

**Subcommittee on Research Safety (SRS) &  
Institutional Biosafety Committee (IBC)  
Standard Operating Procedures**

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## **Statement of Purpose**

VHA Handbook 1200.08 "Safety of Personnel Engaged in Research" is the guiding document for Department of Veterans Affairs Subcommittee on Research Safety (SRS). The purpose of the SRS is to ensure the safety of personnel in Veterans Health Administration (VHA) research. This includes addressing both national and local standards. The committee reviews many hazards that are encountered in VA research that include but are not limited to: (a) Biohazards, e.g., pathogens and etiologic agents corresponding with BSL 1-4, or organisms and viruses containing recombinant deoxyribonucleic acid (DNA) molecules; (b) Chemical hazards; and (c) Physical hazards. The purpose of this Standard Operating Procedures (SOPs) is to describe procedures used for all recurring processes by the Durham VAMC (DVAMC) SRS.

## **Membership**

Membership on the DVAMC SRS consists of voting members, ex-officio/voting members, and ex-officio/non-voting members.

Voting members and ex-officio/voting members are appointed by the Medical Center Director (MCD) for terms of three years. Ex-officio, non-voting members have indefinite terms by virtue of their positions and are not issued appointment letters.

A Chairperson is elected on an annual basis by the voting members and appointed for a term of one-year by the MCD.

At least two members are not affiliated with the DVAMC and are appointed by the MCD.

Ex-officio/non-voting members that are statutory include:

- Administrative Officer, Research and Development (AO/R&D);

Other ex-officio members may be nominated as deemed necessary by the SRS and appointed by the MCD.

## **New Members**

Voting Members – Voting members are nominated by SRS members or other hospital staff and appointed in writing by the MCD. When a voting member has been nominated, the SRS will review the prospective member's credentials and discuss the prospective member's qualifications at a convened meeting. If the majority of voting members approve the nominee, the nomination is routed through the R&D Committee to the MCD. If the MCD concurs, the new voting member will be appointed as an SRS member at the next convened meeting, or at a mutually agreed upon future meeting.

Ex-officio voting members – Ex-officio voting members are appointed by the MCD if their appointment serves a need identified by the SRS.

Ex-officio non-voting members - Ex-officio, non-voting members are members of the SRS based on their position and do not have a vote. Consequently, they are not appointed via letter, and have indefinite membership duration.

### **Ad Hoc Reviewers**

If a proposal requires expertise not present among the voting members, an ad hoc reviewer may be identified and assigned to review a protocol. The ad hoc reviewer will present his/her review to the SRS and may make recommendations, but does not have SRS voting privileges.

### **Agenda**

SRS meetings are held monthly, on the third Friday of the month. Meeting agendas are distributed at least one week prior to the meeting. The agenda contains the most recent SRS meeting minutes; new project reviews; annual project reviews; reports on safety inspections or other safety reviews; safety manuals and handbooks, as necessary; reports from the Research Compliance Officer (RCO), ACOS/ R&D , and/or SRS Chair and any other items of business that come before the subcommittee. The agenda is available to all subcommittee members, voting, and ex-officio/voting members. Complete agendas and supporting documents are maintained per the VA Record Controls Schedule (RCS-10-1).

### **Deadlines**

SRS deadlines are posted and available to all investigators. Exceptions to the submission deadlines are at the discretion of the SRS Chair.

### **Meeting Minutes**

The minutes of each convened meeting will be recorded for development of the minutes and will contain the information as required by VHA Handbook 1200.08. The number of votes recorded in each voting category (described below) is a component of the minutes. If necessary, SRS meetings may be held via teleconference. All business items noted on the agenda must be distributed to voting members for review and discussion during the teleconference.

### **New Proposal Review**

Initial protocol reviews (other than those described below Administrative Reviews) and three year animal renewal protocols are reviewed by the SRS full committee at a convened meeting.

The Principal Investigator (PI) submits a protocol to the Research Office and it is placed on the next available agenda for review. Assigned Research program staff mail the agenda packet to the SRS members within five business days of the scheduled SRS meeting. Each protocol is assigned to two reviewers. Reviewers may address questions or concerns to the PI prior to the SRS convened meeting.

