

**SUBCOMMITTEE FOR RESEARCH SAFETY
PORTLAND VA MEDICAL CENTER**

STANDARD OPERATING PROCEDURES & POLICIES

CONTENTS

PARAGRAPH	PAGE
1. PURPOSE.....	1
2. DEFINITION OF HAZARD CATEGORIES.....	1
3. SCOPE of the SAFETY PROGRAM	2
4. RESPONSIBILITIES OF THE FACILITY DIRECTOR.....	4
5. RESPONSIBILITIES OF THE ACOS/R&D.....	5
6. RESPONSIBILITIES OF THE R&DC	5
7. RESPONSIBILITIES OF THE SRS.....	6
8. RESPONSIBILITIES OF THE PI OR LABORATORY DIRECTOR.....	8
9. CRADO RISK MANAGEMENT POLICIES.....	10
10. REFERENCES.....	11
Appendix A.....	13
Appendix B.....	15
Appendix C.....	17
Appendix D.....	19
Appendix E.....	20
Appendix F	21

SUBCOMMITTEE FOR RESEARCH SAFETY STANDARD OPERATING PROCEDURES AND POLICIES

1. PURPOSE

a. To define the standard operating procedures (SOP) and policies used by the Subcommittee for Research Safety (SRS) and by the laboratory research Principal Investigators (PIs) that serve as the guidelines to ensure proper oversight and implementation of the research laboratory safety program at the Portland VA Medical Center (PVAMC). These activities involve oversight of procedures that use potential hazards encountered in the research setting, including, but not limited to:

- (1) Biohazards, such as:
 - (a) Pathogens and etiologic agents corresponding to Biosafety Levels (BSL) 1-3, and
 - (b) Organisms and viruses containing recombinant deoxyribonucleic acid (DNA) molecules.
- (2) Chemical hazards.
- (3) Physical hazards.

NOTE: This document covers safety issues in research laboratories. It is not intended to replace general occupational safety and health policy applicable to all Department of Veterans Affairs (VA) employees, whether or not involved with research, or to replace specific regulatory programs mandated by law. This handbook should be used in conjunction with the Research Chemical Hygiene Plan (CHP), which further defines the role of various executive, administrative, laboratory research personnel at the PVAMC.

2. DEFINITION OF HAZARD CATEGORIES

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

- (1) Pathogens and etiologic agents, human and non-human primate tissues including blood and body secretions, and human cell lines corresponding to BSL 1-3;
- (2) Toxins produced by microbial organisms, plants, or animals;
- (3) Poisonous, toxic, parasitic, and venomous animals or plants;
- (4) Recombinant DNA molecules;
- (5) Select agents, as specified in Title 42 Code of Federal Regulations (CFR) Part 73; 7 CFR 331; and 9 CFR 121; and
- (6) Animals experimentally or naturally exposed to any of the preceding agents.

b. **Chemical Hazards.** Chemical hazards include any substance or mixture of substances with properties capable of producing adverse effects on the health and safety of humans. Chemical hazard categories include, but are not limited to, the following:

- (1) Corrosives;
- (2) Toxic substances (poisons, irritants, asphyxiates);
- (3) Sensitizers;
- (4) Carcinogens, mutagens, and teratogens;
- (5) Flammables; and
- (6) Explosives.

c. **Physical Hazards.** Physical hazards include, but are not limited to, the following:

- (1) Ionizing and non-ionizing radiation,
- (2) Noise,
- (3) Vibration,
- (4) Extremes of temperature and pressure,
- (5) Explosive hazards,
- (6) Electrical hazards, and
- (7) Mechanical hazards.

3. SCOPE of the SAFETY PROGRAM

a. Research laboratories are included in the medical center occupational safety and health program. The role and responsibilities of the Research Office is defined within this program. VA facilities with research laboratories must maintain a Research Safety Program that is consistent with VA policies, Federal statutes and regulations from Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Nuclear Regulatory Commission (NRC), etc., and any applicable State and local requirements. All applicable National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) guidelines also must be followed.

(1) **Biohazards.** The combined Research Service Chemical Hygiene Plan and Laboratory Safety Manual (CHP) serve as the service-wide safety manual. This document is prepared by the PVAMC Facilities Management Service, and is reviewed/approved by the SRS annually. It includes a description of biohazard controls (e.g., use procedures, engineering, and personal protective equipment), emergency procedures, and an emergency cascade phone list specific to the facility. This document must be reviewed, updated as needed, and approved annually by the SRS and forwarded to the Research and Development Committee (R&DC) for final approval. Individual laboratories must adhere to the CHP and CDC/NIH safety and health guidelines. Those laboratories that work at BSL-3 containment must maintain a separate, written, regularly updated laboratory manual that includes standard operating and emergency procedures, referencing, but not limited to: spills, power outages, or breaches of security.

(a) **Bloodborne Pathogens.** The risk of exposure to bloodborne pathogens will be minimized in the research setting by ensuring that all research personnel are aware of, and use, universal precautions in the handling of biologic fluids of any type according to the specifications of the Bloodborne Pathogen Standard. Similarly, the risk of exposure to airborne pathogens must be minimized and strict adherence to all applicable Federal statutes, regulations, policies and guidelines must be rigorously upheld.

