



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
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R&D 537/151
March 30, 2010
Version 1.2 (revised 6/30/10)

**SOP: R&D Laboratory
Research and
Environmental Safety
Subcommittee
Operations**

PURPOSE

The Standard Operating Procedure (SOP) prescribes the operating procedures of the R&D Laboratory Research and Environmental Safety Subcommittee (note this subcommittee is also referred to as “Subcommittee for Research Safety” or “SRS”).

SCOPE

- A. The SRS is charged by the R&D Committee (RDC) with the responsibility to 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 must be followed.
- B. The provisions of this SOP 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 extra-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.

RESPONSIBILITIES

The SRS is responsible for:

Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for funding. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding and Non-VA funding located off-site.

Providing written notification of the results of SRS review to the R&D Committee (RDC), the Research Office (RO), and the Principal Investigator (PI).

Oversight over 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:

- Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and
- Reporting follow-up results to the RDC.

INFRASTRUCTURE OF SUBCOMMITTEE ON RESEARCH SAFETY (SRS)

Number and Qualification of Members

The SRS must have at least five members, exclusive of ex-officio members. It is recommended that at least one SRS member possesses specific occupational safety and health, environmental, and Department of Transportation (DOT) 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.

It is necessary for the SRS membership to possess expertise in:

- Etiologic agents, including blood-borne and air-borne pathogens.
- Chemical carcinogens and other chemical hazards.
- Physical and radiation hazards.

Core Membership

Voting members of the SRS will include:

- The Research Safety Coordinator (RSC)/Chemical Hygiene Officer (CHO)
- The VMO or a member of the Subcommittee on Animal Studies (IACUC)
- One or more of the following to act as representative of Facility committees:
 - ◆ The Facility Safety Officer
 - ◆ A member of the Infection Control Committee
- A liaison member from the local RDC
- The Radiation Safety Officer (RSO)

Ex-Officio Members (non-voting) Ex-Officio non-voting members must include:

- The ACOS for R&D
- The AO for R&D
- The Research Compliance Officer
- An employee union safety representative

Appointment of Members

The SRS nominates candidates to serve as members on the committee and forwards the nominations to the R&D committee.

The R&D committee selects candidates and forwards their selections to the Medical Center Director. The R&D committee is responsible to the Director for assuring that the SRS membership fulfills the requirements outlined in section 1 above. The SRS committee coordinator maintains a roster of committee members that specifies the qualifications that each member fulfills.

The Medical Center Director must officially appoint members in writing.

Alternate members may be appointed. Alternate members are members who may substitute for regular members if the regular members are unable to attend a meeting. If alternate members are appointed then the roster must specify the person(s) for whom they may substitute. Alternate members should have similar expertise to the regular member that they serve as an alternate for.

The Medical Center Director appoints the SRS chairperson for the term of one (1) year. The SRS Chairperson may be re-appointed without any lapse in time; however, the SRS Chairperson may not simultaneously chair the R&D Committee or another research subcommittee.

Appointment Letters must specify:

- The term of the appointment.
- The type of appointment, i.e. Chair, Core or *Ex Officio*.
- Whether the appointment is for a Regular or Alternate member.
- The Voting Status.

Quorum and Voting

All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the RDC prior to commencement. SRS must review proposed research at convened meetings at which a quorum (majority of voting members) is present.

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 must be tabled and only non-protocol related issues may be discussed.

Meetings

Frequency - The SRS will meet at least monthly, or more often as needed, at a date and frequency determined by the Chair and the Safety Committee Coordinator (SCC).

Agenda - An agenda is to be developed before each SRS meeting and distributed to SRS members at least one week before the meeting.

Recusals - SRS members are informed of potential conflicts through a review of meeting agendas. Agendas are distributed no later than one week prior to each SRS meeting and contain information about the investigators, sponsors and primary reviewers of each project that will be under review. SRS members review the agenda and will declare any potential conflicts of interest prior to the beginning of project reviews.

In general, the SRS member will recuse him or herself from participation in the discussion and vote. If there is any question as to whether or not a conflict exists then the full SRS will discuss the conflict of interest without the member present to determine if a conflict of interest is present. If a conflict of interest is present then recusal will be required.

REVIEW PROCEDURES

Review of Research Protocols

The SRS is responsible for reviewing annually all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source for both on-site at the Jesse Brown VA Medical Center (JBVAMC) or off-site at the University of Illinois at Chicago (UIC) or at Northwestern University (NU).