A Request to Review Form is completed prior to a project being assigned to the SRS Agenda. Each new proposal submitted to the SRS is sent for review by all subcommittee members. Two primary reviewers are assigned with diverse expertise. . All SRS members have the opportunity, at a convened meeting to comment on personnel safety, or any other safety matters deemed relevant for discussion. VA Form 10-0398 "Research Protocol Safety Survey aka 'Appendix G'", and applicable appendices, must be submitted by the PI and reviewed by the SRS Committee if indicated.

### **Modifications to Approved Protocols**

Modifications to an approved protocol that results in revision to Appendix G, chemical inventory or related SOPs are reviewed by the SRS full committee at a convened meeting. A primary and secondary reviewer is assigned to present the modification request to remaining SRS members. A complete copy of the modification including the title and a description of the modification is distributed to all SRS members for review as is described above under New Proposal Review.

### **Annual Project Review**

Annual renewal documents are reviewed by the SRS Chair or designee, who presents the review to the subcommittee for recommendations and actions.

The annual review submission includes a questionnaire that assesses changes to the protocol since the last review, including any changes to the safety protocol (App. G), chemical inventory, SOPs, and processes concerning transfer or shipping of hazardous materials. The Research Safety Coordinator reviews s for new staff and verification of training.

### **Administrative Review**

Administrative reviews are conducted by the SRS Chair or designee for any protocols that have been reviewed and approved previously by the SRS, and found at that time to include no safety issues or concerns related to the protocol (e.g., chart reviews, protocols that have shifted to the data analysis phase, etc.).

### **Recommendation Categories**

Approval – SRS approves the project as submitted without further recommendations, changes, or edits.

Approval with contingencies (contingent approval) – SRS requires conditions or modifications before approval can be granted. The investigator's response to issues raised by the committee is typically reviewed by the originally assigned reviewer. Alternatively, the investigator's responses may be reviewed by the entire committee, by certain committee members other than the originally assigned reviewers, or by only one of the originally assigned reviewers, if the committee determines that this is desirable when the protocol is first reviewed.

Tabled – SRS does not believe that there is sufficient information to formulate a recommendation. A tabled protocol must be re-reviewed at a fully convened meeting.

Disapproval – SRS does not believe that the project, in its current form, should be conducted at the DVAMC. An appeal process available to the PI is described below.

### **Voting Categories/Recusals**

Voting members may record their vote as one of the following:

- (1) Approval – agreement with the motion as presented
- (2) Disapproval – disagreement with the motion as presented
- (3) Abstain – the voting member does not wish to cast a vote as either approval or disapproval. An abstention counts in the quorum count but cannot be tallied as an approval if an agenda item results in a split vote.

Recusal – the voting member is recused from the meeting during the vote, typically due to a conflict of interest on the voting item. There is no recorded vote cast by the recused member and a recusal does not count towards quorum.

### **New Staff Review**

SRS will stay informed of all staff additions to the Institutional Animal Care and Use Committee IACUC and Institutional Review Board IRB committees by notification of such actions through SRS minutes. A notification event will be created and published in the monthly SRS agenda for SRS review when new staff is approved to work from either an IRB or an IACUC protocol. New laboratory staff not associated with either human or animal studies must be approved by SRS review. SRS review of new lab employees may occur either through full committee review or by “administrative” review. SRS “administrative” review of new staff will be conducted by the SRS Chair or designee, and will be conveyed to the SRS via SRS Minutes as a “Notification” of an Administrative review of an amendment or modification to the parent project. For “administrative” review, the Chair or designee will confirm with the Chemical Hygiene Officer and Research Safety Coordinator to ensure that all required safety training is complete prior to lab employee approval.

### **Program Quality Assurance Review**

In compliance with VHA Handbook 1200.01, The R&D Committee”, Section 9.c.(2)(a), “An annual review of the Research Safety and Security Program (RSSP) including planned training, compliance, security issues, etc. is required”. The SRS will participate in this review and present the results to the DVAMC R&D Committee.

### **PI Communication**

All outcomes of SRS proceedings will be transmitted to the (PI) in writing. SRS proceedings will be forwarded to the PI within seven days of the convened meeting.

## Research Safety Reporting

The SRS will review all noncompliance, safety, and security-related incidents as required by VHA Handbook 1058.01. As part of that review, a determination will be made on whether the event requires a report to the Office of Research Oversight (ORO).

Human Deaths. VA personnel, including Without Compensation (WOC) and Intergovernmental Personnel Act (IPA) appointees, must ensure oral notification of the SRS immediately upon becoming aware of any human death that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area).