(b) **Recombinant DNA Research**

1. VA investigators planning to conduct recombinant DNA research must comply with the NIH Guidelines for Research involving Recombinant DNA Molecules, regardless of the source of research funding.

2. VA investigators should note that all funded and unfunded projects and proposals must be reviewed and approved according to the procedures described in the NIH Guidelines for Research involving Recombinant DNA Molecules.

Note: At the present time the SRS is not registered under the NIH Guidelines for Research involving Recombinant DNA Molecules as an Institutional Biosafety Committee. Therefore, the NIH-registered IBC at the affiliate university provides review and oversight of the studies regulated by the NIH Guidelines for Research involving Recombinant DNA Molecules. Review occurs through a memorandum of understanding (MOU) agreement. The service provided by the affiliate university IBC does not absolve the SRS or the R&DC for oversight responsibility.

3. The current policy to ensure adequate SRS review of projects using recombinant DNA is as follows: The initial determination is from evaluation of Part B of the Project Safety and Hazard Assessment (PSHA) form that queries investigators whether their project uses recombinant DNA; all investigators complete the PSHA for all projects, for initial review. Investigators answering “yes” are directed to the OHSU IBC to obtain either approval, or an exemption. Investigators can determine whether their project is exempt without OHSU IBC review. However, that designation is reviewed at the SRS, and investigators may be asked to confirm that status through OHSU IBC review. Any PSHA received by the SRS Coordinator indicating that a recombinant DNA component is not exempt from OHSU IBC review, but does not include OHSU IBC approval documentation, will not be submitted to the SRS for review, and thus the PVAMC SRS will not review any project with a recombinant DNA component without supporting OHSU IBC documentation. After the OHSU IBC has granted approval (or determined exemption) for use of recombinant DNA, a signed approval letter is sent to: the Principal Investigator (PI), the Chair of the SRS, and the Coordinator of the SRS. It is the responsibility of the PI to submit the document to the SRS. The second determination for evaluation of recombinant DNA use is that during the SRS review process, reviewers must indicate in question 3 of the Reviewer Checklist whether: the project involves recombinant DNA, and if so, was OHSU IBC approval required, and if yes to that, has OHSU IBC approval been granted, and have all salient documents been submitted for SRS review.

- (2) **Hazardous Chemicals and Waste.** Policies relating to the management of hazardous chemicals and waste is provided in the CHP. However, the research laboratory program must ensure that all Federal and State occupational safety and health, transportation and shipping, and environmental regulations are adequately addressed.
- (3) **Physical Hazards.** Physical hazards are addressed in the Research Safety program to minimize risk and ensure regulatory compliance. Routine laboratory inspections by facility safety personnel and research safety personnel must include a review of all potential physical hazards. As needed, inspections must be coordinated with program managers and technical

experts such as the Radiation Safety Officer and the Chemical Hygiene Officer (CHO).

b. Off-Site Management of Biohazardous Materials

- (1) The provisions of this document apply to all research that is conducted completely or partially in VA facilities, conducted in approved off-site locations and facilities, or conducted by VA researchers while on VA official duty time. The research may be VA funded, funded from non-VA sources, or conducted without direct funding. As a minimum, facility safety personnel must verify that other or remote facilities adhere to health and safety standards that are equivalent to VA standards.
- (2) The VHA Handbook 1200.8 (Safety of Personnel Engaged in Research) requires that VA-funded research activities of all off-site investigators be appropriately reviewed for the use of biohazardous materials. The SRS is directly responsible for seeing that the review of off-site research takes place, and that this review is documented and duly reported to the R&DC for final approval. Off-site investigators must be aware that they must adhere to VA safety standards including applicable NIH/CDC Guidelines.

4. RESPONSIBILITIES OF THE FACILITY DIRECTOR

The Facility Director is responsible for:

- a. Ensuring that the research safety program is staffed adequately and that resources are available to maintain full compliance with all applicable regulations and standards of safety.
- b. Ensuring that all Research personnel are included in the facility Occupational Safety and Health program and that research space is included in annual workplace inspections.

NOTE: Research personnel must be covered by all other facility safety programs (e.g., the Respiratory Protection program, the Fire Safety program, etc.)

- c. Ensuring the resolution of any facilities-related deficiencies identified in inspections.
- d. Providing engineering support in conducting ventilation maintenance and validation of required specifications.
- e. Ensuring technical assistance is provided by facility safety and health professionals as needed.
- f. In cooperation with the Associate Chief of Staff (ACOS) for R&D, ensuring that measures for the security of the research laboratories and surrounding space is developed and maintained.
- g. Providing adequate administrative support for the SRS, including:
 - (1) Space sufficient to provide privacy for conducting sensitive duties related to biosafety,
 - (2) The personnel to support the review and record-keeping functions of SRS, and
 - (3) Support for the timely preparation of investigator correspondence and other documents.
- h. Ensuring the proper reporting of problems in research as directed by VHA Handbook 1058.01.

5. RESPONSIBILITIES OF THE ACOS/R&D

The ACOS/R&D is responsible for:

- a. Ensuring that safety-related communications from the Chief Research and Development Officer (CRADO) are disseminated to appropriate personnel on time after receipt.
- b. Ensuring the responses to safety “holds.”
- c. Ensuring that research activity ceases until a particular “hold” is lifted.
- d. Ensuring continuous development and evaluation of performance standards of the Research Safety program.
- e. Notify Investigators when the appropriate approvals have been obtained and the project can begin.
- f. Ensuring the proper reporting of problems in research as directed by VHA Handbook 1058.01.

6. RESPONSIBILITIES OF THE R&DC

- a. The R&D Committee must establish either an SRS or multiple subcommittees, as needed, to deal with different aspects of research safety. In some instances alternate safety oversight and review mechanisms may be developed with an affiliate safety committee or committees. Pre-approval by the CRADO is required to use such an alternate mechanism. The alternate mechanism does not absolve the R&D Committee from any responsibilities related to the SRS functions. If using the services of an external subcommittee, VA interests must be adequately represented by the inclusion of at least one VA employee with appropriate qualifications.
- b. The SRS must meet the requirements found in Appendix B.
- c. Reviewing and acting upon SRS minutes.
- d. Appointing a Biological Safety Officer, if research is conducted at the facility involving:
 - (1) The use of recombinant DNA requiring BSL 3 biocontainment, or
 - (2) Large scale (greater than 10 liters of culture) research or production activities involving viable organisms containing recombinant DNA molecules.

NOTE: These activities may require oversight by an NIH-registered IBC, as mandated by the NIH Guidelines for Research Involving Recombinant DNA.

- e. Ensuring the development and implementation of the laboratory CHP.
- f. Appointing a Chemical Hygiene Officer (CHO) to provide technical guidance on the implementation of the Plan. The CHO should be a standing member of the SRS.
- g. Overseeing compliance with VHA Handbooks 1200.08 and 1200.06 by PIs conducting research at the facility.
- h. Ensuring the development and implementation of safety protocols by the PI for individual research projects as needed.
- i. Ensuring that the Research Service Office provides support to the SRS to assist in their functions.
- j. Ensuring that the minutes of SRS meetings are documented correctly, and maintained by the Research Office.

- k. Providing the ACOS/R&D, and facility or Veterans Integrated Service Network (VISN) safety officials, with adequate information to evaluate the performance of the R&D safety program.
- l. Ensuring coordination with other regulatory programs or committees such as the Radiation Safety Officer or Radiation Safety Committee.
- m. Reviewing accident and injury trends reported by SRS, and recommending and ensuring the implementation of corrective action.
- n. Reviewing all citations issued by regulatory agencies and ensuring that appropriate committee members and PIs take prompt corrective actions, and coordinating the necessary responses to regulatory agencies.

7. RESPONSIBILITIES OF THE SRS

The SRS is responsible for:

- a. Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines. This includes a review of all research applications that will be conducted at the VA facility or by VA personnel located off-site.
 - (1) Review and approval of all research projects involving biological, chemical, physical, and radiation hazards is to occur prior to a project's commencement. For the review process the forms VA 10-0398, Research Protocol Safety Survey (RPSS), and/or the local Portland VA Medical Center's Project Safety and Hazard Assessment Form, SRS Continuing Review Form, or SRS Project Amendment Form (see Appendices E and F) are used. These forms evaluate, among other items, a risk assessment of the facilities, level of containment, laboratory procedures and practices, and training and expertise of personnel involved in the specific research conducted, including recombinant DNA research.
 - (2) The SRS must review proposed research projects at convened meetings at which a quorum (majority of voting members) is present. **NOTE:** For the research to be approved, it must receive the approval of a majority of those voting members present at the meeting. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the protocol will not be reviewed, issues requiring a vote will not be closed, and non-protocol related issues may be discussed at the discretion of the Chair.
 - (3) The SRS reviews all projects requiring a safety review at project inception (initial review), annually (continuing review), or through an amendment process. The review cycle for projects is annually and is determined by the date of approval of the initial review. (i) The review process for initial review requires that investigators submit a Program Safety & Hazard Assessment Form (including salient appendices) and a project abstract. SRS Reviewers present a description and evaluation of the project. Following any subsequent and appropriate subcommittee discussions, members of the SRS vote for approval or disapproval based on whether they believe that: (1) the work can be done safely, (2) the benefit of the knowledge outweighs the potential risks to research staff, and (3) there are no scientific or ethical concerns. (ii) For continuing reviews investigators submit a SRS Continuing Review Form that

specifically queries if any changes have been made during the previous 12 months to the chemicals used or the experimental protocols conducted, including possible use of BSL2 agents, radioactive materials, or rDNA. If no changes have been made the project can be reviewed through a designated process and approved to continue for 12 months, with those results presented at the next SRS meeting. If any changes have been made or changes are proposed, the investigator is directed to also complete a SRS Project Amendment Form for review and approval at the next SRS meeting. A continuing review with an included amendment can also follow the designated review process and the results will be presented at the next available SRS meeting. However, the SRS Chair may decide that designated review is not sufficient, and then the project will be reviewed in full committee. (iii) Investigators can also submit amendments to their projects at any time using only the SRS Amendment Form, as described above.

- b. Providing written notification of the results of the SRS review to the R&D Committee, the Research Office, and the PI.
- c. Reviewing annually all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review is based on the date of the initial SRS approval. Research protocol changes not included in the original application must be documented on an SRS Project Amendment Form and must be submitted to and reviewed by the SRS prior to the implementation of the changes. See 7.a.(3).
- d. Ensuring that a complete list of all products containing chemicals designated or identified by OSHA or EPA as “hazardous” has been reviewed and approved by the Safety Officer prior to final approval by the SRS.
- e. Coordinating all safety-related activities in research laboratories including mandatory and non-mandatory training, safety inspections, accident reporting, and liaison activities with all facility safety committees and officials to include:
 - (1) Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and
 - (2) Reporting follow-up results to the R&DC.
- f. Reporting operational problems or violations of directives to the Research Office within 30 days of occurrence or detection, unless the SRS determines that the PI has previously filed a report.
- g. Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising the R&DC and Employee Health Practitioner on the need for such surveillance.
- h. Maintaining adequate documentation of all the SRS or equivalent subcommittee activities.
- i. Forwarding minutes of the SRS to the Research Service Office.
- j. Ensuring that all laboratory personnel receive annual general and research-specific safety training. Because completion of mandatory annual safety training is critical for research personnel, the Research Office has a staff member whose responsibility is dedicated to monitoring and notifying staff of their training status.
 - (1) On the last Monday of the month a report will be generated to identify individuals that have: (a) not completed their training in the past year (and are

- thus “delinquent,”) and (b) their training requirements will expire in the upcoming month. All PIs will be notified with the expectation that they direct their staff to complete their required training modules prior to expiration. The PI will also be asked to respond via email if any staff listed are no longer active. This report is evaluated monthly, and any carry-over delinquencies will be highlighted and reported at the next SRS meeting.
- (2) Research personnel who have not completed their required training after the supervisors have received two notices will have their access to all research space “de-activated.”
 - (3) Personnel access to the research areas may be restored once training has been completed.
- k. Holding SRS meetings monthly, and at least quarterly as a minimum.
 - l. Ensuring coordination with other regulatory programs, personnel, or committees such as the Radiation Safety Officer or Radiation Safety Committee.
 - m. Ensuring the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.
 - n. Evaluating annually the effectiveness of the laboratory’s CHP and making necessary revisions.
 - o. Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.
 - p. Ensuring the proper reporting of injury and illness trends to the R&DC, as appropriate.
 - q. Requesting, when appropriate, the appointment of an *ad hoc* committee (consisting of members with appropriate expertise) to investigate and report on occupational injuries, illnesses, and adverse environmental events.
 - r. Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records and environmental records (i.e., hazardous waste, air monitoring).
 - s. Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.
 - t. Providing technical assistance, where appropriate, in recycling programs and in the reduction of the quantity of hazardous and infectious waste generated by the research laboratories.
 - u. Ensuring the proper reporting of problems in research as directed by VHA Handbook 1058.01.

8. RESPONSIBILITIES OF THE PI OR LABORATORY DIRECTOR

The key element in the PVAMC biosafety program is the Principal Investigator (PI), who is primarily and ultimately accountable for individual research biosafety compliance. The PI or Laboratory Director is responsible for all research activities conducted in her/his assigned space, including:

- a. Submitting an accurately completed VA Form 10-0398, a Project Safety and Hazard Assessment form, a SRS Continuing Review Form, or a SRS Project Amendment Form (as appropriate) to the Research Service Office along with each research proposal. The Project Safety and Hazard Assessment form

includes a complete list of chemicals defined as “hazardous” to be used and must be specific for each research proposal.

NOTE: Not submitting such a list will result in failure to obtain approval by the facility Safety Officer. Review and approval by the Safety Officer is required prior to local review of protocols by the R&D Committee.

NOTE: This chemical inventory is reviewed and maintained locally by the Laboratory Director.

- b. Project Safety and Hazard Assessment forms, SRS Continuing Review Forms and SRS Project Amendment Forms (and applicable attachments) will be submitted exclusively electronically (to the PVAMC managed email box research.grants@va.gov). SRS forms for review will be accepted when they are sent from the Principal Investigator’s email address.
- c. Ensuring that active protocols have been reviewed by SRS, regardless of funding status or source; a review of all research activities requires:
 - (1) Submission, for SRS review and approval, of a Project Safety and Hazard Assessment form, a SRS Continuing Review Form or a SRS Project Amendment Form for all activities involving wet research laboratory activities..
 - (2) Acquiring and maintaining approval (if necessary) for studies involving non-exempt use of recombinant DNA from the affiliate university [see ¶3.a.(1)(b)3]
 - (3) Submission, for SRS and R&D Committee review and approval, of a BSL3 Laboratory Access and Use Form by all laboratory personnel requesting initial access to the BSL3 Laboratory to conduct research laboratory or support activities.
- d. Identifying laboratory specific hazards, and:
 - (1) Ensuring that all personnel receive training specific to the hazard(s). See item 7.j. above.
 - (2) Advising laboratory personnel of any potential risk to themselves or the research environment.
 - (3) Establishing and enforcing standards of practice which minimize employee exposures to biological, chemical, physical, and radiation hazards.
- e. Supervising the performance of the laboratory staff to ensure the correct use of required safety practices and techniques (including personal protective equipment).
- f. Ensuring that Biological Safety Cabinets are certified annually in conjunction with Facilities Management Service.

NOTE: In research settings involving airborne pathogens, certification must be performed on a semi-annual basis.

- g. Reporting problems and concerns about operation and containment practices and procedures to the, Facility Safety Officer, Veterinary Medical Officer (VMO) or Veterinary Medical Consultant (VMC) (if applicable), Radiation Safety Officer (if applicable), and other appropriate authorities.
- h. Ensuring that all accidents are reported to the Employee Health Office and the facility safety office using appropriate VHA forms.
- i. Securing approval of the SRS for any significant changes made in the original research plan.

- j. Coordinating with appropriate safety staff such as the Radiation Safety Officer for removal or disposal of all chemicals, biological agents, radioisotopes, and waste generated by these materials.
- k. Notifying all pertinent personnel prior to departure from the laboratory.
- l. Notifying all pertinent personnel prior to relocating the research laboratory space.
- m. Ensuring that a copy of the laboratory's CHP is readily available to all employees in their work area, that employees have been trained in the contents of the Plan, and that all provisions of the Plan are implemented in all laboratories under the PI's supervision.
- n. Maintaining employee exposure to hazardous chemicals in laboratory activities at the lowest possible levels. At no time may employee exposures to chemicals exceed the Permissible Exposure Limits established by OSHA.
- o. Maintaining an up-to-date inventory of all hazardous chemicals located in the laboratory.
 - (1) Ensuring that all laboratory personnel know the location of this inventory.
 - (2) Providing this inventory to the facility Safety Officer.
 - (3) Updating material safety data sheets on the VISN 20 online database (<http://www.portland.va.gov/research/>) .
- p. Managing all biological and chemical waste in accordance with Federal, State, and local regulations and all VA, VHA, and facility policies.
 - (1) Seeking technical assistance when needed to ensure proper waste management.
 - (2) Implementing waste reduction techniques, where appropriate.
- q. Investigating the deficiencies cited during all inspections of work areas. Submitting a written abatement plan for all deficiencies cited during inspections to SRS.
- r. Ensuring the proper reporting of problems in research as directed by VHA Handbook 1058.01.

9. CRADO RISK MANAGEMENT POLICIES

The CRADO is responsible for:

- a. Requiring the review of mandatory safety surveys by the Biosafety Office prior to release of funding for any approved research proposals.

NOTE: Alternate safety surveys may be submitted following a complete audit and approval of the local research safety program by the CRADO.

- b. Establishing standards for acceptance or non-acceptance of submitted forms. The following is required:
 - (1) VA Form 10-0398 is required for all submissions for funding.
 - (2) Title of submission must correspond to the title listed on the form.
 - (3) Information, including negative responses, must be completely and accurately entered on the form. No blank fields will be acceptable for submission.
 - (4) All authorized signatures and dates must be present and approval must be within 12 months of submission.

NOTE: Failure to meet these standards will result in an administrative "hold."

- c. Establishing procedures for the field to respond to a Hazard "hold."

- (1) The VA medical center receiving notification of the “hold” must respond within 12 weeks of receipt.
- (2) Responses must be forwarded to the ORD service that placed the hold.
- (3) Resubmission of a research proposal does not qualify as a response, and will result in an automatic “hold.” Review for that funding cycle will proceed, but the application will not be reviewed in the following cycle until a response to the original “hold” has been received and approved by the Biosafety Office.
- d. Requesting copies of SRS meeting minutes for review. The Biosafety Office must review SRS minutes.
- e. Scheduling site visits when operational deficiencies in the safety program are detected following new construction or renovation, or as appropriate. Failure to correct deficiencies will result in withholding research funds.
- f. Responding to a CDC notice of failure to comply with the Select Agent Laboratory Registration Program. This is accomplished by a site visit or by withholding research funds or both for the specific research program. Failure to correct deficiencies will result in withholding research funds.

10. REFERENCES

- a. CDC-NIH. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. CDC-NIH, Washington, DC, 2007
<http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>.
- b. Title 42 CFR Part 73
- c. Title 7 CFR 331
- d. Title 9 CFR 121
- e. Title 29 CFR Part 1910, Occupational Safety and Health Standards
 - (1) CFR 1910.38, Emergency Actions Plans
 - (2) CFR 1910.39, Fire Prevention Plans
 - (3) CFR 1910.269, Electric Power Generation, Transmission, and Distribution
 - (4) CFR 1910.1000, Subpart Z – Toxic and Hazardous Substances
 - (5) CFR 1910.1020, Access to Employee Exposure and Medical Records
 - (6) CFR 1910.1030, Bloodborne Pathogens
 - (7) CFR 1910.1200, Hazard Communication
 - (8) CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories
- f. Title 10 CFR Chapter 1, Nuclear Regulatory Commission, Parts 0-199
 - (1) CFR 19, Notices, Instructions and Reports to Workers; Inspections and Investigations
 - (2) CFR 20, Standards for Protection Against Radiation
 - (3) CFR 35, Medical Use of Byproduct Material
- g. Title 40 CFR Chapter 1, Environmental Protection Agency Parts 1-1299
 - (1) CFR 260, Hazardous Waste Management System: General
 - (2) CFR 261, Identification and Listing of Hazardous Waste
 - (3) CFR 262, Standards Applicable to Generators of Hazardous Waste
- h. “National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules,” NIH Guidelines. National Institutes of Health, Bethesda, MD, May 11, 1999 <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

- i. VHA Directive 1105.1, Management of Radioactive Materials
<http://www1.va.gov/vhapublications/index.cfm>
- j. VHA Handbook 1105.1, Procedures for Management of Radioactive Materials
<http://www1.va.gov/vhapublications/index.cfm>
- k. VA Directive 7700, Occupational Safety and Health
<http://www1.va.gov/vhapublications/index.cfm>
- l. National Council on Radiation Protection and Measurements reports:
 - (1) Number 107, Implementation of the Principle of As Low as Reasonably Achievable (ALARA) for Medical and Dental Personnel (Bethesda, MD, 1990)
<http://www.ncrponline.org/Publications/Publications.html>, and
 - (2) Number 116, Limitation of Exposure to Ionizing Radiation (Bethesda, MD, 1993) <http://www.ncrponline.org/Publications/Publications.html>
- m. VHA Handbook 1058.01, Research Compliance Reporting Requirements

Appendix A

INFECTIOUS DISEASES RISK ASSESSMENT

1. RISK. Risk implies the probability that harm, injury, or disease will occur. In the context of the microbiological and biomedical laboratories, the assessment of risk focuses primarily on the prevention of laboratory-associated infections. Choosing the proper level of containment is very important to reduce the employee's and the environment's risk of exposure to an agent to an absolute minimum. Risk assessment can be quantitative or qualitative. If the hazard is known (e.g., residual levels of formaldehyde gas or hydrogen peroxide vapors after a laboratory decontamination), a quantitative assessment is possible. For the most part, it is not possible to do a quantitative assessment of biohazardous agents. A number of factors and considerations for a qualitative risk assessment follow:

2. ASSESSMENT OF RISK. The Laboratory Director or Principal Investigator (PI) is responsible for assessing risks.

a. **Factors of Interest.** The factors of interest must include:

- (1) Pathogenicity of the infectious or suspected infectious agent,
- (2) Route of transmission,
- (3) Agent stability,
- (4) Infectious dose,
- (5) Concentration,
- (6) Origin,
- (7) Availability of data from animal studies,
- (8) Availability of an effective prophylaxis,
- (9) Medical surveillance, and
- (10) An evaluation of experience and skill level of at-risk personnel.

b. **Materials Containing Known Infectious Agents.** Use the:

- (1) Information obtained from laboratory investigations, disease surveillance, and epidemiological studies.
- (2) Infectious agents listed in Agent Summary Statements (Section VII) of Biosafety in Microbiological and Biomedical Laboratories 5th Edition and American Public Health Association's manual, Control of Communicable Diseases.

c. **Materials Containing Unknown Infectious Agents.** Questions to be considered in establishing the appropriate biosafety level include:

- (1) Why is an infectious agent suspected?
- (2) What epidemiological data is available?
- (3) What route of transmission is indicated?
- (4) What is the associated morbidity or mortality rate or both?
- (5) What medical data is available?

d. **Materials Containing Recombinant Deoxyribonucleic Acid (DNA) Molecules.**

NOTE: This includes microorganisms that have been genetically modified through recombinant DNA technologies.

- (1) Use the appropriate reference for establishing appropriate biosafety level: NIH Guidelines for Research Involving Recombinant DNA Molecules.
- (2) Evaluate the potential increased biohazard associated with a particular genetic modification.
- (3) Select the appropriate biosafety level beginning with the classification of a non-modified virus. Carefully consider the nature of genetic modification and quantity of virus when selecting the appropriate biosafety level.
- (4) Consider the following points:
 - (a) Does the inserted gene encode known toxin or relatively uncharacterized toxin?
 - (b) Does the modification have the potential to alter the host range or cell tropism of virus?
 - (c) Does the modification have the potential to increase the replication capacity of virus?
 - (d) Does viral DNA integrate into the host genome?
 - (e) What is probability of generating replication-competent viruses?

e. **Materials that May or May Not Contain Unknown Infectious Agents.** Always use universal precautions when there is no information that an infectious agent is suspected.

f. **Animal Studies.** Animal studies:

- (1) May present many different kinds of physical, environmental, and biological hazards.
- (2) Are unique according to species involved and the nature of the research.
- (3) Need to focus on the animal facility's potential for increased exposure to both human pathogens and to zoonotic agents.
- (4) Need to consider that latent infections most common in field-captured animals or animals that come from unscreened herds.
- (5) Must consider animal routes of transmission.

NOTE: The described risk assessment process also applies to laboratory operations other than those involving use of primary agents of human disease such as chemical hazards.

Appendix B

INFRASTRUCTURE OF SRS

1. NUMBER AND QUALIFICATION OF MEMBERS

- a. The SRS must have at least five members, exclusive of *ex-officio* members. The SRS must include at least one member not affiliated with the VA Research Service; e.g., a member from the affiliate institution.
- b. It is usually necessary for the SRS membership to possess expertise in:
 - (1) Etiologic agents, including bloodborne and airborne pathogens.
 - (2) Chemical carcinogens and other chemical hazards.
 - (3) Physical and radiation hazards.
- c. It is recommended that at least one SRS member possesses specific occupational safety and health, environmental, and Department of Transportation expertise to ensure that all pertinent hazards in protocols are identified. It is also advisable this member have first-hand knowledge of the space and facilities assigned to each PI to ensure that research operations can be conducted safely.
- d. It is highly desirable that the Veterinary Medical Officer, Veterinary Medical Consultant, Veterinary Medical Unit representative, or a member of the IACUC be appointed to SRS.

2. EX-OFFICIO MEMBERS. Ex-officio members must include:

- a. A liaison member from the local R&DC (voting).
- b. The Chemical Hygiene Officer (appointed by the R&DC) (voting).
- c. The Administrative Officer (AO) for R&D or other non-voting representative from the Research Service office.
- d. An employee union safety representative, or other union designee, whose voting status is determined by the applicable union contract or R&DC.

3. APPOINTMENT OF MEMBERS

- a. SRS members and R&DC members forward the names of nominees for membership in the SRS to the medical center Director. The medical center Director must officially appoint members in writing, to a term not to exceed three years. Members may be reappointed without a lapse in service.
- b. The medical center Director appoints the SRS chairperson for the term of 1 year. And they may be re-appointed annually without any lapse in time. However, the SRS chairperson may not simultaneously chair the R&D Committee or another research subcommittee.
- c. Specific *ex-officio* voting members (1) the Veterinary Medical Officer, (2) the Chemical Hygiene Officer, (3) the Radiation Safety Officer, are subcommittee members because of their medical center position. Therefore, renewal of these individuals' appointments are not required.

4. REPRESENTATIVES FROM OTHER MEDICAL CENTER COMMITTEES AND OFFICES. Under a MOU agreement with the affiliate institution, a member of the affiliate institution's IBC serves as a voting member of the SRS.

5. RESEARCH COMPLIANCE OFFICER AND THE SRS.

- a. Per VHA Handbook 1058.01, Research Compliance Reporting Requirements. The Research Compliance Officer (RCO) is an individual whose primary responsibility is auditing and reviewing research projects and does not serve as a voting or nonvoting member of the SRS. The RCO may be invited to attend the SRS meeting as a guest.

Appendix C

FORMAT FOR SUBCOMMITTEE FOR RESEARCH SAFETY MEETING AGENDAS AND MINUTES

Agendas and minutes of the Subcommittee for Research Safety (SRS) must be prepared according to the following format.

1. AGENDA. An agenda is to be developed before each SRS meeting and distributed to SRS members at least 3 working days before the meeting. At a minimum, the agenda is to include:

- a. **Approval of Minutes.** Approval of minutes of previous meeting (date).
- b. **Unfinished Business.** List pending items and individual responsible.
- c. **New Business.** Identify individual responsible when necessary.
 - (1) **Standing Recurring Reports.** Identify individual responsible.
 - (2) **Issues.** Any issues not previously addressed by the body.
 - (3) **Other.** Any other item that warrants review or discussion by the committee and is not routinely reviewed by the committee.
- d. **Announcements.**
- e. **Next Meeting.** Date, time, and place of the next meeting.

2. MINUTES. Minutes of all the SRS meetings must be prepared according to the following format.

- a. Identification of the subcommittee to be centered at the top of the page, including the Department of Veterans Affairs (VA) medical center name and number.
- b. The first paragraph is to include:
 - (1) Place, date, and time of the meeting.
 - (2) Name of presiding officer (chairperson).
 - (3) The attendance record, which must list all individuals identified as members. Members are to be marked "Absent," if the Chairperson or recorder has not been notified in advance. Members are to be marked "Excused," if the Chairman or recorder was notified in advance. For each member, note their role on the committee and whether they are voting or nonvoting.
 - (4) Indication that a quorum is present.

NOTE: A quorum is defined as more than 50 percent of the voting members are present.

- c. Succeeding paragraphs are to identify the recommendations, date of the meeting when the recommendation was initially made, action taken to date or a realistic date to expect resolution, and the status as "Closed" or "Pending." For each project under consideration, list the name of the Principal Investigator (PI) and the complete name of the project.

NOTE: A recommendation is not to be carried for more than two meetings awaiting a resolution unless there is clear documentation that a plan of action is being followed and an anticipated date for resolution is noted.

- d. Minutes are not to be recorded verbatim except for recommendations; however, the substance of the discussion is to be reported clearly and concisely. After summation of the discussion, the minutes must reflect:
 - (1) **Conclusion.** This indicates what was concluded from the discussion; for example, “The follow-up action plan was ineffective, and the issue is not considered resolved at this time.” If analysis of the data occurred in the meeting, then the conclusion of the analysis needs to be in the minutes.
 - (2) **Recommendation.** This includes who or what is expected to change.
 - (3) **Action.** This includes what action is appropriate in view of the cause, scope, and severity of the problem, and who is responsible for implementing the action.
 - (4) **Follow-Up or Evaluation.** This identifies the date a status report is due on the action plan, the date the action plan will be implemented, or the date the action plan will be evaluated for accomplishment of expected outcome or impact of the changes made.
- e. For each new project, the motion passed by the committee (approved, approved pending clarification, deferred, disapproved) must be recorded with the exact vote; this must include the number voting for the motion, the number voting against the motion, and the number abstaining from voting on the motion.

NOTE: The motion needs to be worded in such a way that it is clear which members will review revisions and have the authority to grant approval.

- f. The minutes must note which members excused themselves from voting on which project(s) to prevent conflicts of interest.
- g. Copies of any internal or external reports or correspondence with outside agencies referenced in the minutes need to be attached to the minutes if they are important to understanding the conduct of business.
- h. SRS members having a scientific or monetary conflict of interest for the protocol under consideration may provide information helpful to the SRS prior to deliberations, but must excuse themselves from the meeting once deliberations begin.
- i. Minutes must be written and published within 3 weeks of the meeting date.
- j. Minutes must be signed by the Chairperson of the SRS.
- k. Approved minutes must be forwarded to the Research and Development (R&D) Committee for review and approval. The R&D Committee may review the minutes for content regarding committee functions, protocol review, education of members, and preparation of minutes. Recommendations for changes or improvements in SRS procedures may be made, but the R&D Committee may not alter the SRS minutes.
- l. Minutes must be maintained by the R&D Office and made available to VA Central Office upon request.

Appendix D

RADIATION SAFETY

1. FACILITY REQUIREMENTS. The use of radioactive materials within Department of Veterans Affairs (VA) facilities must comply with the statutory and regulatory requirements of the Nuclear Regulatory Commission (NRC) and with Veterans Health Administration (VHA) policies and procedures for the safety and control of such materials. These policies, procedures, and regulations collectively control the receipt, uses, and disposal of radioactive materials in VHA research programs.

2. RADIATION SAFETY COMMITTEE (RSC) AND RADIATION SAFETY OFFICER (RSO). X-ray devices and their uses, while generally not subject to regulation in Federal facilities, are nevertheless subject to actual standards of practice and the important recommendations of influential national and international councils and commissions. Specific details of local facility requirements are approved and published by a facility RSC and implemented by the RSO. The RSC and the RSO are the primary facility resources for ensuring safe and effective uses of ionizing radiation in research and always need to be consulted.

3. AS LOW AS REASONABLY ACHIEVABLE (ALARA). While Federal regulation and the weight of authoritative commissions establish upper limits for the permissible radiation dose to workers and the public, one of the most effective tools for education on dosage is the facility specific ALARA programs. This is a mandatory commitment to maintain individual and collective radiation doses as low as reasonably achievable and requires participation of management, safety personnel, and individual research users.

4. REFERENCES

- a. VHA Directive and Handbook 1105.1, Management of Radioactive Materials
<http://www1.va.gov/vhapublications/index.cfm>.
- b. Title 10 Code of Federal Regulations (CFR) Chapter 1, Nuclear Regulatory Commission, Parts 0-199.
 - (1) CFR 19, Notices, Instructions and Reports to Workers: Inspections, and Investigations.
 - (2) CFR 20, Standards for Protection Against Radiation.
 - (3) CFR 35, Medical Use of Byproduct Material.

Appendix E

VA FORM 10-0398, RESEARCH PROTOCOL SAFETY SURVEY

VA Form 10-0398, Research Protocol Safety Survey can be found on the Veterans Health Administration (VHA) Forms Intranet at <http://vaww.va.gov/vaforms>.

Appendix F

LOCAL FORMS USED BY THE PORTLAND VA MEDICAL CENTER

All PVAMC local forms can be found on the PVAMC Internet website:
<http://www.portland.va.gov/Research/Committees/safety/index.asp#review>

Investigators are directed to that site to access current editions of forms. All forms are regularly edited to meet the needs of various regulatory bodies, and the needs of investigators and reviewers.

Only electronic submission of PVAMC forms will be accepted. Investigators are directed to submit their documents to the PVAMC managed email box research.grants@va.gov. SRS forms for review will be accepted when they are sent from the Principal Investigator's email address.

Project Safety & Hazard Assessment Form

The Project Safety and Hazard Assessment form is the local form used to evaluate projects for initial review. It is designed to provide complete information so the SRS can determine that personnel are appropriate and their training is up to date, and evaluate use of chemicals and experimental protocols, including use of BSL2 agents, radioactive materials, or rDNA. SRS members then indicate, through quorum vote, that it is believed that: (1) the work can be done safely, (2) the benefit of the knowledge outweighs the potential risks to research staff, and (3) there are no scientific or ethical concerns.

SRS Continuing Review Form

The SRS Continuing Review Form is the local form used to evaluate projects for annual continuing review. It is designed to determine that the PI has reviewed, since the last approval, their project for use of chemicals and experimental protocols, including use of BSL2 agents, radioactive materials, or rDNA. The PI also certifies that all staff are up to date with their annual training.

SRS Project Amendment Form

The SRS Project Amendment Form is the local form used to evaluate changes made to projects. Therefore, details are provided regarding changes in physical space, personnel added (and their training status), chemicals used, or experimental protocols conducted, including possible use of BSL2 agents, radioactive materials, or rDNA since the last approval.