Initial Review

The full SRS will review all initial project applications, only after the application has been reviewed/approved by the RSC/CHO and the RSO (as applicable). In performing the review the SRS will:

Review the Research Protocol Safety Survey (RPSS) (VA Form 10-0398 and Addendum form), (see App. A). The review must include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted. Investigators must submit VA Form 10-0398 and Addendum form in electronic format a minimum of ten (10) working days prior to an SRS meeting in order to be reviewed at that meeting. The SRS must ensure that a complete list of all products containing chemicals designated or identified by OSHA or EPA as “hazardous” has been submitted to the RSC/CHO for review and approval prior to the submission of a protocol for local review. (Procedures are outlined in the SOP for Security & Control of Research Laboratories.) Investigators are responsible for the accuracy and completeness of the lists.

The SRS will identify the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising the R&D Committee and Employee Health Practitioner on the need for such surveillance.

The SRS will identify if the proposed research involve the use of select agents or Toxins.

- Document this in the meeting minutes.
- The SRS Chair will advise the Chair of the R&D committee in writing or by e-mail.
- Initiate the procedures that are outlined in the SOP for Security & Control of Research Laboratories.

The SRS will identify if the proposed research involves the use of radioactive compounds or ionizing radiation. If the application indicates that these will be used then:

- The Radiation review will ensure that any offsite/affiliate radiation activities have been approved by the offsite/affiliate institution.
- The SRS will ensure that the facility Radiation Committee has reviewed and approved the use of radioactive substances and/or ionizing radiation.

The SRS will identify if the proposed research involves the use of recombinant DNA (rDNA). If rDNA is involved then the SRS will refer the application to the appropriate affiliate Institutional Biosafety Committee (IBC) for review. Copies of the minutes from the affiliated IBC meetings where the projects have been reviewed will be reviewed by the SRS accordingly. The SRS will determine if the proposed research involves the storage of tissue samples. If tissue samples are stored, then the SRS will determine if the collection, handling, and storage conditions are sufficient to minimize the risks posed by any biohazards. The SRS will further determine if the staff is adequately trained and qualified.

Initial safety applications will be approved for a period of three (3) years. An “Annual Renewal” report must be submitted on an annual basis.

Annual Review

The date of continuing review is based on the date of SRS approval. Annual reviews may be approved by the SRS Chair if it is determined that:

- The answers to all 11 items on form 10-0398 were either NO or NA at the time of the previous review.
- There has been no change in form 10-0398 since the previous review. If any potential hazard is identified on form 10-0398 then the procedures for the continuing review will be the same as for initial review.

Amendments and Modifications

Research protocol changes in the original application must be documented on an amended Research Protocol Safety Survey (RPSS) (see App. A, VA Form 10-0398 and Addendum) and must be submitted to, reviewed and approved by SRS prior to the implementation of the changes.

Inventory Transfers

Transfers of inventory must be in compliance with the Department of Transportation (DOT), Occupational Safety & Health Administration (OSHA), Nuclear Regulatory Commission (NRC), Center for Disease Control (CDC) and United States Department of Agriculture – Animal Health Monitoring & Surveillance (USDA-APHIS) regulations. Transfer of any hazardous agents, including but not limited to those specifically identified as CDC select agents and toxins and USDA APHIS biological agents and toxins, must be documented as to the identity of the receiver of the materials, where it is being transferred, and the date of the transfer.

- The SRS must approve all transfers of hazardous agents, including exempt quantities of toxins.
- If there are extreme time constraints and there is an appropriate justification for the transfer prior to the next committee meeting, the chair of the SRS may approve the transfer. The full SRS and R&D Committee must be notified of the action at their next meeting.
- Transfers of radioactive materials and/or radioactive sources, and other hazardous agents must be approved by the Radiation Safety Officer prior to transfer.

Review of Policies and Procedures

Annual Reviews

The SRS will annually review and forward the following policies and procedures to the R&D Committee for approval:

- The Safety Plan.
- The SRS SOP.
- The Chemical Hygiene Plan including:
 - ❖ Administrative & Engineering Controls
 - ❖ Chemical Handling
- The Emergency Preparedness and Response Plan
- The Occupational Health and Safety for Personnel Engaged in the Care and Use of Experimental Animals Guidelines (primary review performed by the Subcommittee for Animal Studies).
- The SOP for Security & Control of Research Laboratories (primary review by the Security Subcommittee).

The Chair of the SRS will ensure that the annual reviews are performed. The Chair may delegate member(s) to perform the yearly reviews. In addition to the above reviews the SRS will also review changes to the following procedures that are the primary responsibility of other committees.

Review of Facilities

Two ongoing facility reviews include:

- The Annual Workplace Evaluation (AWE-annual)
- The Environment of Care Review (EOC-semiannual)

Review of Inspection Reports

SRS reviews the finding of the AWE and EOC committees. Because the RSC/CHO briefs inspection results to the EOC this fulfills the requirement that the SRS does conduct inspections.