(1) The SRS must alert ORO by e-mail or telephone within 2 business days after receiving such notification. The VA facility Director and the ACOS/R&D must receive concurrent notification.

(2) VA personnel, including WOC and IPA appointees, must ensure written notification of the SRS within 5 business days of becoming aware of the death.

Human Accident, Injury, Illness, or Exposure. VA personnel, including WOC and (IPA) appointees, must ensure written notification of the SRS within 5 business days after becoming aware of any serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area).

Reportable Incidents Under Applicable Federal Standards. VA personnel, including WOC and IPA appointees, must ensure written notification of the SRS within 5 business days after becoming aware of any incident related to research safety that is reportable under relevant VHA Handbooks or applicable Federal requirements, including Occupational Safety and Health Administration (OSHA) requirements.

SRS Review of Reported Incidents. The SRS must review any report of an incident described above at its next convened meeting.

(1) Incidents that involve a human death or present a significant risk to the safety of research personnel or the environment call for immediate attention and require the SRS to convene an emergency session prior to the next scheduled meeting.

(2) The SRS must notify the MCD and the ACOS/R&D within 5 business days after any determination that a reportable incident has occurred. No individual or committee may reverse or overrule the SRS's decision that a reportable incident has occurred.

(3) The MCD must report the incident or event to ORO within 5 business days after receiving the SRS notification.

(4) The SRS must **also** notify the MCD and the ACOS/R&D within 5 business days after any determination that an incident brought to its attention, based on the required reporting events listed above, was **not reportable**.

Time Period for Required SRS determinations. If the SRS is unable to make a determination within 60 calendar days after receiving notification of the relevant event, it must immediately notify the MCD who, within 5 business days after receiving the SRS's notification, must provide ORO with an acceptable justification for the delay and an acceptable completion timeline.

Additional Review of Reported Incidents. The MCD and others acting within their areas of responsibility may also investigate such incidents and make separate determinations as to reporting, but cannot reverse or overrule a determination by the SRS that a reportable incident has occurred.

- (1) The MCD must be notified within 5 business days after any such separate determination that a reportable incident has occurred.
- (2) The MCD must report to ORO within 5 business days after making or receiving any separate determination that a reportable incident has occurred, and the SRS must receive a concurrent copy of the report.

Memoranda of Understanding (MOU). New or substantially revised MOUs related to research safety must be reported to ORO within 5 business days after the final concurrence/signature. ORO strongly encourages contacting ORO early in the development of new or revised MOUs.

Laboratory Decommissions and Re-assignments. The investigator or laboratory director must obtain authorization (i.e., permission) from the SRS and the ACOS/R&D prior to decommissioning or reassigning existing laboratory space (including modifying, vacating, or converting to non-laboratory use) that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses.

- (1) The request for authorization to decommission or reassign laboratory space must be made in writing to the SRS and the ACOS/R&D at least 1 month prior to implementation.
- (2) Upon receiving such a request the SRS, in collaboration with the ACOS/R&D, must evaluate the space and determine if there are any specific hazards that require remediation.
- (3) The ACOS/R&D must notify the Safety Officer to ensure coordination of efforts in the inventory and efficient removal of hazardous materials, infectious agents, or equipment.
- (4) The ACOS/R&D must notify the MCD and the Safety Officer of any unauthorized decommissioning or re-assignment of laboratory space within 5 business days after becoming aware of the unauthorized decommissioning or re-assignment.
- (5) The MCD must report any unauthorized decommissioning or re-assignment of laboratory space to ORO within 5 business days after being notified.

## **Research Laboratory Security**

Research Laboratory Security Incidents. VA personnel, including WOC and IPA appointees, must ensure written notification of the ACOS/R&D within 5 business days after becoming aware of any physical security concerns that pertain to research laboratories or other areas used exclusively for research, including:

- (1) Any intrusion, physical security breach, break-in, or other security violation that occurs in dedicated research areas.

- (2) Any finding by any entity other than ORO of noncompliance with research laboratory security requirements. NOTE: Related reports to ORO must include all findings and all pertinent documentation.
- (3) Any unplanned suspension or termination of research by the ACOS/R&D or another facility official due to concerns about research laboratory security.
- (4) Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.

