

Subcommittee on Research Safety - 1 of 24
 VAMHCS RESEARCH & DEVELOPMENT SERVICE
 STANDARD OPERATING PROCEDURE

SOP: R&D 01.10

Version	1.1	Origin	Version 1.0
Author	Jessica Mendoza		
Reviewed/ Revised by	Claudia MacAuley	Dates Reviewed / Revised	4/27/11
Changes	Revisions based on ORO on-site review (October 2010) report	New Version #	1.1
Approved	Christopher T. Bever, ACOS/R&D Date 4/28/11		
File Name	\\Subcommittee on Research Safety (SRS) (HRP 01.10) 2011v1.1		

SUBCOMMITTEE ON RESEARCH SAFETY (SRS)

OBJECTIVES:

- To ensure safe conduct of laboratory research at the Baltimore VA Medical Center and to advise principle investigators on safe conduct of research;
- To review all VAMHCS research protocols that involve the use of biohazards, chemical hazards, radiation hazards, and physical hazards in research settings (laboratories, clinical areas, etc) or in the course of research activities and based on those reviews, to suggest modifications aimed at improving research safety;
- To consider personnel safety and the safety and environment of the physical plant as foremost in its deliberations;
- To make recommendations to the VAMHCS Research & Development Committee for approval or other action on these protocols;
- To comply with standards set forth in VHA Handbook 1200.08 and 1200.06 as assigned by the RDC.

BACKGROUND & SCOPE:

The Subcommittee on Research Safety is a subcommittee of the VAMHCS R&D Committee. Its goal is to review new protocols and protocol amendments for safety in the areas of biological, chemical, physical/environmental and radiation hazards. The Subcommittee considers the safety of personnel and the physical plant/environment where the research activities are taking place. It reports to the R&D Committee with recommendations to approve, approve pending further clarification, defer, or disapprove the protocols/amendments. The R&D Committee acts upon the subcommittee's reports and recommendations. The R&D Committee will not approve protocols until the Subcommittee on Research Safety has made its recommendations (unless the study/amendment is exempt from SRS review). The R&D Committee may not approve a protocol that the SRS has disapproved. Further details on the R&D Committee and its interactions with the Subcommittee on Research Safety are in R&D 01.03 / HRP 01.03 ("R&D Committee").

Subcommittee on Research Safety - 2 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

The SRS reviews all research applications for funding that will be conducted at VAMHCS facilities or by VAMHCS personnel with VA funding off-site. Research will be reviewed to ensure that it minimizes risk from exposure to biohazards, chemical hazards, or physical hazards as they are defined below. The SRS evaluates the training of personnel, and safety measures for use, storage, and disposal of biological, chemical, and radiological hazards. No VAMHCS research may be undertaken without the approval of the University of Maryland IRB if humans or human samples are involved, IACUC if animals are involved or the IBC if recombinant deoxyribonucleic acid (rDNA) is involved **and** the approval of the VAMHCS R&D Committee.

DEFINITIONS

Biohazards include but are not limited to: (1) pathogens and/or etiologic agents, human and non-human primate tissues including blood and body secretions, and human cell lines corresponding to biosafety level (BSL) 1-4; (2) toxins produced by microbial organisms; (3) poisonous, toxic, parasitic and venomous animals or plants; (4) recombinant DNA molecules; (5) select agents as specified in Title 42 CFR; (6) animals experimentally or naturally exposed to any of the above.

Chemical Hazards include any substance or mixture of substances with properties capable of producing adverse effects on the health and/or safety of humans. Chemical hazards include but are not limited to: (1) corrosives, (2) toxic substances (poisons, irritants, asphyxiates); (3) sensitizers; (4) carcinogens, mutagens and/or teratogens; (5) flammables; (6) explosives.

Physical Hazards include but are not limited to: (1) ionizing and non-ionizing radiation (2) noise, (3) vibration, (4) extremes of temperatures and pressure, (5) explosive hazards, (6) electrical hazards (7) mechanical hazards (VHA Handbook 1200.08).