- The EOC includes at least one member of the SRS
- The SRS reviews the findings of the AWE and/or EOC and develops a remediation plan within the priorities assigned by the AWE/EOC.
- The R&D AO implements the required actions.
- The RSC/CHO tracks the progress and efficacy of the actions and reports back to the SRS at scheduled meetings.
- The Safety Inspection Enforcement Policy (Appendix C) describes in detail the process for dealing with non-compliance with safety inspection findings and their corrective action plans.

Inventory Controls

Inventory control includes maintaining an up-to-date record of all chemicals including but not limited to exempt quantities of toxins, and other hazardous agents in research laboratories. It also includes following the applicable regulations for the acquisition, transfer, and destruction of these agents.

Inventory List

A current, complete list of all chemical agents, including but not limited to select agents, toxins and other hazardous chemicals, as defined by OSHA and EPA, must be maintained by each research laboratory and when required, be made available to the Local Emergency Planning Committee (LEPC) as required by the Emergency Planning and Community Right-to-Know Act (SARA Title III).

- The inventories must be updated at the time a new chemical or agent is introduced into the VA research laboratory or when other inventory changes occur.
- The investigator must submit a modification to their approved safety form so that a hazard assessment can be conducted prior to introduction of a new hazardous agent or toxin to determine the impact on the facility's emergency preparedness program and on safety and security.
- In accordance with VHA Handbook 1200.8, the facility Safety Officer must review and approve inventories. Or this task may be performed by the Research Safety Coordinator/Chemical Hygiene Officer.
- These inventories may be conducted by VA research laboratory personnel on a daily, weekly, or monthly basis, but the review by the Safety Officer must be documented and done on at least a semi-annual basis.
- The VA investigator is responsible for ensuring that inventory is reported and for informing the ACOS/R&D regarding inventory changes which may affect the security rating.

Review of Chemical Inventory

On a semi-annual basis the RSC will review the chemical inventories of each of the laboratories and report the findings of such to the SRS.

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 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 RSO.

Eye wash - weekly by the Research Safety Coordinator.

Hoods – semiannually by contracted personnel, verified by the RSC.

Biological Safety Cabinets – semiannually by contracted personnel, verified by the RSC

Fire extinguishers – routinely by the Facility Safety Officer (FSO), verified by the RSC

Emergency preparedness and response drills - are coordinated by the RSC and the FSO

Detailed additional information is located in the Chemical Hygiene Plan (CHP).

Findings of each of the inspections as noted above will be reported to the SRS accordingly.

Remediation and Follow-up

The RSC will track progress made in the remediation plan and will report progress and problems to the SRS at regularly scheduled meetings.

Non-Recurrent Processes

Bloodborne Pathogens – The SRS will ensure that the risk of exposure to bloodborne pathogens will be minimized in the research setting by requiring that all research personnel are aware of, and utilize, universal precautions in the handling of biologic fluids of any type according to the specifications of the Bloodborne Pathogen Standard (CFR 191 0.1030, Bloodborne Pathogens)

Recombinant DNA Research - The SRS will identify projects that may involve the use of recombinant DNA and will refer such projects to the Institutional Biosafety Committee (IBC) for review. Copies of the minutes from the affiliated IBC meetings where the projects have been reviewed will be reviewed by the SRS accordingly.

Hazardous and Select Agents - The SRS will identify projects that involve the use of Select Agents or Hazardous Agents. If a project involves the use of such materials then the SRS will

- Conduct a review according to the procedures delineated in the SOP for: Security & Control of Research Laboratories.
- Notify the ACOS Research and the Chair of the R&D Committee if the use is approved.

HAZARDOUS AGENTS AND TOXINS

The JBVAMC does not currently utilize select agents and toxins nor does it have any laboratories listed as “BSL3”.

ACTIONS

If quorum does not attach, the SRS may only vote to defer review.

If quorum attaches, the SRS may vote to:

- Table
- Approve
- Approve Pending
- Approval Withheld
- Disapprove

Projects may be Approved Pending with minor stipulations. Approvals Pending are not Approved until the stipulations have been met. The SRS must clearly state in the meeting minutes the nature of the stipulations. The SRS Chair must communicate the required actions to the Principal Investigator within ten (10) working days of the SRS determination. Unless it is otherwise specified in the meeting minutes, the primary reviewer is responsible for ensuring that the stipulations are fulfilled.

Projects are not normally disapproved unless there is some aspect of the design that would violate JBVAMC policies or procedures.

If a project is Disapproved, then the Chair of the SRS will notify the Chair of the RDC and the PI in writing within ten (10) working days of the decision. This notification must specify the reasons for the disapproval and must inform the PI of the conditions for reconsideration. The PI must provide a rebuttal and request for reconsideration within 2 weeks of receipt of the disapproval notification.

If the SRS chooses to allow the project to be reconsidered then the status will be changed to Approval Withheld. If the SRS does not choose to reconsider, then the PI may petition the RDC. The RDC will work closely with the SRS to resolve the matter.

