SUBJECT: Subcommittee on Research Safety

1. PURPOSE: Establish the Standard Operating Procedures for the Subcommittee on Research Safety (SRS).

2. DEFINITIONS:

ACOS/R	Associate Chief of Staff for Research
AO/R	Administrative Officer for Research
PI	Principal Investigator
WOC	Without Compensation Employee
RDC	Research and Development Committee
SRS	Subcommittee on Research Safety
RSSP	Research Service Safety Program
IBC	Institutional Biosafety Committee

3. OVERVIEW:

a) The Subcommittee on Research Safety (SRS) is established as a subcommittee of the Research & Development Committee (RDC) under VHA Directive 1200.08. The SRS is specifically charged with managing the implementation of the Research Service Safety Program (RSSP). Responsibilities of the SRS include review and approval of hazards in research protocols, and in ensuring that laboratory space used for research activities meet safety, security, inventory control, inspections, emergency management, training, and record keeping requirements mandated under the RSSP as outlined in 1200.08. Specific responsibilities of the SRS include:
   i) Oversight of the control of hazardous agents in research laboratories to ensure compliance with all applicable rules and regulations.
   ii) Oversight of the safety of personnel involved in research including ensuring compliance with all applicable rules and regulations.
   iii) Reviewing and voting to approve or disapprove initial reviews, continuing reviews, and protocol amendments for all research protocols under the primary oversight of the Institutional Animal Care & Use Committee (IACUC) or the Human Research Protection Program (HRPP) that involve hazardous agents or other safety concerns.
   iv) Reviewing and voting to approve or disapprove initial reviews, continuing reviews, and amendments for all protocols for which SRS is the subcommittee of record ("lab-only" studies).
   v) Coordination of all safety-related activities including safety training, safety inspections, accident reporting, and liaison activities with facility safety committees and officials.
   vi) Reviewing SRS SOPs, updating as necessary.

4. PROCEDURES:

a) **Establishment**: The Minneapolis VA SRS is established as an internal committee under the RDC and charged with oversight of research safety at this facility.
b) **Membership**: The SRS will consist of no fewer than five (5) voting members, plus at least two (2) ex-officio (non-voting) members, with specific expertise in all safety matters for which the SRS maintains oversight.
   i) Members of the SRS are appointed in writing by the facility Director to serve on the SRS for terms up to 3 years, with unlimited renewal at the discretion of the Director.
   ii) The SRS Chair is appointed in writing by the facility Director for a term of up to three years, which may be renewed.

iii) Voting and non-voting members of the SRS should include persons with expertise in:
1) Etiologic agents, including bloodborne and airborne pathogens;
2) Chemical carcinogens and other chemical hazards;
3) Physical, environmental, and radiation hazards; and
4) Other hazards inherent in conducting scientific research

iv) Voting members of the SRS must include persons with specific expertise in:
1) Occupational safety and health;
2) Environmental protection;
3) Department of Transportation (DOT) International Air Transport Association (IATA) expertise; and
4) Knowledge of space and facilities assigned to Principal Investigators (PIs) in the Minneapolis VA research program.

v) The SRS must include at least one member from the Facility Safety Committee. Examples of persons who meet this requirement may include the facility Safety Officer, Radiation Safety Officer, or a member of the Infection Control Committee.

vi) The SRS must include at least one member who attends meetings of the Institutional Animal Care and Use Committee (IACUC). This member will serve as a liaison between the SRS and the IACUC, and may be a voting or a non-voting member of the SRS.

vii) The SRS must include a minimum of two (2) ex-officio (non-voting) members:
1) A liaison member from the R&D Committee; and
2) An employee union safety representative.

c) **Review of Research Protocols:** The SRS is charged with review of all research protocols submitted for consideration at the Minneapolis VA. For studies that involve human or animal subjects, the SRS review is in addition to the reviews conducted by the committee of record (the Institutional Review Board [IRB] and IACUC, respectively). For studies that involve hazards but do not fall under the purview of the IRB or IACUC, the SRS may serve as the committee of record.

i) **Studies Exempt from SRS Review:** Studies that meet specific conditions are exempt from SRS review. Studies that satisfy these conditions include:
1) Research involving personnel working in clinical areas. This may include collection and processing of samples in a clinical laboratory, standard clinical procedures performed in a clinical care visit, or similar.
2) Research that does not include collection of specimens or use of a laboratory. This includes studies such as chart reviews, analysis of existing data, health services research, or similar.
3) No Hazards Identified (NHI) studies. This includes studies that are conducted in a VA research laboratory, in which the PI has indicated "No" to all questions on the Research Protocol Safety Survey (RPSS).

ii) **Administrative Review of Exempt Studies:** The SRS Chair, or another designated, qualified individual, may administratively review protocols to determine whether they may be exempt from SRS review.

