VA NEBRASKA-WESTERN IOWA HEALTH CARE SYSTEM
Omaha, NE (636)

SUB-COMMITTEE FOR RESEARCH SAFETY (SRS) STANDARD OPERATING PROCEDURES

A MANUAL

For

SRS Members, Principal Investigators, & Staff

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I. PURPOSE:

The purpose of the Subcommittee on Research Safety (SRS) is to review all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines.

II. POLICY:

It is NWIHCS and Omaha VA Medical Center's policy to comply with all applicable federal, state, and local regulations in the conduct of research activities involving biological, chemical, physical, and radiation hazards.

III. RESPONSIBILITY:

The SRS is responsible to the Medical Center Director through the ACOS/R&D and the Research and Development Committee for ensuring compliance with all applicable regulations, policies, guidelines, and standards of safety.

IV. MEMBERSHIP OF THE SRS:

A. Composition:

1. The SRS will have at least five members, exclusive of ex-officio members.

2. The SRS will include member(s) from the facility safety committee, the Institutional Animal Care and Use Committee (IACUC) and a representative from the Clinical Research Unit (CRU).

3. SRS members should possess expertise in:

a. Etiologic agents, including bloodborne and airborne pathogens

b. Recombinant DNA technologies

c. Chemical carcinogens and other chemical hazards

d. Physical and radiation hazards

B. Ex-Officio Members:

1. A liaison member from the local Research and Development (R&D) Committee (voting).

2. The Chemical Hygiene Officer, appointed by the Chief of Research Service (voting).

3. An AFGE union representative (voting).

C. Appointment of Members:

1. Recommendations for SRS membership are made by the ACOS/Research according to the needs of the SRS. The Medical Center Director officially appoints the members in writing. The length of initial appointments are not to exceed 3 years as specified in this letter.

2. The SRS Chair will be appointed by the Medical Center Director for the term of 1 year and may be re-appointed by the Medical Center Director without any lapse in service. The SRS Chair may not simultaneously chair the R&D Committee or another research subcommittee.

3. The Vice-Chair will be appointed by the Medical Center Director for the term of 1 year and may be re-appointed by the Medical Center Director without any lapse in service. The Vice-Chair will serve in the absence of the Chair.

D. Training:

Investigators, staff, volunteers, students, and WOC personnel – (who conduct research in VA or in VA leased space)

1. Mandatory and Annual Training:

a. Annual Research Safety Training;

b. Radiation Safety, Hazardous Materials, Bloodborne Pathogens, IACUC (if animal research). **TMS and CITI Training documentation should be provided to the Research Office upon request.**

2. Dangerous Goods Shipping Training (if applicable):

VA training package provided via TMS. DOT Training for shipping of hazardous materials via ground transportation must be completed every three years and IATA 1-5 Training for shipping via air transportation must be completed every two years. Employees that need DOT training are individuals performing these functions: Prepares packages of hazardous materials or hazardous waste for shipment (i.e. shipping biological specimens on dry ice); Prepares packages of regulated medical waste for shipment; or Prepares and/or signs hazardous waste manifests, medical waste tracking forms, or other shipping documents for hazardous materials shipments (shipping or receiving). **TMS documentation should be provided to the Research Office upon request.**

3. Training specific to procedures being done in individual laboratories is the responsibility of the Principal Investigator.

V. FUNCTIONS OF THE COMMITTEE:

A. Research Activities:

Review all research activities (unless exempted by Federal Regulation and as outlined in Section VI.E.5.) involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines, prior to submission for R&D review. This includes a review of all research applications that will be conducted at the VA facility or in VA leased space located off-site.

1. The review of the Research Safety Application, Biosafety & Chemical Risk Assessment Summary and the Form 10-0398 where applicable, must include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research.

B. Notification of SRS results:

SRS will provide written notification of the results of reviews to the R&D Committee, Medical Executive Committee (through R&D), and the Principal Investigator.

C. Conflict of Interest:

In general, members are considered to have a conflict of interest if they are participating in a proposed study as a principal or collaborating investigator, are a family member of an investigator, or if a financial arrangement, situation, or action affects or is perceived to exert inappropriate influence during the review of the research. Members with a conflict of interest relating to a study under review may not participate in any review involving that protocol except to provide information as requested by the SRS. They are required to disclose such interests, recuse themselves from deliberations and voting, and should leave the meeting room during the protocol discussion and vote. They are not counted towards quorum.

D. Risk Assessment:

The PI will complete a Biosafety & Chemical Risk Assessment Summary form for all new projects. The committee members confirm the appropriateness when they review the SRS Form. The Chemical Hygiene Officer reviews the chemical listingsection of the form to assure that the PI has listed appropriate precautions to be taken with chemicals used in the project.

VI. OPERATIONS OF THE COMMITTEE:

A. Meetings:

The SRS meets monthly to discuss all research activities involving biological, chemical, physical, and radiation hazards. The meetings require a quorum (majority of voting members present) and quorum must be maintained for each vote to occur.

B. Attendance requirements:

Committee members are expected to regularly attend meetings. When unable to attend, members should notify the SRS Coordinator, in advance when possible, to allow time to arrange an alternate member to attend as required and to maintain quorum. Alternate members attend as needed and/or requested.

C. Agenda:

An agenda is developed by the SRS Coordinator and SRS Chair and is distributed to members at least 1 week before the meeting. At a minimum, the agenda will include the following:

1. Quorum
2. Approval of minutes of the previous meeting (date)
3. Old Business (list pending items and individual(s) responsible)
4. New Business (list items and individual(s) responsible)
5. Miscellaneous items that warrant review/discussion by the committee
6. Research reviews (as applicable)

D. Minutes:

1. At a minimum, the minutes will include the following:

   a. Documentation of members present, absent, and excused, and the name of the presiding Chair.

   b. A statement regarding quorum being met.

   c. Identification of all conflicts of committee members as the protocol is reviewed.

   d. Review of business items, including discussion, action, responsibility, and status, as appropriate.

e. Copies of any internal or external reports or correspondence with outside agencies referenced.

2. Minutes will be written and distributed for review and approval by the SRS.

3. Once the minutes have been approved by the SRS, at a fully convened meeting, they will be forwarded to the R&D committee and the Environment of Care committee for review and approval. Recommendations for changes or improvements in SRS procedures may be made, but neither committee can alter the SRS minutes.

4. Minutes will be filed in the Research Office and made available to VA Central Office upon request.

5. In the event that an urgent situation arises that is not outlined in this SOP, the committee agrees that the Chair or designee will have the immediate responsibility to correct the situation. The Chair or designee will then report the situation to the committee at the next meeting and the committee will decide on a policy to handle the specific situation in the future. Emergency procedure manuals (Emergency Preparedness Plan and Chemical Hygiene Plan) are available in each laboratory to assist laboratory personnel for first response to emergency situations. If necessary, the Chair or designee will enlist additional personnel (ex. Infection Control) to gain advice in resolving the emergent situation.

E. Voting:

Research proposals and amendments which are determined to be reviewed and approved at a convened full committee meeting, the vote will include the number for, against, abstaining, recused, and excused. A quorum, consisting of a majority of all the voting SRS members, must be present to conduct official business of the committee. The SRS Chair can make a motion and vote. The SRS may vote for the following actions:

1. Approved – approval granted by the committee.

2. Contingently Approved – the committee will specify what is required for final approval of the protocol.

3. Tabled – an item may be tabled without review or discussion due to lack of quorum or for other reasons, as outlined in the minutes.

4. Disapproved – the proposal may be disapproved for major safety concerns. The PI will be notified of the reasons for disapproval, and will be given an opportunity to respond in writing to the SRS by a given deadline.

5. Exemptions – Research activities not involving biological, chemical, physical, or radiation hazards may be exempted from Safety continuing reviews by the SRS.

F. Review Policy:

Review of the SRS Application Form. All research projects involving biological, chemical, physical, and radiation hazards must be approved by the SRS (other subcommittees if applicable) and then by the R&D Committee prior to initiation of the research.

1. Initial Full Committee Review:

   a. All protocols/forms will be submitted to the SRS Coordinator by the 25th of the month.

   b. Once the SRS Coordinator has received the submission, the SRS Chair assigns two primary reviewers (members of the SRS) to review the entire protocol submission. Primary reviewers receive a copy of the full protocol. Committee members receive the application form, abstract, Biosafety & Chemical Risk Assessment Summary and the 10-0398.

   c. The SRS will review comments from all reviewers at the fully convened meeting. After the meeting, a Notification of Approval/Contingencies/Tabled letter will be sent to the Principal Investigator detailing any concerns of the committee members.

   d. The Principal Investigator responds to the Chair, <u>in writing</u>, addressing each item of concern. A signed hard copy of the revised document(s) should be attached, as applicable.

   e. After receipt of the revised application form or protocol, if approved, the Chair or designee will issue an approval letter and sign approval on the Safety Application.

   f. The appropriate signatures will be obtained on the Research Safety Application form after the SRS Chair or designee has signed the approval letter.

   g. The SRS is notified of the approval in the minutes of the next scheduled SRS meeting.

G. Annual Review of Research:

1. The SRS reviews information for all research involving biological, chemical, physical, and radiation hazards on an annual basis.

2. The date of continuing review will be based on the date of SRS approval.

3. The SRS Chair selects a committee member to review the Continuing Review submission. All members receive a copy of the renewal form and a current abstract.

4. After the meeting, a Notification of Approval/Contingencies letter will be sent to the Principal Investigator detailing any concerns of the committee members.

H. Closure of studies:

The closure of a study involving biological, chemical, physical, and radiation hazards will be initiated by the submission of an email or other correspondence with a request to close the study. The request will be reviewed and acknowledged by the SRS at a fully convened meeting.

I. Chemical Hygiene Plan:

The SRS is responsible for annually evaluating the effectiveness of the Chemical Hygiene Plan and making necessary revisions.

J. Personal Protective Equipment (PPE):

A PPE assessment must be completed and documented for each person in the laboratory. This Assessment should be reviewed by the PI annually and updated as needed.

K. Laboratory Inspections:

1. All research laboratories at Omaha VA Medical Center as well as VA leased space at the affiliates will be inspected annually for biohazards, and chemical and physical hazards.

2. Members of inspection teams will include a minimum of two SRS members.

3. Deficiencies noted during the inspections will be listed in a letter to the Principal Investigator. The PI must respond with a written corrective action plan by the deadline identified in the letter.

4. The list of deficiencies and the PI responses to these deficiencies are included in the agenda of the next scheduled SRS meeting. The report in the SRS minutes is reviewed by the R&D Committee.

L. Accident Reporting:

1. Injuries/accidents that occur in the research laboratory setting are reported to the immediate supervisor after individuals seek medical attention from Occupational Health or the Emergency Room.

2. If the injury involves radioisotopes, the RSO will be notified also.

3. Work-related health/safety issues such as latex allergies or ergonomic problems are reported to Occupational Health and the Safety Office.

4. Reports of incidents involving research personnel (occurring during the actual process of conducting research activities) are reported by the involved party and/or supervisor using ASISTS. Following the ASISTS process being completed, the ACOS and/or RAO make notification to the SRS prior to the next scheduled meeting.

5. The SRS is responsible for reviewing and evaluating accidents occurring within the Research Service and makes recommendations when necessary to the ACOS/R&D to prevent accidents from recurring.

6. The Research Chemical Hygiene Officer provides updates on exposure monitoring as necessary and reports to the SRS occurrences of exposures exceeding recommended values including a plan of action to remediate the occurrence.

M. Compliance:

1. Compliance Violations:

   a. Failure to file a complete and accurate Safety Application Form.

   b. Violations of safe laboratory practices (i.e. failure to complete mandatory training.)

   c. Failure to address deficiencies discovered during laboratory inspections.

   d. Failure to submit and complete and accurate Continuing Review request.

2. Notification:

   A written warning regarding the compliance issue will be sent to the PI. The letter will request a written corrective action plan be sent to the SRS Chair or designee by the deadline indicated (maximum 10 days).