If Approval is Withheld or the action is Tabled, then the Chair of SRS will notify the PI in writing within ten (10) working days of the decision. This notification must specify the reasons that the action was tabled or approval was withheld and the actions that are required for reconsideration.

TRAINING

All individuals (VA employees appointed as full-time, part-time or intermittent paid employees, and WOC employees, IPA's, as well as contractors) working in a research laboratory, those working with hazardous agents including, those working within BSL-2, laboratories, and all individuals directly administering these VA research laboratories must be appropriately trained to ensure both safety and security within research laboratories and the safe handling of and security of select agents, toxins or other hazardous agents. The training must include training on the Laboratory's Emergency Preparedness and Response Plan.

Training will include:

- General information on safety and security within VA research laboratories, as well as safety, security, containment, and transferring of hazardous agents.
- Specific information related to the laboratory in which they will work and to the agents with which they will work.
- Training requirements set forth by OSHA, CDC, other applicable Federal agencies and other VA policies

The Principal Investigator will ensure that all required personnel complete such training and its completion is documented.

All new research staff and new administrators (e.g., ACOS/R&D, AO/R&D, supervisors, managers) responsible for VA research laboratories, including those using or storing hazardous agents including select agents or toxins, must complete the required training prior to assuming their duties.

For those individuals already working within research laboratories the RO may certify in writing that the individuals have the required knowledge, skill, and abilities to safely carry out their duties and responsibilities. This includes the ability to understand and follow the security requirements in this SOP.

All individuals must receive additional training prior to assignments with new exposure situations or when security systems and procedures are changed

All individuals who are required to obtain initial training or have been certified by the RO as having the appropriate knowledge to work in VA research laboratories must obtain refresher training annually.

The RO or ARO(s) must maintain training records for both the initial training and all annual refresher training; this includes the identity of the individual, the date of training, and the means used to verify that the employee understood the training. A notation must be made in the training log regarding individuals that were certified by the RO. The written certification for these individuals must also be maintained on file.

The SRS is responsible for ensuring that all laboratory personnel receive annual research specific safety training.

Mandatory Facility Training (required of all JBVAMC employees):

- Emergency Preparedness
- Infection Control
- Life(Fire) Safety
- Safety
- Electrical and Equipment Safety

Laboratory Training

- Required of all staff working in JBVAMC and those working offsite who receive VA funding. Onsite staff shall receive briefing from Research Safety Coordinator/Chemical Hygiene Officer and PI. All offsite VA funded investigators and their staff must provide training certificates to the SRS annually or when new workers arrive in lab.

Hazard Specific Training

- Radiation Safety (required for the use of radiation)

QUALITY IMPROVEMENT AND ASSURANCE

The SRS will:

- Ensure 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. In the event of exposure, the Chemical Hygiene Officer will ensure that appropriate actions are taken and will report to the SRS.
- Evaluate annually the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions.
- Ensure the review of investigation reports of all lost-time injuries and all significant adverse environmental events.
- Ensure the proper reporting of injury and illness trends to the R&D Committee, as appropriate.
- Request, 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.
- Ensure the development of a policy for the preservation of employee medical and OSHA exposure records and environmental records (i.e., hazardous waste, air monitoring).

The SRS policy is:

- Employee medical records are maintained by employee health.
- OSHA exposure records are maintained by the Chemical Hygiene Officer.
- Records of hazardous waste are maintained by the Chemical Hygiene Officer.
- Records of environmental monitoring are maintained by the Engineering Service.
- Cooperate with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.
- Provide technical assistance, where appropriate, in recycling programs and reduction of the quantity of waste.
- Review all citations issued by regulatory agencies and ensure that appropriate committee members and PIs take prompt corrective actions, and coordinate the necessary responses to regulatory agencies.

- Review all affiliated IBC Minutes as appropriate. The Chairman and/or the RSC will attend the affiliated IBC Meetings accordingly. This includes review of compliance related issues related to the IBCs, or use of rDNA.

The above information will be conveyed to the RDC as part of the annual review of the subcommittee, including training and security issues.

RECORDKEEPING

The AO R&D will be responsible for maintaining the following records:

