

The purpose of this form is to allow the Research Safety Subcommittee (RSS) to review proposed work and work in progress to ensure that all safety regulations are being followed. All research protocols done at the VA must complete this safety survey even if a project has no safety issues (i.e., chart reviews). It must be reviewed, approved and documented in minutes by the local RSS before any work can begin, and annually thereafter for continuing projects.

Instructions for completing the Research Protocol Safety Form:

1. Download and save the form to your computer.
2. Open with Adobe Acrobat Reader.
3. Click the top right hand corner to highlight form fields.
4. Fill out the survey.
5. When finished, go to File and click Save As.
6. Give this document a different name and click Save.
7. Submit two copies of the Safety Survey (VA Form 10-0398), a chemical inventory list (if applicable), and an abstract. The abstract should have enough information to allow the committee to evaluate the work being proposed. One hard copy is submitted to the Research Office and one copy is submitted electronically.
8. **ELECTRONIC SUBMISSION:** Submit via E-mail as ATTACHMENTS (by using the insert file function) to Charmaine O'Brien @ <mailto:charmaine.o'brien@va.gov>. (***NOTE: If you do not submit the electronic versions of these documents, your project will not be reviewed.***) Your survey will be sent out to the RSS members for review.
9. **HARD COPY SUBMISSION:** **PRINT, SIGN, DATE**, and submit a hard copy of the same forms to Charmaine O'Brien in the R&D Office (F-201D, ACRE Building).
10. After the RSS meets they may request corrections or changes. If so, you will have to submit an updated form to the Research Office. Please make the changes as soon as possible. If you need clarification, please contact Charmaine O'Brien for assistance at ext 66977.

NOTE: To prevent your project from being tabled at the RSS meeting, please bring the ***CORRECTED*** version (if applicable) with Signature and Date to Charmaine O'Brien to update your previous version of the survey. If you are not notified for correction, no update of the hardcopy is required.

HOW TO: Much of this form consists of boxes that are checked with a "Yes" or "No" check box. You can move the cursor over the 'sticky note' or the check boxes themselves for hints, clarification of the question, and/or which question(s) is/are required to be completed when "Yes" is checked. Click opened the attachment icon at the bottom left hand corner for chemical inventory workbook and other documents relevant for this survey.

CHEMICALS: If your research involves the use of chemicals, a comprehensive chemical inventory for your lab is **required** with this survey. You can use your own form (not recommended) or the one provided in the attachment. Using the form provided will help us with our chemical reporting and documentation purposes.

1. Click the paper clip icon at the bottom left corner to open the attachments.
2. Click open the chemical inventory excel workbook (Note: This is a read only file).
3. Click Save As, (give it a different name) and Save this copy to your local drive.
4. Next complete your chemical inventory (remember to save your work periodically).
5. Attach the completed chemical inventory with your survey.
6. You can create a new inventory or update your previous chemical inventory to this workbook format.
7. This workbook will allow you to effortlessly update your chemical inventory yearly by simply clicking on the bottom tab for the following year (i.e. FY2011).
 - a. To update, simply copy the previous year inventory to the next sheet (i.e. Tab FY2011).
 - b. Update the location and chemical quantity.
8. This workbook will allow you to designate which chemicals are protocol-specific.
 - a. Use the drop-down menu to the right of each chemical to designate said chemical as specific to the project being reviewed.

In addition, question 9.a. and b. require that physical hazards be addressed to the employees and that employees receive annual safety training for these hazards, respectively.

References:

NIH Guidelines for Research Involving Recombinant DNA Molecules:
http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_Ink_2002z.pdf.

Information on biological hazards (Microbiological or viral agents, pathogens, toxins, select agents) as defined in “Biosafety in Microbiological and Biomedical Laboratories”:
<http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>.

There is no definitive list of chemicals considered hazardous but a good starting point for information is at: <http://msds.chem.ox.ac.uk/>.

For questions about the form, please contact the research office for assistance.

RESEARCH PROTOCOL SAFETY FORM
RESEARCH AND DEVELOPMENT COMMITTEE – VA TENNESSEE VALLEY HEALTHCARE SYSTEM (626)

PRINCIPAL INVESTIGATOR (PI):
PROJECT TITLE:
DATE OF SUBMISSION:
LIST VA AND NON-VA LOCATIONS IN WHICH PI CONDUCTS THIS RESEARCH:

