

VAMHCS Research Protocol Safety Survey (RPSS)  
(Based on VA Form 10-0398)

The purpose of this survey is to allow the Subcommittee on Research Safety (SRS) to review proposed research to ensure that all safety regulations are being followed. All research protocols that (1) are VA funded, (2) take place in VA facilities or VA leased space, and/or (3) involve VAMHCS veterans and/or samples obtained from Veterans must complete this RPSS even if a project has no safety issues (i.e. chart reviews). The research must be reviewed, approved, and documented in minutes by the local SRS committee before a new project can begin.

If any answers are "YES" in Section 1 (page 2), the Principal Investigator's (PI's) hazard- specific training plan must be submitted with this RPSS. Examples and more information regarding the training plan can be found in Reference #1 (below).

Transport of research samples outside of clinical space: SRS approval is not needed for procedures performed in clinical settings for patient care needs. However, *if samples are carried/transported outside clinical space for research purposes, the transport procedures must be reviewed and approved by the SRS.* If the only hazard associated with your research is transportation of samples (no laboratory research component), please follow these instructions: check "YES" at 1.c. and 4.a, provide details in box under 4.a. and in Section 12 (e.g. research blood is carried outside of clinical space from location x to location y), check "NO" at 4.b., and complete sections 4.d and 13. Staff who handle samples need to be added to Study Personnel (section 11) . In addition, the PI's hazard-specific training plan will be required. 

If your project is VA funded the title on your RPSS must match the grant title.

Refer to VA Handbook 1200.05 for prohibited research and research that may require a waiver (sections 17-20).

If your research utilizes GRECC, MERCE, Pepper Center (UM-OAIC), Mid-Atlantic Nutritional Obesity Research Center (NORC) and/or Baltimore Diabetes Research Training Center (DRTC) resources, contact Lynda Robey (Lynda.Robey@va.gov, 410-605-7000 x5446) or Heidi Ortmeyer, Ph.D. (Heidi.Ortmeyer@va.gov, 410-605-7000 x5419) prior to submitting your RPSS to SRS.

HOW TO: Much of this form consists of boxes that are checked with an "N/A," "YES," or "NO" check box. You can move the cursor over the 'sticky note' for hints, clarification of the question, and/or which question(s) is/are required to be completed when "YES" is checked.

#### Instructions for completing the RPSS:

1. Download and save the form to your computer 
2. Open with Adobe Acrobat XI (preferred) or Adobe Reader
3. Click the top right hand corner to highlight form fields
4. Fill out the form including your electronic signature
5. When finished, go to File and click Save As; give this document a different name and click Save
6. Submissions should be submitted by the 3rd Thursday of the month (2nd Thursday in November and December) for review by the committee on the last Thursday of the month. Submit an electronic copy to Peggy Wess in the Research Office (peggy.wess@va.gov, 3D151, 4 10-605-7000 x 6511).
7. After the SRS meets they may request corrections or changes. If so you will need to submit a revised form. Please make the changes as soon as possible.

CHEMICALS: If your research involves the use of chemicals, the chemical inventory is required with this RPSS. The list can either be specific for the project being reviewed or for the whole lab.

#### REFERENCES:

1. VAMHCS required laboratory safety & security trainings are posted on the R&D Service website at [http://www.maryland.va.gov/research/lab/lab\\_safety\\_training.asp](http://www.maryland.va.gov/research/lab/lab_safety_training.asp)
2. The Federal Select Agent Program's "Select Agents and Toxins List" can be found at <http://www.selectagents.gov/SelectAgentsandToxinsList.html>
3. "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition" can be found at <http://www.cdc.gov/biosafety/publications/bmb15/>
4. "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" can be found at [http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html)
5. An OSHA list of hazardous chemicals can be found at [http://aps.anl.gov/Safety\\_and\\_Training/User\\_Safety/oshatoxicchem.html](http://aps.anl.gov/Safety_and_Training/User_Safety/oshatoxicchem.html)
6. The schedule of controlled substances can be found at <http://www.deadiversion.usdoj.gov/schedules/index.html>
7. The "US Government Policy on Institutional Oversight of Life Science Dual Use Research of Concern" (DURC) can be found at <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>
8. The NIH training slide set re DURC can be found at <http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf>
9. The VAMHCS Safety, Occupational Health, and Fire Protection Program can be found at <http://vhabalwdbfusion/vamhcs/quicklinks/policies/policies/512-0010PS-134.pdf>

For questions about this RPSS please contact Peggy Wess or Heidi Ortmeyer, Ph.D. for assistance.