- Training Records. Including the records of training required under Section 08 (1) for employees of the Research HCG and records of training required of laboratory personnel under section 08 (2,3) above. A mechanism must be implemented to ensure that all records (written, computer databases, spreadsheets, etc.) are accurate and one, which allows for the authenticity of these, records being verified.
- Safety and Security Incident Reports. Safety and Security Incident Reports including:
 - ❖ All safety and health Notices issued by OSHA; the VISN; and the facility safety, health, fire protection, security, and infection control staff.
 - ❖ All incidents reported to the VISN and VA Central Office.
- External Inspections. A record must be kept of all inspections of the VA research laboratories covered by this Handbook, including:
 - ❖ Inspections by authorized entities such as CDC, VA OIG, USDA, GAO, ORD, ORO, the VA facility, and VISN Safety and Health officials.
 - ❖ All inspections of the VA research laboratories covered and required by this SOP.
- Internal Inspections. A record of all findings, deficiencies and corrective action based on the inspections listed in SOP.
- Safety, Security, and Emergency Response Plans and SOP's. Records must also include a record of when last reviewed, the mechanism used to disseminate the plan, and new changes to affected research staff.
- SRS Meeting Agendas and Minutes.
 - ❖ The SRS will provide written notification of the results of SRS review to the R&D Committee, the Research Office, and the PI. Written notification will be through the use of meeting minutes.
 - ❖ Agendas and meeting minutes will be prepared and maintained by the Safety Committee Coordinator.
 - ❖ Agendas and minutes of the Subcommittee on Research Safety (SRS) must be prepared according to the following format

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:

- Approval of Minutes. Approval of minutes of previous meeting (date).
- Unfinished (Old) Business. List pending items and individual responsible.
- New Business. Identify individual responsible when necessary.
 - ❖ Standing Recurring Reports. Identify individual responsible.
 - ❖ Issues. Any issues not previously addressed by the body.
 - ❖ Other. Any other item that warrants review or discussion by the committee and is not routinely reviewed by the committee.

- Announcements
- Next Meeting. Date, time, and place of the next meeting

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

- 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.
- Place, date, and time of the meeting.
- Name of presiding officer (chairperson).
- 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.
- Indication that a quorum is present. NOTE: A quorum is defined as more than 50 percent of the voting members are present.
- Actions and recommendations are to then to be identified, 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.

Recommendations are 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.

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:

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.

The minutes must note which members excused themselves from voting on which project(s) to prevent conflicts of interest.

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.

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

Minutes must be written and published within 3 weeks of the meeting date.

Minutes must be signed by the Chairperson of the SRS.

Approved minutes must be forwarded to the RDC for review and approval. The RDC 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 RDC may not alter the SRS minutes.

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

NON-COMPLIANCE

SRS Audits

The SRS will initiate a review if there is any allegation or other evidence that there has been a violation of safety policies or procedures. The SRS has the authority to examine all records that have a direct impact on safety. The SRS may also choose to review the working environment at any time and without notice.

The SRS will consider the evidence and will determine by vote if the non-compliance is confirmed.

SRS Actions

If non-compliance is confirmed then the noncompliance will be reported as described below.

If the non-compliance is confirmed the SRS will determine by vote if the non-compliance is Serious or Continuing.

The SRS will consider the non-compliance to be Serious if it involves an immediate threat to the safety or health of animals, research participants, or staff.

The SRS will consider the non-compliance to be Continuing if the PI has failed to take corrective remedial action after a previous finding of non-compliance for the same violation, or if there have been more than three (3) findings of non-compliance (all projects for a PI) within three (3) years.

If the SRS determines that a violation is Serious or Continuing, the SRS may recommend that the RDC Suspend or Terminate the Project. If immediate action is required, then the RSC, who serves on the SRS, has the authority to invoke an Administrative Suspension. Reports of Serious or Continuing Non-compliance to external agencies will be made by the RDC as described in the RDC SOP.

Appendix C (JBVAMC SAFETY INSPECTION ENFORCEMENT POLICY) describes in further detail the process for dealing with non-compliance with safety inspection findings and their corrective action plans.

SRS REPORTING

SRS reporting requirements include:

- Adverse Events – reporting adverse events immediately to the Occupational Health Nurse and the ACOS R&D
- Reporting confirmation of Serious or Continuing Non-compliance to the Chair of the RDC and the ACOS R&D within 2 working days of the determination.
- Reporting operational problems or violations of directives to the Research Office within 30 days of occurrence or detection, unless SRS determines that a report has been previously filed by the PI.
- Providing written notification of the results of SRS review to the RDC, the Research Office, and the PI.
- Forwarding minutes of SRS to the R&D Committee through the Research Office

SRS REGULATORY AUDITS

The JBVAMC Research Compliance Officer (RCO) will conduct a regulatory audit of the SRS on a tri-annual basis in accordance to VHA Regulations.

VHA REQUIREMENTS RELATED TO RESEARCH SAFETY (as per VHA Handbook 1058.01)

Reports Within the VA Facility The Facility Director must ensure written SOPs are established and published to effect compliance with the reporting requirements. Investigators, RCOs, and other members of the VA research community must report the research events listed below to the ACOS for R and the Subcommittee on Research Safety (SRS) as soon as possible, but no later than 5 business days after becoming aware of them.

1. An ACOS for R or an SRS Chairperson must report the research events as listed in subparagraphs 8b and 8c of VHA Handbook 1058.01 to the Facility Director and the R&D Committee as soon as possible, but no later than 5 business days after becoming aware of them.
2. An RCO identifying serious or continuing noncompliance, during a regulatory audit, must report the noncompliance to the Facility Director, the ACOS for R, the R&D Committee, and the SRS as soon as possible, but no later than 5 business days after becoming aware of them.

