VA NORTHEAST OHIO HEALTHCARE SYSTEM
Louis Stokes Cleveland DVAMC
Medical Research Service
Subcommittee on Research Safety Policy

Effective Date: JULY 20, 2022

Policy Title: RESEARCH PROTOCOL SAFETY SURVEY (VA FORM 10-0398)

Policy Number: SRS--015

Policy Version: .08

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1. PURPOSE: To identify hazards associated with research protocols on-site at the Louis Stokes Cleveland DVA Medical Center (LSCDVAMC) or in off-site space.

2. DEFINITION OF HAZARDS: Hazards that require full committee review by the SRS include: Biological Agents; Select Agents (as identified in Title 42 Code of Federal Regulations (CFR) 72.6); Human/Non-Human cell or tissue samples; Recombinant or Synthetic Nucleic Acid Molecules; Select Chemicals; Controlled Substances; Ionizing/Non-Ionizing Radiation; Physical Agents, and the Use of Animals.

3. POLICY: All VA Principal Investigators (PI) who are conducting research in laboratories located at the LSCDVAMC or in off-site space are required to complete a Research Protocol Safety Survey (RPSS), VA Form 10-0398, and the associated SRS Local Appendix. This policy includes ***any*** research being conducted by VA Investigators, regardless of performance site or funding source, while on official VA time.

The Subcommittee on Research (SRS) reviews all submissions at regularly convened meetings, which take place on the second Wednesday of each month.

New Projects, Amendments/Modifications, and Continuing Reviews that require full committee review must be received by close of business (4:30pm) on the Tuesday, one week preceding the regularly scheduled meetings of the SRS.

Non-scheduled (emergency) meetings of the SRS will be held when funding for a VA Merit Grant is contingent upon SRS approval. Also, if a non-VA study is deemed "high priority", i.e., COVID-related, an emergency SRS meeting will be held.

Note: Final approval of a research protocol comes from the Research and Development (R&D) Committee. Final R & D Committee approval represents approvals from the SRS, the Institutional Review Board (IRB), and/or the Institutional Animal Care and Use Committee (IACUC).

4. RESPONSIBILITIES:

A. Principal Investigator (PI):

(1) Submits New Projects, Amendments/Modifications, and Continuing Reviews through IRBNet,

which is a secure online system for document submission to the Research & Development Committee, which forwards submissions to the Subcommittee on Research Safety, the Institutional Review Board, and/or the Institutional Animal Care and Use Committee.

Completes an RPSS and the associated SRS Local Appendix when submitting a New Project or an Amendment/Modification that involves additional hazards as identified in section 2 above, for each VA and non-VA funded project submitted through IRBNet. Approval from the Research and Development Committee is required PRIOR to the initiation of any new Research Project.

(2) Submits an SRS Amendment/Modification through IRBNet when work involving additional hazards is needed. An SRS Amendment/Modification is also required when personnel are added to a COVID-related project (all COVID-related training must be documented). Approval for this SRS Amendment/Modification must be received *prior to the initiation of work*.

(3) Completes an SRS Continuing Review, prior to the original SRS approval date.

B. Research Safety Coordinator/Chemical Hygiene Officer (RSC/CHO):

(1) Reviews RPSSs and the associated SRS Local Appendix for compliance and references Biosafety and NIH Guidelines to ensure accuracy.

(2) Instructs PIs with protocols involving Recombinant or Synthetic Nucleic Acid Molecules to submit their project to the Case Western Reserve University IBC for review.

(3) Presents RPSSs and the associated SRS Local Appendix to the SRS for review.

(4) Monitors Continuing Reviews with Principal Investigators.

C. Subcommittee on Research Safety (SRS):

(1) Convenes monthly with a quorum present, i.e., 51 % of voting members must be in attendance.

(2) Reviews and approves/disapproves all new research involving biological agents, select agents (as identified in Title 42 Code of Federal Regulations (CFR) 72.6), human/non-human cell or tissue samples, recombinant DNA, OSHA regulated hazardous chemicals, controlled substances, ionizing/non-ionizing radiation, physical agents, and use of animals. This includes assessments for all listed hazards on the SRS Local Appendix to VA Form 10-0398, as well as the personal protective equipment required when working with these hazards.

(3) Annually reviews all active protocols involving hazardous materials (as noted above) via a Continuing Review. If a Principal Investigator does not submit a Continuing Review before the anniversary of the original SRS approval, all work involving hazardous material must cease. If work continues, the SRS will convene to determine non-compliance. If the SRS determines that non-compliance has taken place, the Medical Center Director will be notified. A notification will also be sent to the Research Compliance Officer/Louis Stokes Cleveland VAMC. This will then be followed-up with a report to the Office of Research Oversite.

(4) See Medical Center Policy 151-007, Subcommittee on Research Safety, for additional information

on the SRS.

5. PROCEDURES:

A. RPSS and SRS Local Appendix:

(1) All VA Principal Investigators (PI) who are conducting research located at the LSCDVAMC or in off-site space are required to complete a Research Protocol Safety Survey (RPSS), VA Form 10-0398, and the associated SRS Local Appendix. This includes any research being conducted by VA Investigators, regardless of performance site, while on their official VA duty time.

The RPSS and the SRS Local Appendix must be submitted through IRBNet.

When a Research Study has been submitted through IRBNet, the Research and Development Coordinator forwards this submission (with all the required documents) to the Subcommittee on Research Safety.

(2) Hazards that require identification on the RPSS and the associated SRS Local Appendix include**:** Biological Agents; Select Agents (as identified Title 42 Code of Federal Regulations (CFR) 72.6); Human/Non-Human cell or tissue samples; Recombinant DNA; OSHA and/or EPA deemed Hazardous Chemicals; Controlled Substances; Ionizing/Non-Ionizing Radiation; and Use of Animals.

(3) Section 1, part b, Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids, or cell lines): If a blood draw, urine collection, biopsy, etc., is to be obtained for research purposes only, part b must be checked "yes", whether the specimen(s) are collected by study personnel or non-study staff (Laboratory Services, Dermatology, etc.),

Section 4, Cells and Tissue Samples will need to be fully completed when study personnel are obtaining, handling, and/or analyzing the specimens.

If the procedure(s) will be performed by non-study personnel, it needs to be documented what service, core facility, etc. will be collecting/analyzing specimens involved with this study. This will confirm that study personnel will not encounter the specimen(s) to be collected/studied.

Note: *A Letter of Support will need to be submitted to the Research and Development Committee if the specimens are being handled by another service, i.e.,. Laboratory Services, Dermatology, Medical Services, etc.*

(4) Recombinant or Synthetic Nucleic Acid Molecules**:** If a protocol involves Recombinant or Synthetic Nucleic Acid Molecules, whether exempt or non-exempt, the Principal Investigator (PI) must complete a Case Western Reserve University Institutional Biosafety Committee (IBC) Recombinant or Synthetic Nucleic Acid Molecules Questionnaire, If determined to be non-exempt, the PI must submit an application to the IBC. The SRS is only permitted to review a study once it has received a copy of the PI's application form and an IBC approval letter. At that time, the SRS will review the above-noted documents and decide by vote if the IBC review is acceptable. The SRSS must also receive a copy of the approved IBC minutes that document the review of the study, which will be acknowledged at a convened meeting of the SRSS.

The SRSS will also review Continuing Reviews, Amendments, and Closures of VA IBC-approved studies.

(5) When approved by the SRS, the RPSS must be signed by the Principal Investigator, Safety Officer (RSC), Chairperson of the SRS, Chairperson of the Research and Development Committee, Radiation

Safety Officer (if applicable), and the Facility Safety Officer. The SRS Local Appendix must be signed by the Principal Investigator.

If a protocol *does not* involve the above noted hazards, see Section C below.

B. Institutional Animal Care and Use Committee (IACUC) *De Novo* Triennial Reviews of Animal Component of Research Protocol (ACORP):

An IACUC *De Novo* Triennial Review is a new review of an already approved ACORP, which takes place every three years for active studies. When a *De Novo* review is required, the IACUC Coordinator will share this submission with the RSC via IRBNet. The RSC will compare the original submission with the *De Novo*. After review, the RSC will submit the original and *De Novo* versions to the SRS Chair for review. If the hazards associated with the study being reviewed have not changed, the SRS Chair will confirm that the *De Novo* is exempt from full SRS Committee revied. If new hazards have been presented, the SRS Chair will confirm that an SRS Amendment/Modification will be needed. This will require the Principal Investigator to complete an SRS Amendment/Modification Form, RPSS VA Form 10-0398, and an SRS Local Appendix, which will need to be uploaded into IRBNet as a new package for this study.

C. Safety-Exempt Submissions (New Projects):

(1) An RPSS (VA form 10-0398) and the associated SRS Local Appendix must be submitted for a study that does not involve any of the hazards listed in Section 1 of the RPSS (parts a – g). The SRS Chair (or Alternate SRS Chair) and the Research Safety Coordinator must review the associated Research Plan. After review, the SRS Chair (or Alternate SRS Chair) will make the determination that the submission is safety exempt.

(2) The SRS will be notified of all new projects that have been approved as being safety-exempt at the next convened SRS meeting.

D. Safety-Exempt Submissions (Amendments/Modifications):

(1) An Amendment/Modification to an SRS-approved study that does not involve additional hazards, i.e., change in personnel, a procedure that does not involve hazards, etc. will be reviewed by the SRS Chair (or Alternate SRS Chair) and the Research Safety Coordinator. After review, the SRS Chair (or Alternate SRS Chair) will make the determination that the submission of an amendment/modification is safety-exempt.

(2) The SRS will be notified of all amendments/modifications that have been approved as being safety-exempt at the next convened SRS meeting.

E. Safety-Exempt Submissions (Continuing Reviews/Closures):

(1) A Continuing Review for an SRS-approved study that does not involve additional hazards will be reviewed by the SRS Chair (or Alternate SRS Chair) and the Research Safety Coordinator. After review, the SRS Chair (or Alternate SRS Chair) will make the determination that the submission of a Continuing Review is safety-exempt.

Note: Changes in personnel are not considered a change in hazards. If additional hazards are noted on a

Continuing Review, an Amendment with an updated RPSS and SRS Local Appendix must be submitted.

(2) A Closure for a study will be reviewed by the SRS Chair (or Alternate SRS Chair) and the Research Safety Coordinator. After review, the SRS Chair (or Alternate SRS Chair) will make the determination that the submission of a study closure has been submitted properly, which will be safety-exempt.

(3) The SRS will be notified of all Continuing Reviews/Closures that have been approved as being safety-exempt at the next convened SRS meeting.

Forms: VA form 10-0398 (Research Protocol Safety Survey), SRS Local Appendix, Amendment/Modification, and Continuing Review forms are available through IRBNet at: https://gov.irbnet.org

5. REFERENCE: VHA Handbook 1200.8, Safety of Personnel Engaged in Research, dated April 24, 2019.

6. RESCISSION: The rescission date of this policy is July 19, 2027.

7. FOLLOW UP: RSC