RESPONSIBILITIES:

1. The Subcommittee on Research Safety is responsible for:
 - a. Reviewing all research activities involving biological, chemical, physical, and radiation hazards per VA Form 10-0398, Research Protocol Safety Survey Form (RPSS) for compliance with all applicable regulations, policies, and guidelines prior to initiating studies;
 - b. Providing written notification of the results of SRS review to the R&D Committee and the PI;
 - c. Annually reviewing all active research protocols involving biological, chemical, physical and radiation hazards, regardless of funding status or source.
 - d. Reviewing all protocol amendments involving biological, chemical, physical, and radiation hazards;
 - e. Ensuring that a complete list of all products containing chemicals designated or identified by OSHA and/or EPA as "hazardous" has been submitted to the Safety Officer for review and approval prior to the submission of a protocol for local review.

Subcommittee on Research Safety - 3 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

- f. Assigning specific members to coordinate 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:
 - i. Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively corrected , and
 - ii. Reporting follow-up results to the R&D Committee;
- g. Reporting operational problems or violations of directives to the Research Safety Coordinator and the Research Office within 10 days of occurrence or detection, unless the SRS determines that a report has been previously filed by the PI;
- h. Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising R&D Committee and the Employee Health practitioners on the need for such surveillance;
- i. Maintaining adequate documentation of all SRS activities;
- j. Forwarding minutes to the R&D Committee via the Research Office;
- k. Ensuring that all laboratory personnel are provided with annual research-specific safety training;
- l. Holding SRS meetings at least quarterly;
- m. Ensuring coordination with other regulatory programs, personnel, or committees, such as the Radiation Safety officer and/or the Radiation Safety Committee;
- n. Ensuring 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;
- o. Annually evaluating the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions;
- p. Ensuring the review of reports of all injuries that occur during the conduct of laboratory research and all significant adverse environmental effects resulting from a research project;
- q. Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate;
- r. When appropriate, requesting the appointment of an ad hoc committee consisting of members with appropriate expertise, to investigate and report on occupational injuries, illnesses, adverse environmental effects;
- s. Ensuring the development of a policy for the preservation of employees' medical and OSHA exposure records;
- t. Cooperating with appropriate medical center personnel to review the quality and type of hazardous waste generated by each PI annually;
- u. Providing technical assistance in the reduction of the quality of waste and/or recycling programs, where appropriate.
- v. SRS will review proposed research at convened meetings at which a quorum (majority of voting members) is present. Voting by email is not permitted.

Subcommittee on Research Safety - 4 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

2. The SRS Coordinator is responsible for:
 - a. Ensuring that all necessary documents are submitted for SRS review.
 - b. Ensuring that the VA Training database is monitored to confirm that all laboratory personnel listed on the study submission have current required training. Notifying the PI (if applicable) that the protocol will not be reviewed if any member of the research staff listed on the protocol does not have current mandatory VA Training.
 - c. Sending protocols to Subcommittee on Research Safety members at least one week in advance of the meeting so members have adequate time to review submission documents.
 - d. Acting as recorder for the proceedings of the SRS meeting on a monthly basis.
 - e. Ensuring a quorum is present to render a determination on protocols.
 - f. Documenting determinations made by the Subcommittee on Research Safety in the minutes (i.e. approved, contingent, disapproved).
 - g. If the protocol receives a contingent or deferred determination, the SRS will forward, in writing, to the PI a document outlining the concerns of the committee and the rationale for the determination.
 - h. Communicating with the R&D Coordinator on protocols receiving contingent or disapproved determinations, so that R&D approval is not awarded until SRS approval has been obtained.
 - i. Forwarding minutes (via the R&D Coordinator) to the R&D Committee members for consideration prior to the VA R&D Committee meeting.
 - j. Ensure the RDC and its subcommittee documents are maintained in each study folder, including but not limited to; initial review, amendments, annual reviews, updates, closures, and final reports.
 - k. Notify the PI of annual review for all studies not formally closed.
 - l. Notify PI of subcommittee results followed by ACOS for R&D notification of study initiation.

