VA NORTHEAST OHIO HEALTHCARE SYSTEM
Medical Research Service
Subcommittee on Research Safety Policy

Effective Date: JANUARY 3, 2019

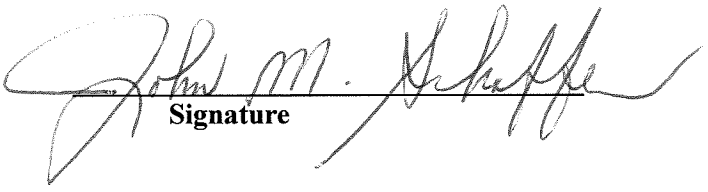
SOP Title: RESEARCH PROTOCOL SAFETY SURVEY (VA FORM 10-0398)

SOP Number: SRS--015

SOP Version: .06

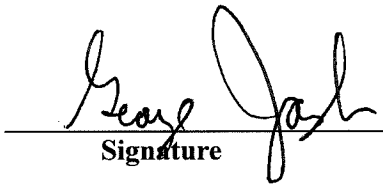
Author:

Name: John M. Schaffer, B.A.
Title: Research Safety Coordinator
Department: Medical Research Service



Signature **Date** 1/11/19

Research & Development Committee Chair:



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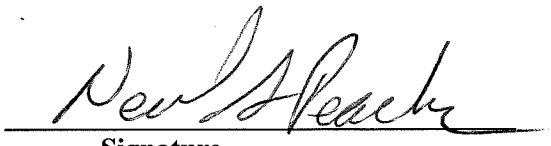
Approved By:

Associate Chief of Staff/Research



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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 identification 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 DNA; Select Chemicals; Controlled Substances; Ionizing/Non-Ionizing Radiation; Physical Agents, and 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, available from the Research Safety Coordinator (RSC). 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 RPSSs at regularly convened meetings, which take place on the second Wednesday of each month.

RPSSs 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 are limited to VA Merit Grant submissions when funding is contingent upon SRS approval.

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) Completes a RPSS, which identifies all hazards identified in section 2 above, for each VA funded proposal. An approved and dated protocol is required PRIOR to the initiation of the research protocol.

(2) Initiates requests for modification (including the addition of new biohazards, chemicals or change in personnel to an approved protocol) *prior to the initiation of the modification*.

(3) Completes annual review, Research Safety Form #8, Investigator's Checklist for Annual Review of Protocols Involving Hazardous Materials, on or before original R & D Committee approval date.

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

(1) Reviews RPSSs for compliance and references Biosafety and NIH Guidelines to ensure accuracy.

(2) Presents RPSSs, original *and* amended, to the SRS for review.

(3) Coordinates annual reviews of RPSSs with Principal Investigators.

C. Subcommittee on Research Safety (SRS):

(1) Convenes on a monthly basis 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.

(3) Annually reviews all active protocols involving hazardous materials (as noted above). If a Principal Investigator does not submit an annual review on or before the anniversary of the original R & D approval, communication regarding delinquency will be forwarded from the SRS to the R & D Committee.

(4) Forwards all RPSS and protocols involving rDNA to the Case Western Reserve University IBC for review.

(5) See Medical Center Policy 151-007, Subcommittee on Research Safety, for additional information on the SRS.

5. PROCEDURES:

A. Long Form:

(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. This includes any research being conducted by VA Investigators, regardless of performance site, while on their official VA duty time.

This form must first be submitted to the Research and Development Coordinator; with the exception of Just in Time VA Merit Grants.

When a Research Study has satisfactorily gone through a pre-review, veterinary review, etc., the Research and Development Coordinator forwards the RPSS and the study's Research Plan to the Subcommittee on Research Safety.

(2) Hazards that require identification on the RPSS 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.),

On the long form, 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 must complete a Case Western Reserve University Institutional Biosafety Committee (IBC) Recombinant or Synthetic Nucleic Acid Molecules Questionnaire,

(5) When approved by the SRS, the long form 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.

If a protocol *does not* involve the above noted hazards, use the Expedited RPSS Form.

B. Expedited Form:

(1) The Expedited Form is used when a study does not involve any of the hazards listed in Section 1, parts a – h. Only the chair or alternate chair of the SRS may approve the Expedited Form.

(2) The RSC receives exempt submissions from the Research and Development Coordinator and reviews the research plan for work involving any hazardous agents listed in parts a-h in Section 1. After review of the Research Plan, if confirmed the study does not involve any hazardous materials, the RSC will sign the expedited Form and forward it to the SRS Chair or Alternate Chair for review.

(3) When reviewed and approved by the SRS Chair or Alternate Chair, the RPSS must be signed by the Principal Investigator, the RSC, and the Chair or Alternate Chair of the SRS.

(4) The SRS will be notified of all RPSS approved via expedited review at the next convened SRS meeting.

C. Forms: VA form 10-0398, Research Protocol Safety Survey, and all other related forms are available upon request or at www.cleveland.va.gov/research/committee_research_safety.asp.

5. REFERENCE: VHA Handbook 1200.8, Safety of Personnel Engaged in Research, March, 2009.

6. RESCISSION: Medical Research Service Policy 151-P dated December 12, 2003. The rescission date of this policy is January 6, 2022.

7. FOLLOW UP: RSC/CHO