1) Administrative review is conducted by the SRS Chair or by a delegate.
    a. Delegates may be assigned to review when the Chair is unavailable, has an apparent conflict of interest, or when the Chair feels that another person may be better suited to evaluate hazards in a specific protocol.
    b. Delegates, if assigned, will be documented in writing in the electronic protocol management system and recorded in the SRS minutes.
2) The Chair or delegate will review the protocol (and accompanying RPSS, if submitted) for consistency with criteria for exemption from SRS review.
    a. Any inconsistency between the research protocol and RPSS will be clarified with the PI.
    b. If a research protocol did not include an RPSS, should any information indicate potential for hazards, the reviewer will request that the PI submit an RPSS.
3) Should the reviewer agree that a protocol meets criteria for exemption from SRS oversight, they will record the protocol as "Acknowledged" in the electronic protocol management system.
    a. This determination will be reported to SRS members and recorded in the minutes at the next convened SRS meeting.
4) If the reviewer determines that a protocol does not meet criteria for exemption, the protocol will instead be referred to the full SRS committee for review.

iii) **SRS Review of Research:** The SRS will review every research protocol that involves biological, chemical, physical, or radiation hazards conducted in a VA research laboratory.
1) A PI proposing use of hazards in research must submit for review a completed VA Form 10-0398 (Research Protocol Safety Survey, RPSS) or an electronic equivalent. Protocols submitted without an RPSS, or submitted with an incomplete RPSS, will be returned to the PI for correction prior to SRS review.
2) The RPSS may be project-specific or may be an umbrella protocol covering multiple projects funded by the same award.
    a. Because of limitations in the current electronic protocol management system, in practice umbrella protocols should be limited to studies in which multiple RPSS submissions would be unnecessarily duplicative, such as studies where one RPSS may cover activities on multiple research protocols funded by the same parent funding grant.
3) Upon submission, the RPSS and accompanying documentation will be reviewed by the SRS Coordinator, who will determine the appropriate reviewer(s) for the protocol.
    a. When multiple persons are assigned to review portions of a specific protocol, one individual (typically the SRS Chair) will serve as primary reviewer of the entire proposal, while secondary reviewers will focus on specific hazards only.
    b. Review of specific hazards will be assigned to persons with expertise in that area; for example, the Radiation Safety Officer will be asked to review protocols involving radiation.

c. If the protocol indicates use of recombinant or synthetic nucleic acid molecules, the protocol will be referred to the Institutional Biosafety Committee (IBC) for review and approval prior to any review by the SRS.

d. Protocols which indicate use of select agents and toxins, stem cell research, nanotechnology, or Dual Use Research of Concern (DURC) may also be referred to the IBC for review and approval prior to any review by the SRS.

4) During SRS review of any new or amended protocol, the SRS will consider:

a. The biological, chemical, and physical hazards associated with the research including, but not limited to, risks to personnel, research subjects, the facility, and the environment;

b. The level of containment, laboratory procedures and practices, personal protective equipment, and training required for the research to be conducted safely;

c. The full list of any hazardous chemicals used in the study;

d. The experience, expertise, and training of personnel involved;

e. The adequacy of the available laboratory space and resources; and

f. The status of the research, with respect to the NIH Guidelines, when the research involves recombinant or synthetic nucleic acid molecule research and whether IBC approval has been obtained, if required.

iv) **Initial Review**: SRS review of all initial RPSS submissions will occur at a convened SRS meeting in which a full quorum (a majority of the total voting membership) is present.

1) All review will occur in real time either in person or virtually via videoconference or teleconference.