3. The PI or Laboratory Director is responsible for:
 - a. Submitting a properly completed VA Form 10-0398 "Research Protocol Safety Survey" (RPSS), including the "Work Proposed" section and a complete list of chemicals defined as "hazardous";
 - b. Ensuring that active protocols, new pilot projects, and protocol amendments have been reviewed by SRS regardless of funding status or source;
 - c. Identifying laboratory specific hazards and
 - i. ensuring that all personnel receive training specific to the hazards,
 - ii. advising laboratory personnel of any potential risk to themselves or the research environment,
 - iii. establishing and enforcing standards of practice which minimize employee exposures to biological, chemical, physical and radiation hazards;
 - d. Reporting problems and concerns about operation and containment practices and procedures to the Research Safety Coordinator, Facility Safety Officer,

Subcommittee on Research Safety - 5 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

- Veterinary Medical Officer (if applicable), Radiation Safety Officer, and other appropriate authorities;
- e. Reporting all laboratory accidents to the Research Service and other relevant personnel (as indicated in the Research Safety Manual);
 - f. Securing approval of the R&D Committee through the SRS for any significant changes to the original research plan (amendments);
 - g. Complying with an abatement plan, for all deficiencies cited during inspections within the specified time limits.

DOCUMENTS:

- (Appendix A) VA Form 10-0398 "Research Protocol Safety Survey" (RPSS)
- (Appendix B) University of Maryland, Baltimore (UMB) Safety Affirmation
- (Appendix C) RPSS Appendix for Radioactive Material
- (Appendix D) Research Protocol Safety Survey Form Instructions

REFERENCES:

- Research Service SOP "Research & Development Committee" (R&D 01.03 / HRP 01.03)
- Research Service Guidance "Flowchart Guidance on R&D Submissions (R&D 01.02 / HRP 01.05G)

PROCEDURES:

1. Composition of the Subcommittee on Research Safety
 - 1.1. Voting Members: The membership of the Subcommittee on Research Safety shall consist of at least 5 members:
 - 1.1.1. Members should possess expertise in:
 - Etiologic agents, including blood borne and airborne pathogens
 - Chemical carcinogens and other chemical hazards
 - Physical and radiation hazards;
 - 1.1.2. It is recommended that at least 1 member must possess specific expertise in occupational safety and health, environmental hazards and the Department of Transportation rules, to ensure that all pertinent hazards in protocols are identified;
 - 1.1.3. The Veterinary Medical Officer (VMO), Veterinary Medical Consultant (VMC), or a member of the IACUC should be a member;
 - 1.1.4. ***If*** the research reviewed involves recombinant DNA not exempt from the current NIH Guidelines for Research involving Recombinant DNA Molecules, the protocol must be reviewed and approved by the UMB *IBC*, and all other specifications of the NIH Guidelines must be followed.
 - 1.1.5. The terms may be staggered to provide partial change in membership annually.

Subcommittee on Research Safety - 6 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

- 1.1.6. SRS members must complete all relevant training as mandated by virtue of their appointment(s).
- 1.2. Ex-Officio Members must include (Member generally taken to be a person, who, by virtue of an office or position held, is officially attached to a committee as a non-voting member)
 - 1.2.1. a liaison member from the local R&D Committee (voting)
 - 1.2.2. the Chemical Hygiene Officer (voting)
 - 1.2.3. the AO/R&D or other representative from the R&D Office (non-voting)
 - 1.2.4. an employee union safety representative or other union designee whose voting status is determined by the applicable union contract.
2. Appointment of Members
 - 2.1. The Medical Center Director must officially appoint members in writing, and must state the duration of the appointment.
 - 2.2. The Subcommittee on Research Safety forwards names of nominees to the Medical Center Director for membership on the SRS.
 - 2.3. The Medical Center Director appoints the SRS Chairperson for the term of one 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.
3. Subcommittee on Research Safety Meeting Agendas
 - 3.1. The Subcommittee on Research Safety Coordinator prepares meeting agendas for the SRS meeting and distributes them to SRS members at least 3 days before the meeting.
 - 3.2. The following shall be included in the agenda:
 - The scheduled date, time and location of the meeting
 - Approval of minutes of previous meeting (date)
 - Unfinished Business (list pending items and individual responsible)
 - New business (identify individual responsible when necessary)
 - Standing recurring reports (identify individual responsible)
 - Review of safety, security and emergency drills
 - Review of internal and external inspection and audit reports including the Annual Vulnerability Assessment Committee minutes. Issues not previously addressed by the body Any other item that warrants review and/or discussion by the subcommittee and is not routinely reviewed by the subcommittee
 - Announcements
 - Date, time and place of next meeting

Subcommittee on Research Safety - 7 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

4. Subcommittee on Research Safety Meeting Minutes

4.1. Minutes shall be recorded and maintained for each meeting of the Subcommittee on Research Safety.

4.2. The minutes must be prepared according to the following format:

4.2.1. Name of the subcommittee centered at the top of the page, including the VAMHCS name and number (512),

4.2.2. In the first paragraph:

- Place, date and time of the meeting
- Name of presiding officer (chairperson)
- List of attendees

NOTE: The attendance record must list all individuals identified as members. Members are to be marked "Absent" if the Chairperson/recorder was not notified in advance; "Excused" if the Chairperson/recorder was notified in advance. For each member, note their role on the committee and whether they are voting or non-voting.

- Indication that a quorum was present (A quorum is defined as more than 50% of the voting members.)

4.2.3. Succeeding paragraphs:

- For each project under consideration, list the name of the Principal Investigator and the complete name of the project.
- A clear and concise summary of the discussion (does not need to be recorded verbatim)
- Conclusion must indicate the conclusion of the discussion. (For example: "The follow-up action plan was ineffective, and the issue is not considered resolved at this time.") If analysis of the data occurred at the meeting, then the conclusion of the analysis needs to be in the minutes.
- Recommendations must indicate what is expected to change; in the case of follow-up reviews, the date of the meeting when the recommendation was initially made.

NOTE: A recommendation is not to be carried for more than 2 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.

- Action taken to date or a realistic date to expect resolution; must indicate what action is appropriate in view of the cause, scope and severity of the problem and who is responsible for implementing the action
- Follow-up/Evaluation and status as "Closed" or "Pending"; must identify the date a status report is due on the action plan, the date the action plan will be implemented, or the date the action plan will be evaluated for accomplishment of expected outcome and/or impact of changes made.

4.2.4. For each new project, the motion passed by the committee (approved, approved pending clarification, deferred, disapproved)

Subcommittee on Research Safety - 8 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

must be recorded with the exact vote; this must include the number voting for/against/abstaining from the motion. 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.

4.2.5. The minutes must note which members excused themselves from voting on which projects for conflicts of interest (COI). It is the responsibility of subcommittee members to identify potential COI.

NOTE: SRS members having a scientific or monetary COI for the protocol under consideration may provide information helpful to the SRS prior to deliberations, but must excuse themselves from the meeting once deliberations begin.

4.2.6. Copies of any internal or external reports or correspondence with outside agencies referenced in the minutes need to be attached to the minutes. Minutes must be written and published within 3 weeks of the meeting date.

4.2.7. Minutes must be signed by the Chairperson of the SRS.

4.2.8. Approved minutes must be forwarded to the R&D Committee for review and approval. The R&D Committee 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 R&D Committee may not alter the SRS minutes.

4.2.9. Minutes must be maintained by the Research Service Office and made available to VA Central Office or any relevant oversight entity upon request.

5. SRS Submission and Review Process

5.1. Principal investigators/staff for all VA Awards, grants, and other applicable protocols and amendments (regardless of funding source) must complete VA Form 10-0398 "Research Protocol Safety Survey" (Appendix A).

5.1.1. If any portion of the research in the protocol under review will be conducted in space at the academic affiliate, the University of Maryland Baltimore, UMB IBC consultation and review is required. The UMB, EHS Director or Biosafety Officer then sign the University of Maryland, Baltimore (UMB) Safety Affirmation, (Appendix B).

5.2. If the answer to ***any*** of the questions on page 1 of VA Form 10-0398 is "Yes", then the protocol must be reviewed by the SRS. (If ***all*** the answers on page 1 of VA Form 10-0398 are "No", then the Chairperson of the SRS [or designee] reviews the protocol.)

5.2.1. The Principal Investigator is responsible for submitting all necessary documents (see instructions, Appendix D).

5.2.2. If the research involves the use of radioactive materials in VA facilities the "Appendix for Radioactive Material" is required (Attachment C).

Subcommittee on Research Safety - 9 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

- 5.3. The SRS Coordinator checks that all necessary information has been submitted with VA Form 10-0398. The Coordinator then places the protocol/amendment on the agenda for the next SRS meeting.
- 5.4. The SRS may vote for the following actions, with specific clarification of the action to be provided to the investigator (the action will be reported to the PI in a notification memo shortly after the meeting) and the R&D Committee.
- Approved – The SRS approves the safety profile of the protocol/amendment.
 - Approved Pending Clarification – Used for minor concerns; the notification memo will specify what is required for final approval. Once made, modifications shall be reviewed and approved by the SRS Chairperson or designee. The decision will be documented in the SRS minutes.
 - Tabled – A proposal may be tabled if there are major concerns that must be resolved before the SRS will reconsider the proposal for review. A tabled proposal must be reviewed again by the fully convened subcommittee. The materials, information, modifications, or conditions necessary for reconsideration by the SRS will be stipulated in the notification memo
 - Disapproved - The SRS does not approve the protocol/amendment because of significant concerns about the proposal
- 5.5. If a protocol/amendment is deferred or disapproved, all members will re-review if/when the revised protocol/amendment is resubmitted. If the protocol/amendment has received conditional approval, the SRS Chairperson is responsible for reviewing the revised materials.
- 5.6. Research studies involving animals must be reviewed by the Animal Use Subcommittee before they can be reviewed/approved by R&D Committee. Research studies involving human participants must be reviewed by the University of Maryland's IRB and/or the VA Central IRB before they can be reviewed/approved by R&D Committee.
- 5.6.1. Studies may be submitted to all applicable subcommittees simultaneously. Subcommittees make decisions on protocols/amendments independently of each other.
- 5.6.2. The SRS Coordinator notifies the R&D Committee Coordinator if the SRS has disapproved a study/amendment. The R&D Coordinator is then responsible to hold R&D approval letters until the SRS has approved the study/amendment.
If the SRS disapproves the study/amendment, the R&D Committee may not approve it, even if other subcommittees have approved it.

REFERENCES

- VHA Handbook 1200.08 "Safety of Personnel Engaged in Research"
VHA Handbook 1200.06 "Control of Hazard Hazardous Agents In VA Research Laboratories"

Subcommittee on Research Safety - 10 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE



Christopher T. Bever, Jr., M.D., M.B.A.
ACOS for R&D

Appendix A

VA FORM 10-0398

“RESEARCH PROTOCOL SAFETY SURVEY” (RPSS)

RESEARCH PROTOCOL SAFETY SURVEY

PRINCIPAL INVESTIGATOR (PI):

PROJECT TITLE:

DATE OF SUBMISSION:

LIST VA AND NON-VA LOCATIONS IN WHICH PI CONDUCTS RESEARCH:

1. DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

a. Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6, or animals)

YES () NO ()

b. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines)

YES () NO ()

c. Recombinant deoxyribonucleic acid (DNA)

YES () NO ()

d. Chemicals:

(1) Toxic chemicals (including heavy metals)

YES () NO ()

(2) Flammable, explosive, or corrosive chemicals

YES () NO ()

(3) Carcinogenic, mutagenic, or teratogenic chemicals

YES () NO ()

(4) Toxic compressed gases

YES () NO ()

(5) Acetylcholinesterase inhibitors or neurotoxins

YES () NO ()

e. Controlled Substances

YES () NO ()

f. Ionizing Radiation:

(1) Radioactive materials

YES () NO ()

(2) Radiation generating equipment

YES () NO ()

g. Nonionizing Radiation:

(1) Ultraviolet Light

YES () NO ()

(2) Lasers (class 3b or class 4)

YES () NO ()

(3) Radiofrequency or microwave sources

YES () NO ()

If the answer to any of these questions is YES, complete all sections of this survey that apply.

If all answers are NO, a documented review by the local Subcommittee on Research Safety is still required prior to submission. If the research involves the use of human subjects or human tissues, Institutional Review Board (IRB) review is required. *NOTE: Use of animals also requires submission of an Institutional Animal Care and Use Committee (IAUC) -approved Animal Component.*

VAFORM
MAY 2002

10-0398

Subcommittee on Research Safety - 13 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

2. BIOLOGICAL HAZARDS

a. Does your research involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom? YES () NO ()

If NO, skip to the section on **Cells and Tissue Samples**.

If **YES**, list all Biosafety Level 2 and 3 agents or toxins used in your laboratory. It is the responsibility of each PI to:

(1) Consult either:

(a) The National Institutes of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or

(b) The CDC online reference (<http://www.cdc.gov>)

(2) Identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin. Enter it into the following table.

Organism, Agent, or Toxin	Biosafety Level**
----------------------------------	--------------------------

** For each Biosafety Level 2 or 3 agent or toxin listed, provide the information requested on the following page(s). (Description of Biosafety Levels 2 and 3 can be found in Appendix A.)

b. Are any of the biohazardous agents listed above classified as a "Select Agent" by the Centers for Disease Control? YES () NO ()

3. BIOLOGICAL HAZARDS - Description of Use *NOTE.- Photocopy this page, as necessary.*

a. Identify the microbiological agent or toxin (name, strain, etc.):

b. If this is a Select Agent (42 CFR 72.6), provide the CDC Laboratory Registration # and the date of the CDC inspection:

c. Indicate the largest volume and/or concentration to be used:

d. Indicate whether antibiotic resistance will be expressed, and the nature of this antibiotic resistance:

Subcommittee on Research Safety - 15 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

- (1) Identify the NIH classification (and brief description) for these recombinant DNA studies:

- (2) Biological source of DNA insert or gene:

- (3) Function of the insert or gene:

- (4) Vector(s) used or to be used for cloning (e.g., pUC18, pCR3.1):

- (5) Host cells and/or virus used or to be used for cloning (e.g., bacterial, yeast or viral strain, cell line):

6. USE OF CHEMICALS

a. Has the use of chemicals in your laboratory been reviewed by an appropriate committee or subcommittee in the past 12 months? YES () NO ()

b. Are personnel knowledgeable about the special hazards posed by:

- | | | | |
|---|--------|---------|--------|
| (1) Carcinogens? | NA () | YES () | NO () |
| (2) Teratogens and Mutagens? | NA () | YES () | NO () |
| (3) Toxic gases? | NA () | YES () | NO () |
| (4) Neurotoxins? | NA () | YES () | NO () |
| (5) Reactive and potentially explosive compounds? | NA () | YES () | NO () |

NOTE: Submission of the laboratory chemical inventory is required for local review.

7. CONTROLLED SUBSTANCES

a. Does your research involve the use of any substance regulated by the Drug Enforcement Agency? YES () NO ()

If yes, list controlled substances to be used:

- (1)
- (2)
- (3)
- (4)
- (5)
- (6)

Subcommittee on Research Safety - 16 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

b. Are all Schedule II and III drugs stored in a double-locked vault

NA () YES ()
NO ()

*NOTE. The schedule of controlled substances can be found at the Internet site
<http://www.usdoj.gov/dea/pubs/schedule.pdf>*

8. RADIOACTIVE MATERIALS

Does your research involve the use of radioactive materials?

YES ()
NO ()

If YES, provide the following:

a. Identity of radioactive source (s):

b. Radiation Safety Committee Approval (date):

9. PHYSICAL HAZARDS

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan?

YES () NO ()

b. Do employees receive annual training addressing physical hazards?

YES () NO ()

Acknowledgement of Responsibility and Knowledge

Subcommittee on Research Safety - 17 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of, biohazardous materials, chemicals, radioisotopes, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA)-regulated hazardous chemicals is attached to this survey.

Principal Investigator's Signature

Date

Certification of Safety Officer's Approval

A complete list of chemicals to be used in the proposal has been reviewed. Appropriate occupational safety and health, environmental, and emergency response programs will be implemented on the basis of the list provided.

Safety Officer's Signature

Date

Certification of Research Approval

The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional surveys used locally are available from the Research and Development (R&D) Office.

Chair, Subcommittee on Research Safety

Date

Chair, Research & Development Committee

Date

Radiation Safety Officer (if applicable)

Date

Facility Safety Officer

Date

Appendix B

“Appendix B University of Maryland, Baltimore (UMB) Safety Affirmation”

**University of Maryland, Baltimore (UMB) Safety Affirmation
Appendix**

Principal Investigator (PI):

UMB Building:

Room Number(s):

Protocol Title:

The University of Maryland Baltimore maintains safety programs that are compliant with Federal, State, and local regulations with regard to hazardous chemicals, ionizing radiation, potentially infectious materials, and other hazards. The research protocol noted above was reviewed by EHS staff for compliance with applicable regulations. Any deficiencies noted as a part of that review have been corrected.

I acknowledge that the PI has identified a list of chemicals to be used in protocols utilizing hazardous chemicals.

James Jaeger, Director, EHS, University of Maryland, Baltimore or _____ Date
Melissa Morland, Biosafety Officer, EHS, University of Maryland, Baltimore

Appendix C

“VAMHCS RESEARCH PROTOCOL SAFETY SURVEY Appendix A” (RADIATION FORM)

Subcommittee on Research Safety - 21 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

PRINCIPAL INVESTIGATOR (PI):

CO-INVESTIGATOR:

PROJECT TITLE:

THE RESEARCH ABOVE INVOLVES THE USE OF RADIOACTIVE MATERIAL IN VA FACILITIES:

a. Principal Investigator or the Co-Investigator have a VAMHCS permit to use radioactive material:

YES () NO ()

If Yes, write Permit #:

If No, stop and contact the RSO at (410) 605-7032 to complete necessary requirements to obtain a VAMHCS permit to use radioactive material.

b. List of proposed radionuclides:

c. List expected maximum amount of each radioisotope in laboratory at any given time:

d. List personnel that will handle radioactive material and date of last radiation safety training:

e. List manufacturer and model number of radiation survey meter available to do radiation surveys:

f. Permittee disposing radioactive material via the sanitary sewer system?

YES () NO ()

g. Proposed material to be disposed via sanitary sewer contains other hazardous components?

YES () NO () N/A ()

h. Permittee has approved radioactive material disposal sink (hot sink)?

YES () NO () N/A ()

i. Permittee generating mixed waste (radioactive and other hazardous material, i.e. organic solvents, caustic, toxic, heavy metals)

YES () NO ()

I have read and understood the requirements in the Research Safety Manual, VAMHCS Radiation Safety Policy and the radioactive material permit. I shall ensure that the usage of radioactive material is conducted in accordance with the documents mentioned above.

Radiation Permit Holder's Signature

Date

Appendix D

“RESEARCH PROTOCOL SAFETY SURVEY FORM INSTRUCTIONS

Department of Veterans Affairs

MEMORANDUM

Date:

From: Baltimore VA R&D Subcommittee on Research Safety (SRS)