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

- a. **Biological Hazards** (Defined as: Microbiological or viral agents, pathogens, toxins, or select agents in [Title 42 CFR 72.6](#)):  YES NO
 If **YES**, refer to questions 2 & 3
- b. **Human or non-human cell or tissue samples** (including cultures, tissues, blood, other bodily fluids or cell lines): YES NO
 If **YES**, refer to question 4
- c. **Recombinant Deoxyribonucleic Acid (DNA):**  YES NO
 If **YES**, refer to question 5
- d. **Chemicals (specify in Attachment A):** 
 Indicate the location where chemical will be utilized in this research:
 VA-TVHS Vanderbilt N/A
- (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
 If **YES**, refer to question 7
 Indicate the location where controlled substance will be utilized in this research:
 VA-TVHS Vanderbilt N/A
- f. **Ionizing Radiation:**
- (1) Radioactive materials: YES NO
- (2) Radiation generating equipment: YES NO
 If **YES**, refer to question 8
- g. **Non-ionizing 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, but will be exempt from *Annual Biosafety Review* (see Appendix B). 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 (IACUC)-approved Animal Component.* Proceed to signature page.

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 Bio-safety Level 2 and 3 agents or toxins used in your laboratory (see Attachment C).

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.** (Organism, Agent, or Toxin Biosafety Level):

Organism/Agent/Toxin	Bio-Safety Level**

**For each Bio-safety Level 2 or 3 agent or toxin listed, provide the information requested on the following page(s). (Description of Bio-safety Levels 2 and 3 are attached).

b. Are any of the bio-hazardous agents listed above classified as a “Select Agent” by the Centers for Disease Control? YES NO

3. BIOLOGICAL HAZARDS – Description of Use

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

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- 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:
- e. Describe the containment equipment (i.e., protective clothing or equipment, biological safety cabinets, 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: 

4. CELLS and TISSUE SAMPLES

- a. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones?  YES NO

If YES, specify:

- b. Will research studies represent a potential biohazard for lab personnel? YES NO NA

If YES, specify the potential hazard and precautions employed to protect personnel in the laboratory:

Universal safety precautions will be employed. 

NOTE: If these studies involve animals, the Animal Component of Research Protocol (ACORP) must be completed.

5. RECOMBINANT DNA

- a. Are procedures involving recombinant DNA used in your laboratory?  YES NO

If YES, provide the following:

- (1) Institutional Biosafety Committee (IBC) Approval? YES NO

Provide a copy of the lab IBC (BioWise) Approval Letter

- b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES NO NA

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(1) If **YES**, your recombinant DNA studies are exempt from restrictions described in the NIH Guidelines for Research Involving Recombinant DNA Molecules (If yes, skip c).

(2) If **NO**, it is the responsibility of each PI to:

(a) Consult the current NIH Guidelines for Research Involving Recombinant DNA Molecules which can be found at the Internet site http://oba.od.nih.gov/rdna/nih_guidelines_oba.html.

(b) Identify the experimental category of their recombinant DNA research.

c. Description of Recombinant DNA Procedures:

(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 6 months? YES NO NA

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

(1) Carcinogens?

YES NO NA

(2) Teratogens and Mutagens?

YES NO NA

(3) Toxic gases?

YES NO NA

(4) Neurotoxins?

YES NO NA

(5) Reactive and potentially explosive compounds?

YES NO NA

NOTE: Submission of a comprehensive laboratory chemical inventory is required for local review regardless of location (see Attachment A). 

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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:

b. Are all Schedule II and III drugs stored in a double-locked vault? YES NO NA

If YES, provide location:

NOTE: Submission of a comprehensive controlled substances inventory is required for local review regardless of location (see Attachment D).

8. RADIOACTIVE MATERIALS

a. Does your research involve the use of radioactive materials? YES NO

If YES, provide the following:

(1) Identity of radioactive source (s):

(2) Radiation Safety Committee Approval? YES NO

If yes, location where training was completed: Date:

Provide a copy of the training certificate and Radioisotope Authorization Material Permit

(3) Location (check all that apply): VA ACRE Building Vanderbilt Other:

9. PHYSICAL HAZARDS

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan? YES NO

Guidelines and procedures to address physical hazards are outlined in the Tennessee Valley Healthcare System Occupational Safety and Health Plan.

b. Do employees receive annual training addressing physical hazards? YES NO

Facility officials will ensure appropriate training of all staff in accordance with OSHA and VA policies and procedures. The PI will ensure that all laboratory and/or research staff will complete initial and annual training in accordance with Tennessee Valley Healthcare System policies and procedures.

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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, bio-hazardous 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 bio-hazardous 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: Jeffrey Davidson, PhD	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 Bio-hazardous 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, Signature: Jeffrey Davidson, PhD	Date:
Radiation Safety Officer's (if applicable) Signature: David Burkett	Date:
Chair, Research & Development Committee, Signature: Jeffrey N. Rottman, MD	Date:
Facility Safety Officer's Signature: Jake Silvensky	Date: