SUBCOMMITTEE ON RESEARCH SAFETY
VA PORTLAND HEALTH CARE SYSTEM
STANDARD OPERATING PROCEDURES & POLICIES

CONTENTS

PAGE

SUBCOMMITTEE ON RESEARCH SAFETY
STANDARD OPERATING PROCEDURES AND POLICIES

1. PURPOSE

To define the standard operating procedures (SOPs) and policies used by the Subcommittee on Research Safety (SRS) and by the laboratory research Principal Investigators (PIs) that serve to ensure proper oversight and implementation of the VA Portland Health Care System (VAPORHCS) research laboratory safety and security program (RSSP), in compliance with the VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research. These policies involve oversight of procedures that use potential hazards encountered in the research setting, including, but not limited to:

a. Biohazards, such as:
   (1) Pathogens and etiologic agents corresponding to Biosafety Levels (BSL) 1-3, and
   (2) Organisms and viruses containing recombinant or synthetic nucleic acid molecules.

b. Chemical hazards.

c. Physical hazards, including ionizing and non-ionizing radiation.

2. DEFINITION OF HAZARD CATEGORIES

a. **Biohazards.** Biohazards include, but are not limited to, the following:
   (1) Pathogens and etiologic agents, human and animal tissues, blood, body secretions and 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 or synthetic nucleic acids.
   (5) Select agents, as specified in Title 42 Code of Federal Regulations (CFR) Part 73; 7 CFR 331; and 9 CFR 121 (list located at https://www.selectagents.gov/SelectAgentsandToxinsList.html).
   (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 and irritants.
   (2) Toxic substances (poisons, asphyxiates).
   (3) Sensitizers.
   (4) Carcinogens, mutagens, and teratogens.
   (5) Flammables.
   (6) Explosives.
   (7) Any chemical that can cause a physical or a health hazard, as defined by the Hazard Communication Standard (29 CFR 1200).

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.
(7) Mechanical hazards.

3. SCOPE OF RESEARCH SAFETY AND SECURITY PROGRAM (RSSP)

This RSSP specifically addresses the management of safety and security in VA research laboratories. It is not intended to replace the general occupational safety and health policy applicable to all VA employees, regardless of their role, security policies applicable to all VA medical facilities, or specific regulatory programs mandated by law.

a. The RSSP requires individuals conducting VA research to comply with all applicable Federal policies, statutes, regulations, and guidelines, including those issued by the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), United States Dept. of Agriculture (USDA), and National Institutes of Health (NIH), as applicable. State and local policies and regulations also must be followed.
b. Local hazard management policies
    (1) Biohazards. The VAPORHCS R&D Service Biosafety Manual serves as the service-wide biosafety manual. It includes a description of biohazard controls (e.g., procedures for use, engineering, and personal protective equipment), emergency procedures, regulations for transport of biohazardous materials, and guidelines for work with mammalian cells, tissues, and biological toxins. This document is reviewed/approved by the SRS and the R&D Committee (R&DC) annually. Those laboratories that work at BSL3 containment must maintain separate, written, regularly updated SOPs referencing but not limited to spills, power outages, and breaches of security.
    (2) Recombinant or Synthetic Nucleic Acids Research. The SRS is not registered as an Institutional Biosafety Committee (IBC) under the NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules. (“NIH Guidelines”). Therefore, the NIH-registered IBC at the affiliate university provides review and oversight of recombinant or synthetic nucleic acids studies regulated by the NIH Guidelines. Review occurs through a memorandum of understanding (MOU) agreement and according to the procedures outlined in Section 8. The service provided by the affiliate university IBC does not absolve the SRS or the R&DC for oversight responsibility.
    (3) Hazardous Chemicals and Waste. The Research Chemical Hygiene Plan (CHP) serves as the service-wide chemical safety manual. This document is managed and updated by the Chemical Hygiene Officer (generally an Industrial Hygienist) of the VAPORHCS Occupational Safety Service and is reviewed/approved by the SRS and the R&DC annually. Policies relating to the management of hazardous chemicals and waste are provided in the CHP, and individual labs must adhere to these policies.

However, the research laboratory program must also ensure that all Federal and State occupational safety and health, transportation and shipping, and environmental regulations are adequately addressed.

(4) Physical Hazards. Physical hazards are addressed in the RSSP through regular laboratory inspections by facility safety personnel and research safety personnel. These inspections include a review of all potential physical hazards. As needed, inspections are coordinated with program managers and technical experts such as the Radiation Safety Officer and the Chemical Hygiene Officer.

(5) Emergency Management. The Research and Development Service Emergency Preparedness Plan serves as the service-wide plan for procedures to follow in the event of emergency. It covers most significant adverse events that could impact research areas. This plan is reviewed/approved by the SRS and the R&DC annually.

c. Local forms used in hazard assessment

(1) Project Safety and Hazard Assessment Form (PSHA Form). This form is used in conjunction with a VA-format abstract to evaluate projects during initial review. Together they are designed to provide complete descriptions of proposed work so that the SRS can evaluate lab space, personnel and their training, physical hazards, and use of chemical, biological, or radiological agents, or recombinant or synthetic nucleic acid molecules.

(2) VA Form 10-0398. This form is used for all VA-funded studies. It is submitted to the SRS along with the PSHA Form and a VA-format abstract.

(3) SRS Continuing Review Form. This form is used to evaluate individual projects for annual continuing review. It is designed to determine that the PI has reviewed, since the last approval, their project for changes in the use of lab space, chemicals or experimental procedures, including use of BSL2 agents, radioactive materials, or recombinant or synthetic nucleic acids. The PI also certifies on this form that all staff are up to date with their annual training.

(4) SRS Project Amendment Form. This form is used to evaluate proposed modifications to individual projects, either as part of the annual continuing review or as experimental plans change during the year. The PI provides details regarding requested changes to lab space, personnel (including their training status), chemicals used, or experimental protocols to be conducted, including possible use of biohazardous agents, radioactive materials, or recombinant or synthetic nucleic acids.

d. Off-site Management of Hazardous Materials

(1) The provisions of the RSSP apply to all research that is conducted in VA research facilities, whether that research is unfunded or is funded by the VA or by other sponsors. The provisions also apply to research conducted in approved off-site research laboratories using VA funding or by researchers while on VA official duty time.

(2) Approved off-site locations conducting VA research must also be integrated into the annual laboratory inspection program, with any

necessary feedback regarding findings provided to the off-site investigator. The SRS may rely on inspections conducted by non-VA entities with primary responsibility for the space (e.g., academic affiliate) provided that the inspections are conducted at least annually and the SRS reviews the results of those inspections.

4. RESPONSIBILITIES

a. **Facility Director**. The VAPORHCS Medical Facility Director is responsible for:

(1) Ensuring the availability of adequate staffing and resources to cover key functions of the RSSP such as Facility Safety Officer functions or Chemical Hygiene Officer functions, as well as ensuring the availability of appropriate expertise in research safety, biosafety, radiation safety, and facility security.

(2) Ensuring that the Facility Safety program coordinates with Occupational Health, VA Police, Research Safety, Engineering, and other relevant parties to insure overall safety of research personnel, according to Federal and VA regulations.

(3) Ensuring that research areas are included in facility safety, security, and emergency management plans as appropriate, and ensuring the physical security of both standard and specialized research areas, including animal care facilities.

(4) Appointing, in writing, members to serve on the SRS for terms up to 3 years, with unlimited renewal at the Director's discretion.

(5) Appointing, in writing, the SRS Chair for the term of up to 3 years, which may be renewed.

(6) Ensuring the proper reporting of problems in research as directed by VHA Handbook 1058.01.

b. **Facility Safety Officer.** The VAPORHCS Medical Facility Safety Officer is responsible for ensuring that current inventories of all chemical hazards, as well as select agents and toxins, in each VA local research laboratory are maintained and reviewed at least semi-annually so that appropriate security and safety measures can be implemented.

c. **ACOS/R&D**. The ACOS/R&D is responsible for:

(1) Overseeing the implementation of all requirements set forth in VHA Directive 1200.08.

(2) Ensuring the creation of and updating the VAPORHCS RSSP and establishing mechanisms to ensure that all personnel comply with the plan, including VA contractors, students, and visiting fellows.

(3) Ensuring that Research service provides the VA Police with information and support to meet police responsibilities for research security. This includes ensuring that research receives routine security vulnerability assessments performed by police and alerting the police to any changes in research that affect the facility's security.

(4) Establishing mechanisms to ensure that access to VA research areas is monitored and evaluated regularly to prevent unauthorized persons from gaining access.

(5) Notifying ORD and ORO when a new BSL3 research laboratory is constructed or designated, or an existing BSL3 research laboratory is inactivated, reactivated, or closed.
(6) Ensuring that the SRS is notified whenever wet lab space is decommissioned or when identification and disposal or decontamination of hazardous materials/equipment is required between uses.
(7) Supporting routine security and incident response drills required by the Emergency Manager or facility Safety office.
(8) Identifying an individual qualified through training or experience and delegating Research Chemical Hygiene Officer responsibilities to that person if the medical facility does not have someone specifically appointed to that role.
(9) Appointing a Biological Safety Officer if the VAPORHCS research program involves the use of recombinant or synthetic nucleic acid molecules either at BSL3 or in large quantities (greater than 10-liter cultures).
(10) Working with the SRS as needed to ensure that research activities stop when the SRS imposes either a safety hold or suspension, until the hold or suspension is lifted.

d. **R&D Committee.** The R&D Committee is responsible for:
(1) Ensuring that the SRS includes experts on research safety, as established in the facility's RSSP, and has the delegated authority for oversight of research safety.
(2) Establishing an Institutional Biosafety Committee (IBC) of record for review of work that falls under the scope of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The IBC at the affiliate university may serve in this role provided an appropriate Memorandum of Understanding (MOU) is in place and the affiliate IBC is registered as the VA's IBC of record.
(3) Ensuring that the SRS and, when appropriate, the IBC review all protocols that involve safety hazards to personnel and the environment and all research within the scope of the NIH Guidelines, respectively.
(4) Reviewing and, as appropriate, acting on communications from the SRS and IBC, including the minutes of all meetings.
(5) Under VAPORHCS policy, reviewing and approving all R&D service-level SOPs and manuals, e.g., the Chemical Hygiene Plan and Biosafety Manual.

e. **Radiation Safety Officer.** The VAPORHCS Medical Facility Radiation Safety Officer is responsible for overall oversight of radiation safety in research, including safe use of radioactive agents and sources and review of all protocols that involve radioactive materials and sources.

f. **Chemical Hygiene Officer.** The VAPORHCS Chemical Hygiene Officer (generally the VAPORHCS Industrial Hygienist) is responsible for:
(1) Ensuring that inventories of all hazardous chemicals, as defined by OSHA or the EPA, in each local VA research laboratory are maintained by the PI, and reviewing and approving these inventories at least semi-annually.
(2) Reviewing and updating the Chemical Hygiene Plan at least annually.
(3) Reviewing all protocols that involve hazardous chemicals.