2) SRS members who have conflicts of interest on a specific protocol may answer questions about the study, but will recuse themselves during deliberation and vote on the affected protocol. Recusal and verification of quorum must be documented in the SRS meeting minutes.

3) If at any time quorum cannot be maintained, due to recusal or other reasons, no voting can occur until the quorum is restored.

4) If the protocol is under purview of the IBC, the SRS will review the findings of the IBC including the assigned Biosafety Level (BSL) and required safety measures.

5) Approval of a protocol is obtained via majority vote of the voting members present. Voting on any SRS motion will only occur via real-time, in person or virtual process. The SRS may vote to:

a. Approve: Protocol is approved as submitted.

b. Approve with modifications: Protocol is provisionally approved, with final approval coming only after a Designated Member Review (DMR) verification that requested modifications have been added to the protocol.

c. Withhold approval: Should a majority vote not to approve a protocol, the SRS will provide a response to the PI explaining the reasons for this action.

6) The PI and the RDC will be notified of the outcome of SRS review in writing.

   a. For protocols in which changes were requested by the SRS, or where a reviewer requested clarification or additional information, such requests will be communicated to the PI in writing by the SRS Coordinator.

   b. The outcome of the SRS review of the protocol will be communicated to the PI in writing and to the RDC via the SRS meeting minutes.

v) **Amendments:** Any amendment that impacts the safety components of an approved protocol must be reviewed and approved by the SRS before proposed changes are implemented.

1) Amendments that are considered minor may be approved via DMR review. Examples of minor amendments include but are not limited to:

   a. Change in personnel (other than the Principal Investigator)

   b. Addition of procedures that do not increase the research hazards currently approved by the SRS

   c. Reduction or removal of hazards previously approved by the SRS

2) Amendments that are not considered minor will be reviewed at a convened SRS meeting. Such amendments are reviewed following the same general procedure as outlined above for initial reviews. Amendments that require full SRS review include but are not limited to:

   a. Amendments that add new hazards

   b. Amendments that seek to change the PI

3) As with initial review, for amendments requiring review at a convened SRS meeting, the SRS may vote to approve, to approve with modifications, or to withhold approval. Amendments that are approved with modifications may secure final approval via DMR.

4) The outcome of the SRS review of the amendment will be communicated to the PI in writing and to the RDC via the SRS meeting minutes.

vi) **Continuing Review:** Each approved SRS protocol will be reviewed once annually by the full SRS committee at a convened meeting.

1) The SRS will consider under this review any change in personnel, in hazards, in laboratory space, and any reports of injury or illness related to the protocol.

2) As with initial review, a protocol under continuing review approved with modifications may secure final approval via DMR.

vii) **Designated Member Review:** DMR may be used in some cases to secure final SRS approval. At any point during the DMR process, any member of the SRS may request that the protocol be returned to the SRS for full committee review.

1) DMR may be used to secure final approval for:

   a. Any initial review, amendment, or continuing review that was approved with modifications by the SRS at a convened meeting; or

   b. Any minor amendment as defined by this SOP.

2) DMR may only be conducted by a voting member of the SRS, identified by the SRS Chair as having the appropriate expertise to make the determination.

3) The designated reviewer may only approve or approve with modifications. If the reviewer instead feels that approval should be withheld, the protocol must be referred back to the SRS for full committee review.

4) The outcome of any DMR review of a protocol, including date of approval, will be reported to the SRS at the next convened meeting and will be documented in the SRS meeting minutes.

viii) **Annual Review:** The laboratory program of each PI will be reviewed by the SRS at least once annually at a convened meeting.

1) Annual review of the laboratory program at the Minneapolis VA is secured through:

   a. Annual review of each individual approved SRS protocol under the supervision of the PI, including review of all changes or amendments;

   b. Annual inspection of each active laboratory overseen by the PI; including review of any change in space allocation;

   c. Annual reports of any issues related to employee safety and security for any protocol under the supervision of the PI; and

   d. Reports of non-compliance or other issues brought to the SRS by the Research Compliance Officer, Environment of Care committee, or other outside group.

2) At a convened SRS meeting, the committee will evaluate:

   a. The list of SRS protocols currently approved under the supervision of the PI, including date and outcome of last initial or continuing review, and any reports of injury, illness, or unanticipated problem report related to research safety under these protocols;

   b. Whether hazards, BSL, risk assessments, and training were up to date for these protocols at the time of review;

   c. Inspection report of any research laboratory space assigned to that PI, including plans to address any identified deficiencies related to laboratory space; and

   d. Any instances of continuing non-compliance of the PI with respect to SRS requirements.

3) Based on the materials reviewed, the SRS may vote to approve, require modifications, or terminate active protocol(s) for that PI.

   a. While the laboratory program of a given PI is reviewed as a whole, the SRS will determine approval on a per-protocol basis during annual review of that protocol.

   b. Modifications to protocol(s) will be requested if review of the overall laboratory program under a PI indicates deficiencies that should be addressed.

   c. In cases where laboratory safety issues cannot be easily mitigated, continuing non-compliance, or other issue the SRS agrees poses an unacceptable risk, the SRS may withdraw approval for one or all protocols under a PI.

4) The outcome of the SRS review of the investigator's laboratory program will be communicated to the PI in writing and to the RDC via the SRS meeting minutes.

5. SRS MEETINGS:

a) **Meetings:** The SRS will hold convened meetings at least quarterly, either in person or via videoconference/teleconference. A quorum must be present for the meeting. If at any time quorum is lost, no business may be conducted until quorum is reestablished.

b) **Agenda**: An agenda will be developed before each SRS meeting and distributed to SRS members via the electronic protocol management system at least 3 working days before the meeting whenever possible. The SRS agenda will include:
   i) Any items requiring SRS action as well as a list of those items which have been resolved in the prior month;
   ii) A list of any initial reviews, amendments, or closures submitted for SRS vote;
   iii) A list of any actions completed via DMR that have occurred since the last convened SRS meeting;
   iv) Any monthly or annual reports to the SRS.

c) **Minutes**: Minutes of all SRS meetings will be recorded and maintained for each SRS meeting.
   i) The minutes will document:
      1) Place, date, and time of the meeting;
      2) Name of presiding officer (chairperson);
      3) The attendance record documenting presence of a quorum, including names of attendees and whether they are voting or non-voting members;
      4) Whether any alternate members are present, and if so, which member the alternate is replacing;
      5) Any recusals, including documentation that quorum was maintained for affected votes; and
      6) A complete record of all items of business brought before the SRS and the action taken, including all actions taken by the SRS itself.
   ii) The SRS minutes will be reviewed and signed by the SRS Chair or Vice Chair. Minutes will be maintained in the electronic protocol management system.
   iii) Approved SRS minutes will 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.

d) **Voting:** For each business item requiring a vote, the motion passed by the committee (approved, approved with modifications, approval withheld, as described above under Initial Review) will be recorded.
   i) For any recusals, minutes must specify which members excused themselves from voting on each affected motion, and document whether quorum was maintained.
   ii) Voting tabulations will be recorded in the meeting minutes.

e) **Records:** Records will be archived as directed by National Archives and Records Administration Request for Records Disposition Authority DAA-0015-2015-0004.
   i) SRS records, including agendas, meeting minutes, and copies of all submitted protocols, will be maintained in an electronic protocol management system provided by the VA Office of Research & Development. Any documents that cannot be maintained in this system will be stored electronically on the VA Research network storage array.
   ii) Protocols approved by the SRS will be kept for 6 fiscal years, and disapproved protocols or those withdrawn by the investigator will be retained for 3 fiscal years.

iii) Files related to the ongoing operations of the SRS will be kept for 3 fiscal years (implementation records, including SOPs, policies, agreements with non-VA review committees, committee/subcommittee assessments and compliance) or 6 fiscal years (SRS records, including membership rosters, appointment letters, CVs, training records, meeting minutes and related documentation).

6. REFERENCES:

VHA Directive 1200.08 "Safety of Personnel and Security of Laboratories Involved in VA Research" (8 January 2021).
https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number

7. SRS Committee Approval: August 29,2023

8. RECISSIONS:

Minneapolis Research Service SOP SRS-012 "Subcommittee on Research Safety (SRS) Standard Operating Procedures (SOP)" (30 March 2021)

EXPIRATION DATE: N/A

FOLLOW-UP RESPONSIBILITY: Subcommittee on Research Safety (SRS)