Reports to ORO ROs

The Facility Director must report the following research events to the appropriate ORO RO as soon as possible, but no later than 5 business days after being informed of them.

1. Work-Related and Other Injuries Any work-related injury to personnel in VA research, or any research-related injury to any other person, that requires more than minor medical intervention or leads to serious complications or death.
2. Work-Related Exposures Any work-related exposure of VA research personnel to hazardous materials at greater than routine levels or that requires more than minor medical intervention or leads to serious complications or death.
3. Serious or Continuing Noncompliance Any serious or continuing noncompliance with VA or other Federal requirements related to research safety (e.g., VHA Handbook 1200.06; VHA Handbook 1200.8; 7 CFR 331; 9 CFR 121; 29 CFR 1910 and 1960; and 42 CFR 72 and 73).
4. Suspensions or Terminations Suspensions or terminations of ongoing research activities related to concerns regarding the safety, rights, or welfare of research staff or others.
5. Laboratory Decommissions Laboratory space that is being reassigned, vacated, or converted to non-laboratory use and requires identification and disposal of hazardous materials and/or equipment between uses. *NOTE: Such laboratory decommissions must also be reported to the VISN Safety Office, the Research Safety Coordinator, and the Radiation Safety Officer*
6. External Noncompliance Findings Any findings of noncompliance related to research safety by any VA office, any other Federal department or agency (e.g., United States Environmental Protection Agency), or any other entity (e.g., State Environmental Protection Agency). The Facility Director's report to ORO must include a copy of the entity's official findings.

Reports to ORO Central Office

As soon as possible, but no later than 5 business days after being informed of any change in an MOU with an affiliate institution (or other entity related to research safety arrangements), the Facility Director must report the change to ORO Central Office, with a copy to the appropriate ORO RO.

REQUIREMENTS RELATED TO RESEARCH LABORATORY SECURITY

(as per VHA Handbook 1058.01)

Reports Within the VA Facility

The Facility Director must ensure written SOPs are established and published to effect compliance with the reporting requirements as listed in subparagraphs 9a(1) through 9c of VHA Handbook 1058.01.

1. Investigators, RCOs, and other members of the VA research community must report the research events listed in subparagraphs 9b and 9c of VHA Handbook 1058.01 to the ACOS for R as soon as possible, but no later than 5 business days after becoming aware of the problem.
2. An ACOS for R must report the research events listed in subparagraphs 9b and 9c of VHA Handbook 1058.01 to the Facility Director and the R&D Committee as soon as possible, but no later than 5 business days after becoming aware of them.
3. An RCO identifying serious or continuing noncompliance, during a regulatory audit, must report the noncompliance to the Facility Director, the ACOS for R, and the R&D Committee as soon as possible, but no later than 5 business days after becoming aware of them.

Reports to ORO ROs

The Facility Director must report the following research events to the appropriate ORO RO as soon as possible, but no later than 5 business days after being informed of them.

Injuries. Any injury or harm to a human individual or laboratory animal related to a break-in, security breach, or other security problem involving a VA research facility.

Serious or Continuing Noncompliance. Any serious or continuing noncompliance with Federal, VA, or VHA requirements related to research laboratory security.

1. **Biosafety Level 3 (BSL-3) Breaches.** Any break-in or security breach involving a VA BSL-3 research laboratory.
2. **Other Breaches.** Any break-in or security breach involving a VA research facility that results in any of following:
 - (a) Loss of any quantity of a select agent or toxin.
 - (b) Loss of any quantity of a highly hazardous agent (see VHA Handbook 1200.06).
 - (c) Substantial damage to the facility.
 - (d) Substantial loss of equipment or resources.

External Noncompliance Findings. Any findings of noncompliance related to research laboratory security by any VA office, any other Federal department or agency (e.g., Department of Homeland Security), or any other entity. The Facility Director’s report to ORO must include a copy of the entity’s official findings.

Reports to ORO Central Office

As soon as possible but no later than 5 business days after being informed of any change in an MOU with an affiliate institution or other entity regarding research laboratory security arrangements, the Facility Director must report the change to ORO Central Office, with a copy to the appropriate ORO RO.

RECERTIFICATION

This SOP must be reviewed and approved at least annually by the SRS and RDC

Approved:

Chair, SRS

Date

Chair, RDC

Date

DEFINITIONS

Audit: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s)

Conflict of Interest: A convergence of an investigator's private interests with his or her research interests, such that an independent observer might reasonably question whether the investigator's professional actions or decisions are improperly influenced by considerations of personal financial gain.