(4) Fulfilling additional duties delegated to this role by the SRS.

g. **Biosafety Officer.** If the VA research program involves the use of recombinant or synthetic nucleic acid molecules at BSL-3, or large-scale (greater than 10-liter) cultures or production involving recombinant or synthetic nucleic acid molecules, NIH Guidelines require appointment of a Biosafety Officer. The VAPORHCS Research Biosafety Officer is responsible for:

(1) Carrying out the duties defined in the NIH Guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)

(2) Serving as a voting member of the affiliate Institutional Biosafety Committee (IBC).

h. **Subcommittee for Research Safety (SRS).** The SRS is responsible for implementation of the RSSP, which includes:

(1) Review of VA Research. All proposed VA research activities involving biological, chemical, physical, and radiation hazards are reviewed for compliance with all applicable regulations and policies. This evaluation, which includes an assessment of VA research occurring at off-site locations, takes place before initiation of the research activities to ensure implementation of proper security and safety measures.

(2) Chemical Inventories. The SRS works with the facility Safety office to ensure that current inventories of all hazardous agents in VA research facilities are maintained and reviewed by the Chemical Hygiene Officer and/or the Facility Safety Officer at least semi-annually.

(3) Semi-Annual Review of Select Agent and Toxins. For this review, a PI who possesses any quantity of an agent found on the Health and Human Services and U.S. Dept. of Agriculture Select Agents and Toxins list submits a log semi-annually showing use or dispensation of that agent over the previous six-month period. The PI also states the quantity of unused material still in their possession and provides a copy of their SOPs for security and safe usage of the material or states that the SOP on file in the Research office has not changed. The SRS reviews the use log to ensure that all material is accounted for, confirms that the total amount of material on hand is below the threshold for registration with the Federal Select Agent Program, and reviews the SOP.

(4) Annual Review of Lab Programs. Each PI's lab program must be reviewed annually. At VAPORHCS, the following elements of the lab program are reviewed at convened meetings throughout the year and documented in the SRS minutes:

(a) Annual assessments of all active safety protocols are performed as part of the Continuing Review process outlined in Section 7d. Results are communicated to the R&DC and the PI according to Section 7e. This ensures that the hazards, training, and project status remain up-to-date.

(b) Inspections of the PI's lab space occur according to Section 4h(8).

(c) All amendments to safety protocols throughout the year are reviewed and communicated to the R&DC and the PI according to Sections 7c and 7e. This includes any changes in space allocation, which must be approved by the amendment process.

(d) Any issues that arise involving employee safety and security are discussed at the next convened meeting. Additionally, once per year the SRS

reviews a list of all accidents that occurred in research lab space during the previous 12 months. The SRS may vote to suspend work if it determines that hazards cannot be appropriately managed. In this case, the PI and the R&DC will be notified in writing of the date of study suspension and the reasons for the action.

(5) Health Surveillance Recommendations. Research personnel are advised by Employee Health at their time of initial appointment regarding any health surveillance recommended for their job duties. If duties change as experimental plans evolve, the SRS will provide additional health surveillance recommendations (e.g., vaccinations) as part of the review of the proposed research.

(6) Safety Training. The SRS ensures that all research personnel receive annual safety training. Personnel are assigned safety training modules by the Research office according to their work duties and required to complete this initial training before beginning those duties. They are then contacted annually to confirm their continued need for research access and to remind them to review training modules again as a refresher. If an individual is more than 30 days overdue with this refresher, based on the date of their last training, their access to research space is de-activated. This access is restored upon completion of the training. The SRS reviews the monthly training reports and may withhold approval for research studies if they determine that training requirements are not being met.

(7) Oversight of Lab Closures. If the ACOS/R&D notifies the SRS that a lab will be decommissioned, including closure, transfer to new space, or renovation of existing space, members of the SRS will oversee the process with the use of the Chemical Hygiene Plan's lab closeout checklist so that hazards are managed safely. Individual protocols may also be closed by notifying the SRS and confirming that any protocol-specific hazards have been safely removed from the lab. These protocol and lab closures are reported at a convened SRS meeting.

(8) Lab Inspections. The SRS conducts annual safety and security inspections of all VA research labs using the SRS inspection checklist. A subset of labs randomly chosen by the SRS Chair is also inspected at the half-year mark, along with any labs deemed to engage in "high risk" research (e.g., work with high volumes of hazardous chemicals, or work with particularly hazardous chemical or biological agents). Individual lab results are reported to the PI and then to the SRS as part of the PI's annual lab program review, along with the PI's plan for correction of any deficiencies. Aggregated inspection results are also reviewed by the SRS and the R&DC to assess facility trends over time. If a PI is cited on two consecutive inspections for the same issue, they are asked to submit a letter to the SRS outlining a more extensive plan for permanent abatement of the problem. If the lab is cited a third consecutive time for that item, the SRS requests the PI's attendance at an SRS meeting to discuss the issue in person and find permanent resolution.

(9) Review of Additional Inspections. The SRS reviews the results of other research safety inspections (e.g., Environment of Care, Annual Workplace Evaluations, Security Vulnerability Assessments, inspections by regulatory agencies) and ensures corrective action is taken, if needed.

(10) Review of Accidents or Safety/Security Incidents. In the event of a research-related accident or other employee safety or security incident, the SRS reviews the incident at a convened meeting, provides recommendations to the PI to prevent further incidents, and reports the findings according to the requirements of VHA Handbook 1058.01 (Research Compliance Reporting Requirements). If deemed necessary, the SRS may also vote to suspend a PI's lab program until proper safety precautions can be implemented. Incidents are also documented in minutes reported to the R&DC.

(11) Safety Manuals and Plans. The SRS is responsible for developing and implementing research-specific biosafety/biosecurity, chemical hygiene, and emergency management plans, and ensuring that appropriate drills to test the plans are conducted annually by facility personnel such as facility Safety, Emergency Management, and VA Police.

(12) Approval for BSL3 Facility Access. Individual BSL3 facility access requests are reviewed and approved by the SRS initially and then annually thereafter. The annual review must assess the continued need for access and the individual's appointment status. The status of the individual's Security Risk Assessment by the Criminal Justice Information Services of the FBI must also be reviewed annually by providing Human Resources (HR) personnel with the list of those individuals with BSL-3 access. HR will check the FBI security status of each person, report any who have had a change to their security status, and determine the underlying reason for the status change. The BSL3 Director will use this information to determine whether this status change renders the individual a security risk for the facility and may revoke access if so. The Director may request assistance from the SRS Chair in making this determination.

(13) Review of BSL-3 Facility Safety and Security. The SRS is responsible for:

(a) Review and approval of the BSL-3 Facility SOP on at least an annual basis. The SOP, along with results of the SRS review, are then forwarded to the R&DC.

(b) Review of reports from the BSL-3 Facility Officer and the VAPORHCS Facility Management Service (FMS) documenting annual maintenance tasks in the facility, as well as monthly updates on alarm function and user access/egress. These reports are documented in the SRS minutes.

(14) Review of the RSSP. The SRS must evaluate the RSSP annually for effectiveness by reviewing the RSSP SOP, along with the results of safety drills, results of safety inspections of research labs, reports of research-related accidents or injuries, and concerns raised during Police vulnerability assessments. These reviews are documented in SRS minutes and sent to the Facility Director via the R&DC.

i. **Principal Investigator.** The PI is responsible for the safety of all research activities conducted in her/his assigned space, including:

(1) Ensuring compliance with all regulatory and facility requirements that apply to safety or security in the research that the PI supervises.

(2) Ensuring that research activities involving chemical, biological, physical, or radiological hazards have been reviewed by appropriate committees, regardless of funding status or source. This review requires:

(a) Submitting an accurately completed VA-formatted abstract, VA Form 10-0398, Project Safety and Hazard Assessment form, SRS Continuing Review Form, or SRS Project Amendment Form, as appropriate, to the SRS. This documentation must include:

1. A description of the work proposed.
2. A list of all hazards involved in the work, description of procedures to meet current standards for safe handling, and where the hazards will be located.
3. The measures that will be taken to ensure appropriate security of the hazardous materials and equipment.
4. The requirements to be met by personnel before participating in the research project.

(b) Acquiring and maintaining approval for studies involving non-exempt use of recombinant or synthetic nucleic acids from the affiliate university's Institutional Biosafety Committee (IBC).

(c) Ensuring that all SRS, other appropriate subcommittee, and R&D Committee approvals are obtained before any new work begins, and that protocols are conducted as approved by the SRS and/or IBC.

(d) Securing approval of the SRS and/or IBC for any changes made to the original research plan.

(3) Minimizing safety risks to lab personnel by:

(a) Ensuring that personnel are aware of laboratory-specific hazards and have been advised of any potential risk to themselves, the facility, or the environment.

(b) Providing training to personnel for precautions to be followed when storing, handling, transporting, and disposing of any hazardous materials. This includes training on any lab-specific SOPs required by OSHA for particularly hazardous chemicals.

(c) Establishing and enforcing standards of practice to minimize employee exposures to research hazards per OSHA/NIOSH recommendations, including:

1. Correct use of personal protective equipment (PPE).
2. Ready access to safety data sheets for chemicals.
3. Consultation as needed with the VA industrial hygienist to ensure that employee chemical exposures are as low as reasonably achievable.

(d) Ensuring that the most current plans for biosafety, chemical hygiene, and emergency management are readily available to all employees and that employees know the content of the plans.

(e) Identifying those who are to work with non-exempt quantities of select agents and/or toxins and ensure that a proper Security Risk Assessment is completed by the Federal Bureau of Investigations prior to access being authorized. The Security Risk Assessment is in addition to the routine background investigation required at the time of appointment to a research position. *NOTE: Exempt amounts of the select agents or toxins do not require the additional Security Risk Assessment.*

(4) Maintaining an up-to-date inventory of hazardous chemicals in the lab (including safety data sheets), ensuring that all lab personnel know the location of the inventory, and providing this inventory to the Facility Safety Officer. The hazardous materials to be included are:

(a) Chemicals defined as hazardous by OSHA or the EPA (i.e., listed as flammable, toxic, corrosive, etc., on safety data sheets).

(b) Select agents.

(c) Toxins.

(d) Hazardous drugs as identified in the most current version of the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

(e) Expired chemicals that may become hazardous.

(f) Gas anesthetic agents.

(g) Controlled substances and pharmaceuticals.

(5) Managing all hazardous waste, including proper disposal and record keeping when appropriate (e.g., radioactive material disposal logs), in accordance with Federal, State, and local regulations and all VA, VHA, and facility policies.

(6) Ensuring that biological safety cabinets and chemical fume hoods are certified annually in conjunction with Facilities Management Service.

(7) Submitting BSL3 laboratory access paperwork for all research personnel requesting initial access to this lab to conduct research activities.

(8) Reporting problems and concerns about operation and containment practices and procedures to appropriate VA authorities.

(9) Ensuring that all accidents are entered into the Automated Safety Incident and Surveillance Tracking System (ASISTS).

(10) Notifying the ACOS/R&D at least two months before departing or relocating research lab space and completing any necessary lab close-out paperwork.

(11) Submitting a written abatement plan to the SRS for all deficiencies cited during inspections by the SRS and ensuring that these corrective actions are carried out.

j. **Individuals Working in VA Research Laboratories.** All individuals working in VA research space are responsible for:

(1) Complying with all educational and training requirements related to their assigned duties and hazards or sensitive materials present in the lab. All new research staff must complete this training prior to assuming their duties.

(2) Assisting the PI in a risk assessment of potential exposure to hazards that could occur as part of their job duties.

(3) Reporting work-related injuries, illnesses, and exposures to hazardous materials.

(4) Reporting any loss, release, theft, or misuse of any hazardous materials to the PI and to the Research office.

(5) Reporting any suspicious persons or activities in research lab areas to the VA Police.

5. INFRASTRUCTURE OF SRS

a. **Number and Qualifications of Members.**

(1) The SRS must have at least five members, exclusive of *ex-officio* members.

(2) The SRS membership must include members who possess expertise in:
(a) Etiologic agents, including bloodborne and airborne pathogens.
(b) Chemical carcinogens and other chemical hazards.
(c) Physical and radiation hazards.
(d) Conducting scientific research.
(3) Among the voting members of the SRS, specific expertise regarding the following must be available:
(a) Occupational safety and health.
(b) Environmental protection.
(c) Department of Transportation (DOT) International Air Transport Association (IATA) expertise.
(d) Knowledge of the space and facilities assigned to each PI to ensure that research operations can be conducted safely.
(4) The SRS must include members from the facility safety committee, such as the Facility Safety Officer or a member of the Facility Infection Control Committee.
(5) At least one SRS member must also regularly attend the Institutional Animal Care and Use Committee (IACUC) to serve as liaison between the SRS and IACUC. This member may be voting or non-voting.

b. **Ex-officio Members.** *Ex-officio* members include:
(1) A liaison member from the facility R&D Committee (required member; non-voting).
(2) The Radiation Safety Officer (required member; voting).
(3) The Veterinary Medical Officer (voting).
(4) The Chemical Hygiene Officer (voting).
(5) A member of Infection Control or another member from the facility safety committee (voting).
(6) An employee union safety representative, or other union designee, if required by the current union contract. Voting status is determined by the union contract or (if not designated in the union contract) by the R&D Committee. The role of the union *ex-officio* member is to assist in identifying safety issues related to research employees.

c. **Appointment of Members.**
(1) The SRS recommends members to the R&DC. The R&DC forwards 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, with unlimited renewal at the Director's discretion.
(2) The medical center Director appoints the SRS Chair for a term of up to three years, with unlimited renewal at the Director's discretion.
(3) Ex-officio members are SRS members because of their medical center position and their membership is therefore not approved or renewed by the medical center Director.

d. **Representatives from the Affiliate University.** Whenever possible, an individual from the affiliate institution's IBC or Environmental Health & Radiation Safety office should serve as a voting member of the SRS.

e. **Research Compliance Officer and the SRS.** 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.

6. FORMAT FOR SRS MEETING AGENDAS AND MINUTES. Agendas and minutes of the Subcommittee for Research Safety (SRS) must be prepared according to the following format.

a. **Agenda.** An agenda is to be developed before each SRS meeting and distributed to SRS members at least one week before the meeting. The agenda should include:

(1) Minutes. Review and approval of minutes of previous meeting.

(2) Old Business (if any). Items carried over from a previous meeting.

(3) New Business. Identify individual responsible for presenting the following items, when necessary:

(a) Safety issues raised by SRS members.

(b) Standing recurring reports.

(c) Any other item that warrants review or discussion by the committee and is not routinely reviewed by the committee.

(4) Protocol reviews.

(a) Initial Reviews.

(b) Continuing Reviews of active protocols.

(c) Study Closures.

(d) Amendments, both expedited and those to be reviewed by full committee.

Note that all review types may not be needed at every meeting. Each review will indicate the name(s) of the designated reviewer(s).

b. **Minutes.**

(1) Minutes of all the SRS meetings will be prepared according to the following format:

(a) Identification of the subcommittee at the top of the page, along with the VA medical center name.

(b) The first section will include:

1. Date and time of the meeting.

2. Name of Chair for that meeting.

3. The attendance record, which must list all individuals identified as members. Members are to be marked “Excused” if the Chair or recorder was notified in advance of the member’s absence. Members are to be marked “Absent” if the Chair or recorder was not 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 present.)

5. Any guests in attendance, along with their role.

(c) Succeeding paragraphs are to identify each agenda item, the date of the meeting when discussion originally took place (for open items), the committee discussion and recommendations, action taken to date or a realistic date to

expect resolution, and the status of the agenda item at the close of discussion. For each project under consideration, list the name of the 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.

(2) Minutes are not to be recorded verbatim; however, the substance of the discussion is to be reported clearly and concisely. After summation of the discussion, the minutes must reflect the following, as appropriate for that agenda item:

(a) Conclusion**.** This indicates the consensus opinion of the committee following the discussion; for example, "The follow-up action plan was ineffective, and the issue is not considered resolved at this time." If analysis of information such as tables, lists, or other data occurred in the meeting, then the conclusion of this analysis must be in the minutes.

(b) Recommendation. This includes who or what is expected to change.

(c) 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.

(d) 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.

(3) For each new project, the motion passed by the committee (approved, approved pending clarification, tabled, 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. The name(s) of the reviewer(s) of the projects must also be recorded; these listed individuals will also be responsible for reviewing revisions and granting final approval for the project.

(4) The minutes must note the names of members who recused themselves from voting on an agenda item or protocol.

(5) Copies of any internal or external reports or correspondence with outside agencies referenced in the minutes will be attached to the minutes if they are critical to understanding the conduct of business.

(6) Minutes must be signed by the Chair for that meeting.

(7) Approved, signed minutes are emailed to the Research and Development Committee (R&DC) Coordinator, to be added to an R&DC agenda for review and approval. Should any finding or recommendation of the SRS be questioned, the issue will be discussed and recorded in the R&DC minutes, but the R&DC may not alter the SRS minutes.

(8) Minutes must be maintained by the R&D Office and made available to VA Central Office upon request.

7. PROTOCOL REVIEW PROCESS

a. **General Considerations.**

(1) The SRS reviews all projects involving work occurring in research labs with chemical, biological, physical, or radiation hazards prior to initiation/activation (initial review), annually thereafter (continuing review), or through an amendment process if the scope of experimental work should change.
(2) For the review process, the forms VA 10-0398 (Research Protocol Safety Survey), and/or the local VAPORHCS Project Safety and Hazard Assessment (PSHA) Form, SRS Continuing Review Form, or SRS Project Amendment Form are used. These forms all evaluate, among other items:

(a) The risks to personnel, research subjects, the facility, and the environment.

(b) The adequacy of the proposed lab space, including the required level of containment.

(c) Laboratory procedures and practices, including use of personal protective equipment (PPE).

(d) The training and expertise of personnel involved in the specific research conducted.

(e) The IBC approval status, if needed, for research involving recombinant or synthetic nucleic acids.

(3) Exemption from SRS Review.

The following types of research are exempt from the requirement for SRS review:

(a) Research that only involves the collection and analysis of biospecimens by VA personnel within clinical or clinical research areas, or the performance of standard clinical procedures in clinical areas or offices. Exemption from safety review is determined by the ACOS/R&D or Deputy ACOS/R&D at the time of Proposed Project Questionnaire (PPQ) submission.

(b) Research that clearly does not involve collection of specimens or use of VA research laboratory space. Exemption from safety review is determined by the ACOS/R&D or Deputy ACOS/R&D.

(c) Research that is conducted in VA research laboratory space, but which does not involve any hazards. This work requires completion of either the VA Form 10-0398 or the PSHA form, indicating that the answers to all questions are “no”. In this case, the form will be reviewed by the SRS Chair, and the outcome of the review will be reported to the SRS at its next meeting. The result will also be documented in the meeting minutes.

(4) Safety forms will be submitted exclusively electronically. Therefore, to serve as proxy for the PI’s physical signature, SRS forms will be accepted only when they are sent from the PI’s email address.
(5) The SRS must review proposed research projects at convened meetings at which a quorum (majority of voting members) is present, either in person or via teleconference or video conference. 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 that don’t require a quorum or a vote may be discussed at the discretion of the Chair.

Note: If neither the Chair nor the Alternate can attend a meeting, the other members in attendance may vote for a one-time chair pro tempore as allowed by Robert's Rules, so that a meeting can be held and business conducted. A quorum of voting members is still required for this meeting.
(6) Any SRS member with a conflict of interest must be recused during deliberation and voting on that protocol. An SRS member is deemed to have a conflict if they are the principal investigator, or if they or staff members under their direct supervision are listed as proposed members of project personnel. The recused member may answer questions about the study if requested by the SRS, but must leave the room for deliberation and may not participate in the vote. Quorum must be maintained during the recused member's absence for voting to occur.

b. **Initial Review.**

(1) All new research protocols that are subject to SRS review must be initially reviewed at a convened SRS meeting.
(2) Reviewers for protocols are selected by the SRS Coordinator from the voting members of the SRS. Reviewers are assigned based on specific expertise, to the extent possible given the composition of the committee. The Chair may add or exchange reviewers, if deemed necessary to provide a full review of the proposed work.
(3) The review process requires that investigators submit a VA-format abstract and a PSHA Form (including salient appendices and other supporting documents such as agent-specific procedures). Additionally, a VA Form 10-0398 is required for all VA-funded studies. Reviewers present a description of the proposed work and an assessment of the project hazards at the SRS meeting. This assessment must include an evaluation of the following:

(a) The risks to personnel, research subjects, the facility, and the environment.
(b) The level of containment, lab procedures, and personal protective equipment needed for the work to be conducted safely.
(c) The experience and training of personnel involved and the adequacy of available lab space and resources.
(d) Any recombinant or synthetic nucleic acids work to be performed, along with any necessary IBC approvals.

(3) The Chemical Hygiene Officer will be provided the list of chemicals for the project one week in advance of an SRS meeting as part of the SRS meeting packet. Final SRS approval may be withheld if concerns about any chemical are expressed during the meeting or are emailed to the SRS Chair or SRS Coordinator before the meeting (and are not resolved before the start of the meeting).
(4) Following any subsequent and appropriate subcommittee discussions, members of the SRS vote based on whether they believe that: (a) the work can be done safely, (b) the benefit of the knowledge outweighs the potential risks to research staff, and (c) there are no scientific or ethical concerns. Members may vote to approve, approve pending minor modifications/clarifications, defer (table), or disapprove the project. The vote will be recorded with number of members

voting for the motion, the number voting against, and the number abstaining or recusing from voting on the motion. The result of the review is communicated to the PI by a memorandum.

(5) If minor modifications or clarifications are required, the SRS member(s) who initially reviewed the protocol will also review any revisions made by the PI and will grant final approval for the protocol. However, at the time of initial review, any SRS member may request instead that the protocol return for a full committee review once revisions are made.

(6) Approval is valid for one year from the date of the SRS meeting at which the protocol was reviewed and approved, either fully or pending minor modifications.

c. **Amendments.** Investigators may submit requests to modify their projects at any time during the year using the SRS Project Amendment Form. The review of this amendment may be expedited, or may occur at a convened meeting and require a vote from the full committee, as follows:

(1) Expedited review. Changes which may be approved via an expedited process are those which do not substantially increase the risk of the research project, including but not limited to most room changes, personnel changes, or addition of chemicals, recombinant DNA, or biohazardous agents that have similar hazard profiles to agents already in use in the lab. In this case, reviewers provide their approvals via an email which is saved in the study folder. If minor modifications are needed to secure approval, these members also review any revisions made by the PI and grant final approval for the amendment. The results of this review are reported at the next SRS meeting and recorded in the minutes. The reviewers may also refer the amendment back to the full committee for review at any point during the process but may not withhold approval for the amendment.

(2) Full committee review. Changes which increase the overall risk to the project, such as requests to use particularly hazardous chemicals or biohazardous agents that require an increased containment level in the lab, must be reviewed and approved at a convened meeting. The primary reviewer presents a description of the proposed work and, along with any additional reviewers, provides an assessment of the project hazards at the meeting. Following any discussion, members may vote to approve, approve pending minor modifications/clarifications, defer (table), or disapprove the amendment. If minor modifications or clarifications are required, the SRS member(s) who initially reviewed the amendment will also review any revisions made by the PI and will grant final approval. However, at any point during this process, any voting SRS member may request instead that the amendment return for a full committee review once revisions are made.

(3) Reviewers. In either instance, the SRS Chair is the primary reviewer of the amendment and determines expedited versus full committee review status. Other SRS members with relevant expertise, such as the Industrial Hygienist or Radiation Safety Officer, may also act as reviewers as requested by the Chair.

d. **Continuing Review.** Every active protocol that has received past SRS approval is also evaluated annually as part of the PI's laboratory program review. The annual continuing review cycle for projects is determined by the date of approval of the initial SRS review or the date of the previous continuing review.

(1) For this review, investigators submit the SRS Continuing Review Form that specifically queries if any changes have been made during the previous 12 months to personnel, lab space, or to the chemicals used or the experimental protocols conducted, including possible use of BSL2 agents, radioactive materials, or recombinant DNA. If changes are proposed, then the PI also submits the SRS Amendment Form.
(2) The SRS Chair reviews all submitted Continuing Review and (where appropriate) Amendment Forms. If no changes have been made to a project, the Chair presents this information to the committee at a convened meeting, where members may vote to approve, require modifications to secure approval, or disapprove the continuation of the project. In the case of approval with minor modifications, the Chair reviews revisions and approves the project. Approval is valid for one year from the date of the SRS meeting at which the protocol was reviewed and approved, either fully or pending minor modifications.
(3) If changes to the project are requested, based on an SRS Amendment Form accompanying the SRS Continuing Review form, the SRS Chair determines whether the amendment can be reviewed in an expedited manner or whether it must be reviewed by the full committee. The criteria for this decision are the same as outlined above for other amendments and the review proceeds as follows:

(a) If the requested modifications are considered minor, then the SRS Chair determines whether the amendment is appropriate and reports this information to the SRS during review of that protocol. The SRS takes that information into consideration when voting to approve, approve with modifications, or disapprove continuation of the project.
(b) If the amendment requires full committee review, the SRS Chair presents a description of the proposed work and a full assessment of the project hazards at the meeting. After discussion, the SRS votes to approve continuation of the project with requested changes, to approve continuation pending modifications, or to disapprove continuation of the project. In the case of approval with minor modifications, the Chair reviews revisions and approves the project.

e. **Notifications of SRS Reviews.** Notification of the results of SRS reviews are provided to the R&D Committee as follows: for initial reviews, the safety paperwork, reviewer checklist, and IBC approval letters are emailed to the R&DC Coordinator; for continuing reviews and amendments, the result of the SRS review is presented during the R&DC review of the SRS minutes. Notifications of the results of all SRS reviews are provided to the PI as a memorandum emailed by the SRS Coordinator. SRS correspondence is signed by the SRS Coordinator or, in the case of final and unconditional initial approval, the SRS Chair or Alternate Chair. In the case of SRS disapproval, (initial, continuing, or amendment), correspondence is signed by the SRS Chair or Alternate Chair and the PI is provided with reasons for the disapproval. Copies of all correspondence are filed electronically in the appropriate investigator research project folder located on the VAPORHCS network.