3. Penalties for Noncompliance:

   If a corrective action plan is not received by the deadline identified, penalties commensurate with the severity of the violation could result in:

   a. Restriction of types of chemicals or biological agents that an investigator is authorized to use.

   b. Suspension of the research performed in the investigator's laboratory.

c. Restriction of personnel activities.

N. Laboratory Closures:

1. In addition to properly closing out all active research studies, the Principal Investigator should create a list of hazardous chemicals, biohazards, radioactive substances, freezer, refrigerator, and liquid N2 contents.

2. The Principal Investigator should send a letter to the SRS Chair indicating that:

   a. All experimental samples and laboratory solutions were properly disposed of;

   b. Arrangements have been made with the Safety Office to have all hazardous waste removed;

   c. Arrangements were made with the Radiation Safety Officer for a final laboratory check, and

   d. Arrangements have been made to disperse usable chemicals, cell lines, laboratory ware, and equipment to other on-site investigator laboratories. Chemicals not claimed are disposed of through the chemical hygiene officer.

   e. Personnel leaving the VA

O. Emergency Preparedness Plan:

The SRS Emergency Preparedness Plan follows the facility's Emergency Plan which addresses all types of threats or emergencies. These may include fires; explosions; spills; release of chemicals, biological agents, toxins or radioactive materials; bomb threats; severe weather and other natural disasters or emergencies. In addition to the Emergency Preparedness and Response Plan, the Research Chemical Hygiene Plan addresses research lab specific emergency contingencies. Included in this plan are personnel roles, training, escape procedures and emergency alerting and response procedures, emergency medical treatment and procedures for all employees during an emergency. Any radiation emergencies will be dealt with as recommended by the Facility 's Emergency Plan, Appendix 4 to Annex U, Radiation Exposure/ Contamination.

P. Security:

The Research Service (Bldg 15) will be locked 24/7. All visitors must

remain with their host party while in the building. Laboratories located in leased Affiliated University space will be expected to comply with the universities policies for security.

VII. REFERENCES:

1. SAFETY OF PERSONNEL ENGAGED IN RESEARCH. VHA HANDBOOK 1200.08.

2. Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH). Biosafety in Microbiological and Biomedical Laboratories 5th Edition. HHS Publication N. (CDC) 21-1112 Revised December 2009.

3. 42 C.F.R. Part 72, Interstate Shipment of Etiologic Agents (including, among others, 42 C.F.R. Part 72.2, Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements; 42 C.F.R Part 72.3, Transportation of materials containing certain etiologic agents; minimum packaging requirements; and Appendix A to Part 72, Select Agents). Add: This has been replaced by DOT regulations applicable to the transport in commerce of infectious substances. HHS replaced sections of Part 72 that deal with select biological agents and toxins with a new set of regulations found in HMR; 49 CFR Parts 171-177, Subchapter C – Hazardous Materials Regulations.

4. 29 C.F.R. Part 1910, Occupational Safety and Health Standards; Part 1910.38, Emergency Plans; Part 1910.134, Respiratory Protection; Part 1910.139, Respiratory protection for m. tuberculosis; Part 1910.269, Electric Power Generation, Transmission, and Distribution; Part 1910.1000, Air contaminants, Part 1910.1020, Hazardous waste operations and emergency response; Part 1910.1020, Access to employee exposure and medical records; Part 1910.1030, Bloodborne pathogens; Part 1910.1450, Occupational exposure to hazardous chemicals in laboratories.

5. 10 C.F.R. Chapter 1, Nuclear Regulatory Commission, Parts 0-199 (including, among others, 10 C.F.R. Part 19, Notices, instructions and reports to workers; inspections and investigations; Part 20, Standards for protection against radiation; and Part 35, Medical use of byproduct material).

6. 40 C.F.R. Chapter 1, Environmental Protection Agency (including, among others, Part 260, Hazardous waste management system; Part 261, Identification and listing of hazardous waste; Part 262, Standards applicable to generators of hazardous waste).

7. "National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules," NIH Guidelines. National Institutes of Health, November 2013 http://www4.od.nih.gov/oba.

VIII. ATTACHMENTS:

1. Research Safety Application

2. Biosafety & Chemical Risk Assessment Summary

3. Research Protocol Safety Survey, VA Form 10-0398

4. SRS Roster