Continuing Review Deadline: The Continuing Review Deadline is exactly one year after the date of the most recent review of the study at a convened SRS meeting, or shorter if required by the SRS. Beyond this date, study approval expires and a study cannot continue.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Select Agents and Toxins: A hazardous agent is a biological material including the CDC list of select agents and toxins (42 CFR Part 73), APHIS biological agents (7 CFR Part 331, 9 CFR Part 121), and products of such biological material, ie., toxins. For purposes of this SOP, the term also includes highly toxic chemicals, exempt quantities of toxins, or gases that have the potential for being used as weapons of mass destruction.

Investigator: An individual who is under the direction of the principal investigator (PI) who is involved in some or all aspects of the research project, including the design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator may be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act of 1970. The FDA considers an investigator and a principal investigator to be synonymous.

Ionizing Radiation: Particles or rays with sufficient energy to cause the ejection of orbital electrons from absorber atoms. Includes diagnostic and therapeutic procedures done for research purposes. Sources of radiation include: nuclear medicine, radiation therapy and radiology.

Lapse: A condition that exists when a study has failed to be re-approved within the time frame that was specified at the time of the previous approval. Unlike suspensions and terminations, a lapse results from a failure to act, by either the investigator or the IRB, rather than as a result of an IRB action. All research activities must stop except for the continuation of follow-up activities necessary to protect the participants' safety. Unlike suspended studies, lapsed studies are not approved. Unlike terminated studies, lapsed studies may be re-approved.

Principal Investigator: An individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers an investigator and a principal investigator to be synonymous.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents

Quorum: More than half of the voting members are present including at least one nonscientist. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting

Recusal: When an SRS or R&D Committee or other committee member declines to participate in a matter because of a potential conflict of interest under the Code of Ethics. As distinguished from abstention, the official recusing him/herself will not be present in or participate in deliberations or voting on the matter where there are potential conflicts of interest.

Regulatory Noncompliance: Failure to adhere to institutional policies and procedures, state laws, federal laws or other regulations governing the conduct of human subjects research including failure to follow the requirements of VHA Handbook 1200.08. This includes such acts as failure to obtain or maintain approval for research or to adhere to an approved protocol, failure to submit applications for study continuing review, or adhere to the Safety Plan.

Research: as defined by the Department of Health and Human Services regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Researcher: Principal investigator or the investigator

SRS approval: The determination of the SRS that the research has been reviewed and may be conducted at an institution within the constraints set forth by the R&D Committee and by other institutional and Federal requirements.

Standard Operating Policy and Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function

Suspension: An action recommended by the SRS to the R&D Committee that temporarily or permanently stops all or some of the research activities must stop until issues have been satisfactorily resolved

ABBREVIATIONS

ACOS	Associate Chief of Staff
AO	Administrative Officer
ARO	Alternate Responsible Official
CDC	Center for Disease Control and Prevention
CFR	Code of Federal Regulations
CHO	Chemical Hygiene Officer
CHP	Chemical Hygiene Plan
DOT	Department of Transportation
EPA	Environmental Protection Agency
FSO	Facility Safety Officer
IACUC	Institutional Animal Care & Use Committee
IBC	Institutional Biosafety Committee
IPA	Intergovernmental Personnel Agreement
ORD	Office of Research and Development, VA Central Office
ORO	Office of Research Oversight
OSHA	Occupational Safety and Health Administration
PI	Principal Investigator
R&D	Research & Development
RDC	Research & Development Committee
RCO	Research Compliance Officer
RO	Responsible Official
RSC	Research Safety Coordinator
RSO	Radiation Safety Officer
RPSS	Research Protocol Safety Survey (VA Form 10-0398 & Addendum)
SCC	Safety Committee Coordinator
SOP	Standard Operating Procedures
SRS	Subcommittee for Research Safety
VA	Veterans Administration
VAMC	VA Medical Officer
WOC	Without Compensation

REFERENCES

1. Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002"
2. Title 5 CFR Parts 731 and 736
3. Title 18 U.S.C. § 175b
4. Title 7 CFR Part 331
5. Title 9 CFR Part 12.
6. Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989
7. Title 29 CFR 1910.38, 1910.120, 1910.1450 and 1960
8. Title 42 CFR Parts 72 and 73
9. CDC-NIH "Biosafety in Microbiological and Biomedical Laboratories" 4th edition
10. NIH Guidelines: "Recombinant DNA and Gene Transfer," April 2002
11. VA Directive and Handbook 0710
12. VA Directive and Handbook 0730
13. VA Handbook 5005
14. VHA Handbook 1058.01
15. VHA Handbook 1100.19
16. VHA Handbook 1200.1
17. VHA Handbook 1200.6
18. VHA Handbook 1200.7
19. VHA Handbook 1200.8
20. VHA Handbook 7701.1

Appendix A

Research Safety Survey Application (Form #10-0398) and Addendum

Appendix B

HAZARDOUS BIOLOGICAL AND CHEMICAL AGENTS

The Centers for Disease Control and Prevention (CDC) has identified certain biological, chemical and radioactive materials or agents as having potential for use as weapons of mass destruction. Improper use and/or containment of these materials or agents pose a risk to national security because of their:

- Ease of dissemination or transmittal between individuals;
- Potential for high mortality rates and major public health impact;
- Potential for causing public panic and social disruption; and
- Risk for public health preparedness.