8. REVIEW OF RECOMBINANT DNA RESEARCH

a. **Initial Review.** The current policy to ensure adequate SRS initial review of projects using recombinant or synthetic nucleic acids is as follows:

(1) All investigators complete the Project Safety and Hazard Assessment (PSHA) form for initial review of new projects. The initial determination of recombinant or synthetic nucleic acids involvement is made by evaluating Part B of that form, which queries investigators whether their project uses recombinant or synthetic nucleic acids.

(2) Investigators answering "yes" are directed by the form to the OHSU IBC to obtain either approval or an exemption. Investigators can also determine whether their project is exempt without IBC review by consulting the NIH Guidelines. However, that designation is also reviewed at the SRS, and investigators may be asked to confirm exempt status through IBC review.

(3) Any PSHA that is received by the SRS Coordinator which indicates that a recombinant or synthetic nucleic acids component requires IBC review, but which does not include OHSU IBC approval documentation, will not be submitted to the SRS for review.

(4) The second evaluation of recombinant or synthetic nucleic acids use occurs during the SRS review process, in which reviewers must indicate on the Reviewer Checklist whether the project involves recombinant or synthetic nucleic acids, and if so, whether IBC approval is required. If yes, the reviewer must confirm that IBC approval was granted and that all salient IBC documents have been submitted for SRS review.

(5) The SRS must review the findings of the IBC, including but not limited to the assigned BSL and the required safety measures, prior to final SRS approval.

(6) After the IBC has granted approval (or determined exemption) for use of recombinant or synthetic nucleic acids, a signed approval letter is sent to the PI. It is the responsibility of the PI to submit the document to the SRS. The SRS Coordinator is also notified electronically during the IBC review/approval process that the review is taking place.

(7) After the OHSU IBC has granted approval for initiation of recombinant or synthetic nucleic acids work as part of a new project and the SRS has received a copy of the approval letter, the SRS Coordinator will request a copy of the relevant minutes from the IBC meeting in which this project was discussed and voted upon. The SRS Coordinator will then provide these minutes to the R&DC Coordinator for presentation at a future R&DC meeting.

b. **Project Amendments.** Changes to an established recombinant or synthetic nucleic acids protocol at any time during the year (including during the annual IBC continuing review) must be approved by the OHSU IBC by an amendment process. The decision whether to require a full committee meeting to discuss changes or whether instead to approve the changes administratively resides with the IBC and depends on the complexity and level of risk of the changes sought. After IBC amendment approval, regardless of whether granted administratively or by the full IBC, the PI will then be required to submit an SRS Amendment Form, requesting that an established VA project be updated to incorporate the new, approved changes. Salient IBC documents including the safety paperwork and the IBC approval letter must be submitted for SRS review at the same time. The SRS

Amendment is reviewed according to the procedures listed in Section 7c. After receiving an IBC amendment approval letter from the PI, the SRS Coordinator will then request a copy of IBC meeting minutes for full IBC reviews. The minutes will be provided to the R&DC Coordinator for presentation at a future R&DC meeting. In the case of minor amendments receiving administrative, (extra-committee) IBC approval, a copy of the amendment approval letter will be provided to the R&DC Coordinator instead of meeting minutes.

c. **Continuing Review.** Continuing review of an established IBC registration is required annually by the OHSU IBC. If changes to the scope of any projects covered by the registration are requested, then the registration review is conducted by the IBC and SRS amendment process outlined above. If no changes to the scope of any project are sought, then the IBC review takes place via an extra-committee administrative process, and notification of continued IBC approval is provided by letter to the PI. The SRS Coordinator is also notified electronically during the IBC review/approval process that the continuing review is taking place. Once the review is complete, the SRS Coordinator will then request a copy of the approval letter and will provide this to the R&DC Coordinator for presentation at a future R&DC meeting. The SRS Coordinator will also determine which VA projects are covered by this approval letter by consulting the IBC database, and place a copy of the approval letter in each project's file. During the annual SRS continuing review of VA projects covered by this IBC registration, the SRS Chair will check to ensure that the project in question has a current IBC approval letter. If one is not found, it is the PI's responsibility to provide a copy of this letter to the SRS, as requested on the SRS continuing review form.

9. REFERENCES

a. CDC-NIH. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. CDC-NIH, Washington, DC, 2009

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 or Synthetic Nucleic Acid Molecules," (NIH Guidelines). National Institutes of Health, Bethesda, MD, April 2019

i. VHA Directive 1105.1, Management of Radioactive Materials

j. VA Directive 7700, Occupational Safety and Health

k. 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), and

(2) Number 116, Limitation of Exposure to Ionizing Radiation (Bethesda, MD, 1993)

l. VHA Handbook 1058.01, Research Compliance Reporting Requirements