*NOTE: The VA Police Service must be notified immediately of all laboratory security incidents.*

Reports to the MCD and ORO. The ACOS/R&D must notify the MCD and the VA Police (if not previously notified) within 5 business days after becoming aware of any research laboratory security incident described above. Concurrent notification must be provided to other authorities in accordance with local reporting requirements. *NOTE: This pertains to areas used exclusively for research.*

- (1) The MCD must report the incident to ORO within 5 business days of being notified.
- (2) These incidents are not subject to the SRS deliberation and must be reported to ORO. However, the SRS must carefully review all incidents involving research laboratory security and determine if any changes in the Research Security Plan or other local policies are necessary to prevent future occurrences.

## **R&D Committee Communication**

As a subcommittee of the R&D Committee, all SRS actions and recommendations for protocols are reported to the R&D Committee via SRS/IBC meeting minutes. Tabled or disapproved projects are not forwarded to R&D for review. If a protocol that previously was disapproved receives approval, it may then be forwarded to the R&D Committee. To facilitate communication with the R&D Committee, the SRS Chair provides a written executive summary of items of business and of any particularly sensitive or convoluted issues discussed at the most recent SRS meeting.

## **“Science only” Protocol Review**

Overall project review and review of research not involving human subjects (IRB) or animal subjects (IACUC) will be accomplished by the R&D Committee as outlined in the R&D SOPs. However, like all research protocols this research will receive full review by the SRS.

## **Appeal Process**

If a project is disapproved, the PI will be given the opportunity to provide a written response to the SRS. At his/her request, the PI will be given the opportunity to provide an oral presentation to the SRS and answer questions posed by committee members.

Upon reconsideration by the SRS, no further appeals will be granted for that protocol should the protocol again be disapproved.

## **Communication with the Medical Radioisotope and Radiation Control Committee**

All protocols involving the use of radiation and/or radioactive materials must be reviewed by the Medical Radioisotope and Radiation Control Committee (MRRCC). The Radiation Safety Officer, who is an ex-officio, voting member of the SRS, will review protocols and determine the need for MRRCC review, if applicable. SRS approval will be contingent upon the MRRCC review of the project.

## **Interim Meetings**

An interim meeting can be called by the SRS Chair at any time to deal with emergent issues, to continue a meeting that lost quorum, or other related issues. The same rules for quorum apply to the interim meetings.

## **Confidentiality**

All proceedings of the SRS are considered confidential. As such, SRS members should only discuss SRS proceedings and decisions in a context relevant to the business of providing oversight and communicating results.

## **Status as the DVAMC Institutional Biosafety Committee (IBC)**

The DVAMC SRS also is designated as the DVAMC IBC. IBC Membership requires no fewer than five members, with collective expertise in recombinant DNA research and assessment of risk to the environment and to public health. No fewer than two members are required to be unaffiliated with DVAMC.

The DVAMC currently has no research involving Appendix P of the National Institute of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (*NIH Guidelines*), “Physical and Biological Containment for Recombinant DNA Research Involving Plants”, as such, does not include a member with expertise in plant, plant pathogen, or plant pest containment principles. If there is an occasion where these types of experiments were proposed to be conducted at the DVAMC, appropriate ad hoc consultant expertise would be enlisted.

If the DVAMC approves research involving BSL3 or 4 containment or practices, it will appoint a biological safety officer for this purpose as defined in the *NIH Guidelines*.

The DVAMC IBC is registered with the NIH Office of Biotechnology Activities (OBA), and provides annual membership updates, as required.

The IBC responsibilities include:

- 1) Review of recombinant DNA research for conformity with *NIH Guidelines*.
- 2) Review of recombinant DNA research for potential risk to environment and to public health.

The IBC Assessment Includes:

- 1) Containment levels per *NIH Guidelines*.

- 2) Facilities, SOPs, PI and laboratory personnel training.
- 3) Institutional and investigator compliance.

For human subject gene transfer research, or other human subject research involving recombinant DNA, the IBC will not approve research until documentation is received of Recombinant DNA Advisory Committee (RAC) review. Final approval of the research will not be granted until IRB review is completed and approved. The SRS acting in the capacity of an IBC will be so noted in the SRS Minutes in the individual project action summaries.

### **References**

VHA Handbook 1200.08, Safety of Personnel Engaged in Research, March 6, 2009.

NIH Guidelines for Research Involving Recombinant DNA Molecules (*NIH Guidelines*), October 2011.

VHA Handbook 1200.01, Research and Development (R&D) Committee, June 16, 2009

VHA Handbook 1058.01, Research Compliance Reporting Requirements, June 15, 2015