Storage and/or use of these materials or agents in any quantity in a (VA) research laboratory requires special consideration for physical security, personnel access, inventory control, and emergency preparedness. These include:

- Select Agents and Toxins. A current list of select agents and toxins may be found at <http://www.cdc.gov/od/sap/>. This site also includes agents and toxins that are included on the United States Department of Agriculture (USDA) list of biological agents and toxins that overlap with the CDC list. This website contains:
 - ❖ A list of toxin amounts (exempt quantities) permissible for an investigator to store or use without requiring compliance with Title 42 Code of Federal Regulations (CFR) 73; and
 - ❖ A list of agents and toxins that have been excluded from the list of select biological agents and toxins.
- List of USDA Biologic Agents and Toxins. A list of USDA biologic agents and toxins may be found at: <http://www.aphis.usda.gov/>.
- Chemical Agents Considered to be Hazardous Agents. As of the date of publication of Handbook 1200.6, the following chemicals are considered hazardous agents. This list may be updated in the future and updates will be found on the Office of Research and Developments website: <http://vaww1.va.gov/resdev/>.
 1. 3-quinuclidinyl benzilate (BZ);
 2. Chlorine gas;
 3. Cyanogen chloride (CK);
 4. Cyclosarin (GF);
 5. Diphosgene (DP);
 6. Hydrogen cyanide (AC);
 7. Lewisite (L); NOTE: There are three individual chemicals included in this category.
 8. Nitrogen Lyserg; Mustard acid (FIN-i, diethylamide HN-2, or (LSD); I{N-3);
 9. Phosgene (CG), also known as carbonyl chloride;
 10. Phosgene oxime (CX);
 11. Sarin (GB);
 12. Soman (GD);
 13. Sulfur mustard (H, or HD, or HT), also called mustard gas or mustard agents;
 14. Tabun (GA)
 15. VX (VX is both the name and symbol).

- Radioactive Materials and/or Sealed Radiation Sources
 - ❖ The special considerations required for radioactive materials and/or sealed radioactive material sources need to be based on the specific radionuclide, the half-life, the chemical form, the physical form and the quantity present. For a “radiation high-risk” situation, more restrictive security measures need to be followed. For a “radiation low-risk” situation, basic security measures need to be followed.
 - ❖ “Radiation high-risk” is a single location or room where the total activity of a single radionuclide with a half-life of more than 3 days is greater than one Curie and the radionuclide is received, stored, or used. “High radiation-risk” situations may also be defined at lower levels by the Radiation Safety Officer depending on all of the radionuclides in use, the activities of each radioactive material, chemical and physical forms, and the procedures that will be performed. “Radiation low-risk” is any location other than a “radiation high-risk” location and where radioactive materials and/or radiation sources are received, stored, or used.

Appendix C

JBVAMC SAFETY INSPECTION ENFORCEMENT POLICY

Several entities inspect the research building for compliance with safety regulations, policies, and procedures. They include but are not limited to ORO, Subcommittee for Research Safety (SRS), Nuclear Regulatory Commission (NRC), National Health Physics Program (NHPP) and OSHA. Deficiencies found during these inspections must be corrected quickly.

To insure timely correction of safety deficiencies, the Research Administrative Office will notify the deficient lab Principal Investigator (PI) within ten (10) days outlining the deficiency, the regulation/policy it violates, and suggest corrective actions. The PI then has ten (10) days to respond in writing with the corrective actions he/she is going to take. Corrective actions must be completed within thirty (30) days of the initial notification. Research Administrative Personnel or committee members then will follow up to insure compliance has been attained, with a report to the SRS at the next scheduled meeting.

In the event a lab is not brought into compliance within thirty (30) days, the Research Office administrative personnel will initiate a meeting between the PI and the ACOS/R&D to discuss the deficiency. The ACOS/R&D will report this through the SRS to the RDC. Research will cease in the deficient lab until compliance is achieved. If compliance is not achieved within sixty (60) days of the initial notification, the PI and staff of the deficient lab will have their access to the lab denied until the PI with guidance from the Research Office or committee members can bring the lab into compliance.

Repeated deficiencies will be reported to the RDC by the SRS who may, with a majority vote, close the lab to further research by the deficient PI.

References: VHA Handbook 1200.8, 4.a. & 4.c.

Approved:

Chair, SRS

Date

Chair, RDC

Date