# VAMHCS Research Protocol Safety Survey (RPSS)

Date submitted to SRS	
PRINCIPAL INVESTIGATOR (PI):	
PI's Phone & E-mail Address	
Study Coordinator(s) or Point of Contact	
Study Coordinator or Point of Contact's Phone and Email Address	
▶ IRB, IACUC and/or IBC #s (if applicable)	
Project Title	
List all VA and Non-VA Locations where PI conducts Research on this Project (Bldg. & Room numbers).	

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

- ▶ a. Biological Hazards (microbiological or viral agents, pathogens, toxins, or select agents) \_\_\_\_\_ YES  NO
- b. Animals \_\_\_\_\_ YES  NO
- c. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) \_\_\_\_\_ YES  NO
- ▶▶ d. Recombinant or Synthetic Nucleic Acid Molecules \_\_\_\_\_ YES  NO
- ▶▶ e. 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
- ▶▶ f. Controlled Substances \_\_\_\_\_ YES  NO
- ▶▶ g. Ionizing Radiation:
- (1) Radioactive materials \_\_\_\_\_ YES  NO
- (2) Radiation generating equipment \_\_\_\_\_ YES  NO
- ▶▶ h. Nonionizing Radiation:
- (1) Ultraviolet Light \_\_\_\_\_ YES  NO
- (2) Lasers (class 3b or class 4) \_\_\_\_\_ YES  NO
- (3) Radiofrequency or microwave sources \_\_\_\_\_ YES  NO

**If all answers above are NO, check here to be directed to section 13.**

**COMPLETE all YES checked sections, SKIP all NO checked sections of this survey.**

If all answers are NO, YOU NEED ONLY TO ANSWER SECTION 13 AND SIGN THE LAST PAGE. A documented review by the local SRS is still required. Use of human subjects or human tissues requires Institutional Review Board (IRB) review. Use of animals requires submission of an Institutional Animal Care and Use Committee (IACUC)-approved Animal Component. Use of recombinant or synthetic nucleic acid molecules, human blood/tissue, pathogens, or potentially pathogenic material requires Institutional Biosafety Committee (IBC) review.

 2. BIOLOGICAL HAZARDS: (IF NOT APPLICABLE SKIP TO #4) \_\_\_\_\_ N/A

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 (Section #4).

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 the Centers for Disease Control (CDC) publication entitled "Biosafety in Microbiological and Biomedical Laboratories" (see Reference #3), and
- (2) Identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin.

Organism, Agent, or Toxin	Biosafety Level**
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____

\*\* 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 of Reference #3.)

b. Are any of the biohazardous agents listed above classified as a "Select Agent" by the CDC (see Reference #2)? \_\_\_\_\_ YES  NO

c. Are any of the biohazardous agents listed above included in the "US Government Policy on Institutional Oversight of Life Science Dual Use Research of Concern (DURC)" (see Reference #7)? \_\_\_\_\_ YES  NO

If YES, all personnel involved in laboratory research need to review the NIH DURC training slide set (see Reference #8).

d. My laboratory staff and I have reviewed the NIH DURC training slide set. \_\_\_\_\_ YES  NO

3. BIOLOGICAL HAZARDS – Description of Use. (IF NOT APPLICABLE SKIP TO #4) \_\_\_\_\_ N/A

NOTE: Photocopy this page, as necessary

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

\_\_\_\_\_

b. If this is a Select Agent (see Reference #2), provide the CDC Laboratory Registration # and the date of the CDC inspection:

Registration #: \_\_\_\_\_ Date: \_\_\_\_\_

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:

\_\_\_\_\_

 e. Describe the containment equipment (protective clothing or equipment, biological safety cabinets, chemical fume hoods, containment centrifuges, etc.) to be used in this research:

\_\_\_\_\_

f. Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research:

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4. ANIMALS, CELLS, and TISSUE SAMPLES: (IF NOT APPLICABLE SKIP TO #5) \_\_\_\_\_ N/A

a. Will personnel work with human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines)? \_\_\_\_\_ YES  NO

If yes, specify:

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b. Will research studies represent a potential biohazard for *laboratory* personnel? \_\_\_\_\_ YES  NO

If yes, specify the potential hazard (check all that apply):

1. Exposure to bloodborne pathogens
2. Exposure to human or animal microbiological pathogens
3. Exposure to animal dander/fur
4. Exposure to animal bite, scratch or other trauma
5. Other: \_\_\_\_\_

c. Specify precautions employed to protect personnel working in the laboratory (check all that apply):

