Compensation (WOC) is 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. Principal investigators must also annually complete CITI Working with the Institutional Animal Care and Use Committee (IACUC) Working with the IACUC, and animal training prior to starting work with an

approved protocol. Principal investigators send copies of completion certificates to the IACUC Administrative Coordinator to update Access database.

(2) Annual training: All employees are required to complete all mandatory hospital-wide Environmental Care Training (VA intranet or hard copies). Training will be documented with a training outline and require signature. Principal investigators will maintain copies of completed training.

d. Associate Chief of Staff for Research and Development (ACOS for R&D): The ACOS for R&D is responsible official for providing safe working conditions within Research Service. This includes the responsibility to ensure the following:

- (1) Maintenance of a commitment to 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,
- (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:

- (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, Subcommittee for Research Safety 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. The SRS Administrative Coordinator provides administrative support to the SRS, and ensures the timely and effective communication from the Committee to investigators, research personnel, AO, ACOS for R&D, and R&D Committee.

e. 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 an MSDS is on file for each hazardous chemical used in work area,
- (2) Ensuring employees complete all appropriate training in safety practices and proper procedures to be employed to eliminate safety, health, and fire hazards inherent in the work area and maintaining documentation of employee training. Supervisors are responsible for providing Research Site Specific Training and 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, Room Q202, Subcommittee for Research Safety Administrative Coordinator, and
- (7) Ensuring attendance of research laboratory personnel at safety subcommittee meetings.

f. Employees: Employees involved in research are responsible for the following:

- (1) Applying safe work practices with a positive attitude toward 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) Ensuring that a MSDS is on file 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 Employee for record keeping and promptly reporting occupational illness and traumatic injuries to their supervisor.
- (6) Complying with safety and environmental rules and regulations for safe job performance and using and maintaining personal protective equipment when required.

g. Occupational Safety and Health: The VA Industrial Hygienist is responsible for ensuring annual occupational safety and health surveys are conducted on all VA-employed Research Service personnel working. The Hygienist will send annual surveys to SRS Administrator Coordinator for forwarding to researchers', veterinarian, and VMU Husbandry staff. UTHSCSA is responsible for conducting this annual survey for all their employees, including STVHCS WOC appointments.

h. Veterinary Medical Unit (VMU): Anyone entering VMU animal rooms must be escorted and don appropriate personal protective equipment provided by Husbandry Staff and removes it upon departure of animal rooms. The VMU Supervisor's office is also designated as a staff break area. Husbandry staff must remove PPE before entering VMU supervisor's office or departing VMU.

5. RESPONSIBILITY: ACOS Research

6. REFERENCES:

VHA Handbook 1200.8 *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*
- 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 Matters*. OSHA

*Biosafety in Microbiological and Biomedical Laboratories (5th Edition)*. CDC, NIH, 2007

*NIH Guidelines for Research Involving Recombinant DNA Molecules*, NIH, 2002

VHA Directive 1105.1, *Management of Radioactive Materials*, 2004

VHA Directive 2005-003, *Requirements for Submittal and Approval of Biosafety Level-3 (BSL-3) Research*

6. RESCISSION: Research Service Memorandum 05-2, Research Service Safety Program.

7. RECERTIFICATION: March 2011

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Research and Development