Subj: Research Protocol Safety Survey Instructions for the PIs

1. All protocols that are either VA funded, take place in VA facilities, investigate veterans or samples obtained from veterans, or involve VA collaborators require Subcommittee on Research Safety (**SRS**) approval. If at least one of these conditions is present, research cannot be initiated or conducted without full SRS review. Submission of the Research Protocol Safety Survey (**RPSS**) form and Appendices are required for SRS review.
2. The SRS deals with safety of laboratory research. The SRS does not deal with human or animal use, although the IRB and IACUC approval numbers must be provided to the SRS immediately following the title of your study on the front page of the RPSS.
3. The SRS does not review or regulate laboratory procedures performed in clinical settings for patient care needs. However, if clinical laboratory is used for research or if clinical samples are carried outside clinical space for research purposes, these procedures must be reviewed and approved by the SRS.
4. If your research utilizes GRECC, Pepper Center (UM-OAIC), Maryland Clinical Nutritional Research Unit (CNRU) and/or Baltimore Diabetes Research Training Center (DRTC) resources, contact one of the following prior to submitting your RPSS to SRS (Kara Longo at 410-605-7000 x4804, klongo@grecc.umaryland.edu; Lynda Robey at 410-605-7000 x5446, Lynda.Robey@va.gov); Heidi Ortmeier, Ph.D. at 410-605-7000 x5419, hortmeyer@grecc.umaryland.edu.
5. The Research Protocol Safety Survey requires the following information be submitted to the Subcommittee on Research Safety.
 - The RPSS form - answer all questions in explicit detail; make certain that for every question you correctly check the Yes, No, or N/A box.
 - Before submitting your completed form, please make certain that your answers on the front sheet match the information that you provide in the rest of the form.
 - Please clearly indicate in Section 5 (RECOMBINANT DNA) whether you do new cloning or utilize already available plasmids (e.g. from commercial sources) without transferring inserts into the new constructs. If you do not do new cloning and only confirm validity of your constructs by PCR, answer "yes" to question 5b and write "no new cloning" under 5b(1). Otherwise, fill out section 5 completely.
 - If you use adenoviruses in your studies, they are often classified as BSL-2, in some cases BSL-1 in Section 2 (BIOLOGICAL HAZARDS). Adenoviruses with animal work most likely will be III-D-4a. Adenoviruses in tissue culture would normally be III-D-1a or III-D-3a.
 - Remember that many anesthetics used in animal work are classified as controlled substances and must be listed in the corresponding section 7

Subcommittee on Research Safety - 24 of 24
VAMHCS RESEARCH & DEVELOPMENT SERVICE
STANDARD OPERATING PROCEDURE

- Also on Page #3-Under Cell and Tissue Samples-Please indicate how animal and/or human tissue will be disposed.
 - If bloodborne samples are being transported, a statement must be included indicating that the samples are being transported in a double bagged leak-proof container and marked Biohazard.
 - Helpful terminology and suggestions:
 - Standard precautions not universal precautions
 - Bloodborne pathogens not blood-bourne pathogens
 - Class II BSC (biosafety cabinet or biological safety cabinet) not BSC-2
 - Laboratory safety eyeglasses or goggles
 - Please note that proposal/protocol titles must match on all forms. In the case of VA funded studies the titles on all compliance documents must match the proposal title.
 - The Work Proposed/Methods section of the study that you are going to conduct. Provide a detailed description of the **methods** and **techniques** that are being used in the research protocol with specific emphasis on the hazards. Do NOT attach a complete grant application. Do NOT provide any information on the hypothesis, specific aims, or biomedical significance of your study. Copying the Methods section from a grant application is OK.
 - If your Research involves the use of Radioactive materials in VA facilities the Appendix for Radioactive Material is required.
 - If your research involves Human Subjects please contact Ann Kimball (5-6506). Your protocol will have to be reviewed by the University IRB and the VA Human Subjects Subcommittee. **List the IRB approval number** next to the project title on the front page of the Research Protocol Safety Survey Form.
 - If your research involves Animal Subjects please contact Dr. Edwin Kriel, Attending Veterinarian (5-7127). Your protocol will have to be reviewed by the University IACUC. **List the IACUC approval number** next to the project title on the front page of the Research Protocol Safety Survey Form.
 - A complete list of chemicals in your laboratory is required. If your work is conducted entirely in the VA, contact Grazyna Zaidel (grazynazaidel@yahoo.com, 5-6518) for the most recent list of your chemicals, and update the list with recently purchased or discarded chemicals in your laboratory. If at least part of your work is performed outside of the VA, you are solely responsible for the completeness of your chemical list.
6. If you have any questions regarding the Research Protocol Safety Survey please contact Sergei P. Atamas, M.D., Ph.D. Chair, Subcommittee on Research Safety at 410-605-7000 x 6468 (5-6468 if calling from the UMB campus), or email satamas@umaryland.edu.
 7. Submit both an electronic copy and a hard copy of your information to Peggy Wess. Peggy is located in the Research Office and can be reached by phone at 410-605-7000 x 6511 (5-6511 if calling from the UMB campus) or 410-605-7130 (this is the main telephone number for the Research Office), or email peggy.wess@va.gov.