- 1. \*Standard Precautions will be adhered to in accordance with VAMHCS infection Control Guidelines for Standard Precautions and Exposure Control Plan, and staff are trained by the PI or designee on the proper usage of Personal Protective Equipment (PPE) and on study-specific safe work practices.
- 2. \*All laboratory staff are required to complete annual mandatory training on laboratory safety and security, bloodborne pathogens, infection control, emergency management, hazardous chemicals, and radiation safety (when applicable) (see Reference #1).
- 3. \*Staff are trained in safe laboratory work methods and practices by PI or designee as it pertains to the specific research environment. This is documented in both: (1) a written laboratory hazard-specific training plan submitted with this RPSS and (2) documentation of attendance at/competency in the training (see Reference #1).
- 4. \*Personnel who handle human samples have been offered a vaccination for hepatitis B, or have signed a form of declination. List of names of personnel that have been offered the vaccination are to be kept on file by the PI.
- 5. \*Personnel who handle animals, unfixed animal tissues, or who enter the animal husbandry unit are enrolled in the VA or UMB animal allergy exposure monitoring programs.
- 6. Other (Specify): \_\_\_\_\_

\* Required precautions to protect personnel working in the laboratory

d. Are samples that may contain bloodborne pathogens being transported? \_\_\_\_\_ YES  NO

If YES, check all that apply:

- 1. Samples are being transported/received in a double bagged leak-proof container and marked "Biohazard."
- 2. Staff responsible for transporting samples have been offered the hepatitis B vaccine, receive appropriate hazard-specific training, and this training is documented in the PI's hazard-specific training plan.
- 3. Samples are being transported/received by carrier and will be shipped per IATA and DOT regulations.
- 4. Staff responsible for preparing samples for shipping will be trained in IATA and DOT regulations (certification required every two years).
-   5. International samples are being transported/received per IATA regulations.

5. Recombinant or Synthetic Nucleic Acid Molecules: (IF NOT APPLICABLE SKIP TO #6) \_\_\_\_\_ N/A

 a. Are procedures involving recombinant or synthetic nucleic acid molecules used in your laboratory? YES  NO

b. Are recombinant or synthetic nucleic acid procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? \_\_\_\_\_ YES  NO

1. If YES, your recombinant or synthetic nucleic acid studies are exempt from restrictions described in the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (see Reference #4).

2. If NO, it is the responsibility of each PI to:

- a) Consult the current "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (Reference #4), and
- b) Identify the experimental category of their recombinant or synthetic nucleic acid research.

c. Description of Recombinant or Synthetic Nucleic Acid Procedures:

1. Identify the NIH classification (and brief description) for these recombinant or synthetic nucleic acid 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: (IF NOT APPLICABLE SKIP TO #7) \_\_\_\_\_ N/A

a. Has the use of chemicals in your laboratory been reviewed by the Safety Officer in the past 12 months? \_\_\_ YES  NO

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

- (1) Toxic chemicals? \_\_\_\_\_ N/A  YES  NO
- (2) Reactive and potentially explosive compounds? \_\_\_\_\_ N/A  YES  NO
- (3) Teratogens Mutagens and Carcinogens? \_\_\_\_\_ N/A  YES  NO
- (4) Toxic gases? \_\_\_\_\_ N/A  YES  NO
- (5) Neurotoxins? \_\_\_\_\_ N/A  YES  NO

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

 7. CONTROLLED SUBSTANCES: (IF NOT APPLICABLE SKIP TO #8) \_\_\_\_\_ N/A

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. \_\_\_\_\_

b. Are all controlled substances stored in the VA Pharmacy Service's vault? \_\_\_\_\_ N/A  YES  NO

If NO, where are they stored? \_\_\_\_\_

8. RADIOACTIVE MATERIALS: (IF NOT APPLICABLE SKIP TO #9) \_\_\_\_\_ N/A

Does your laboratory 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): \_\_\_\_\_
- c. Location of Use (build/room) No.: \_\_\_\_\_



**➤ 12. WORK PROPOSED/METHODS**

Provide a detailed description of the methods and techniques that will be used, *including PPE*, with specific emphasis on the laboratory hazards, e.g. descriptions of the specific biological, chemical, physical, and/or radioactive hazards. If using animal and/or human samples indicate how they will be disposed. Do NOT attach a complete grant application. Do NOT provide any information on the hypothesis, specific aims, or biomedical significance of your study.

**13. PHYSICAL HAZARDS**

All personnel involved in the research study are required to understand the physical hazards addressed in the facility Safety, Occupational Health, and Fire Protection Program (see Reference #9).

a. Do you and your employees receive annual training addressing physical hazards? \_\_\_\_\_ YES NO

### Acknowledgement of Responsibility and Knowledge

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 (when applicable).

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.

Subcommittee on Research Safety Chair's Signature

Date

Research & Development Committee Chair's Signature

Date

VAMHCS Radiation Safety Officer's Signature (check here if not applicable) Date

UM Radiation Safety Officer's Signature (check here if not applicable) Date

Facility Safety Officer's Signature

Date