

**RESEARCH PROTOCOL SAFETY SURVEY (RPSS)
COVER SHEET**

All research performed at SFVAMC¹ whether funded or not (donation/recruitment funds, unfunded/pilot studies etc.) must be registered as a PROJECT. For each new individual Project, PI must submit a Request for R&D Approval form and a RPSS form to the Research Office for approval prior to initiating any research. RPSS will be reviewed only if approved or pending-approved Protocols are in place.

1	PI's Name		
2	Title of Project		
3	Is this a funded Project?	YES	NO
	If Yes, answer the following:		
	Agency Name		
	Agency Grant Number		
4	Provide titles or, if approved, numbers for all Protocols associated with this Project		
	BUAs		
	ACORPs		
	UCSF IRB or VA CIRB approvals		
	Radiation Safety Protocols		
5	Specimen Collection		
	Is blood, urine or any other human specimen collected, analyzed or shipped?	YES	NO
	If Yes, answer the following:		
	a) Where is the blood, urine or other human specimen(s) collected?	Bldg/Room #:	
	b) Who is drawing blood/collecting urine or other human specimen(s)?		
	c) Who is analyzing the blood, urine or other specimen(s)?		
	d) Who is doing the packaging if samples are being shipped?		
6	Project Type		
	a) Does this Project ONLY provide funds for, or ONLY involve, administrative costs, office supplies, computer hardware/ software, data gathering from existing databases, data analysis, patient reimbursement, staff salary, education and/or training (i.e. no specimen collection/analysis)?	YES	NO
	If Yes, <i>do not</i> complete the RPSS		
	b) Will wet lab research be done, including collecting and/or analyzing and/or shipping human fluids/tissues outside of standard clinical care?	YES	NO
	If Yes, <i>complete</i> all Sections of the RPSS even if the answers to all parts of Section 1 of the RPSS are NO.		
7	Sign below and send the completed Cover Sheet to the appropriate Grants Manager electronically.		
	PI Signature	Date	

RPSS Coversheet
Lab Based (NOT Project Based)

Check the box/es below if you are using/storing any of the following hazardous materials in your lab:

- Biologically Derived Toxins (BDTs)**
Examples: Botulinum Toxin, Tetrodotoxin, Pertussis Toxin, LPS
- Carcinogens, Mutagens and Reproductive Toxicants (CMRTs)**
Examples: Acrylamide, Benzene, Buprenorphine, Ethidium Bromide, Formaldehyde
Click here for other examples (Table 1)
- Compressed Gases**
Examples: Carbon Monoxide, Ammonia, Carbon Dioxide, any of Hydrogen gases
- Corrosives**
Examples: Hydrochloric acid, Hydrofluoric acid, Ammonium Hydroxide, Phenol
Click here for other examples (Table 2)
- Cryogenics and Dry Ice**
Examples: Liquid Nitrogen, Dry Ice, Liquid Oxygen
- Flammables and Combustibles**
Examples: Acetaldehyde, Acetone, Acetonitrile, Ethanol, Benzene, Ether, Hydrazine
Click here for other examples (Table 3)
- Irritants**
Examples: Formaldehyde, Glutaraldehyde, Sodium dodecyl sulfate, Dichloromethane
Click here for other examples (Table 4)
- Reactive or Unstable Substances**
Examples: Ether (Ethyl Ether, Diethyl Ether), Hydrogen Peroxide, Perchloric Acid, Picric Acid
Click here for other examples (Table 5)
- Sensitizers**
Examples: Ammonium Persulfate, Potassium Persulfate, Glutaraldehyde
Click here for other examples (Table 6)
- Specific Target Organ (STO) Toxicants**
Examples: Hydrazine, Hexane, Cyanide, Mercury, Benzene, Lead
Click here for other examples (Table 7)

NOTE:

- SOPs for appropriate hazardous material categories NOTED above must be made available to and read/signed by all laboratory personnel
- Also be aware of the supplier's Safety Data Sheet (SDS) information pertaining for each specific agent used in the laboratory
- All chemicals used and stored in your laboratory must be listed in RIO (<http://vhasfcapprio.v21.med.va.gov/RIO/>) and updated at a minimum of every 6 months

Select Agents (Permissible Amounts): If you are planning to use any "Permissible Select Agents", please contact the SRS Chair, as a separate SOP will be required. Click [here](#) for the permissible amounts of Select Agents (this short list of agents is delineated in Table 8). Select Agents amounts above permissible amounts require prior approval for Dual Use Research of Concern (DURC) from SRS Internal Review Committee (IRC) and registration with the National Select Agent Registry (NSAR) Program. (See <http://www.selectagents.gov/SelectAgentsandToxinsList.html>)

Controlled Substances: Controlled substances must be stored in a securely locked cabinet, located where access is limited to those individuals with controlled substances authorization. Please contact VA Pharmacy for acquiring and storing Controlled Substances.

Selected hazardous agents by category of SOP based on current inventories [Examples Only]

Table 1: Carcinogens, Mutagens and Reproductive Toxicants (CMRTs)

<ul style="list-style-type: none"> • 4-Dimethylaminoazobenzene • 5-Bromo-2'-deoxyuridine (BrdU) • Acetaldehyde • Actinomycin D • Acrylamide • Benzene • Benzidine • Bleomycin • Butanediol • Carbon Tetrachloride • Carboplatin • Chloramphenicol • Chloroform • Cycloheximide • Diazomethane • Dichloroacetic acid • Dimethyl Sulfate • Dimethylformamide • Doxorubicin hydrochloride • Ethidium Bromide 	<ul style="list-style-type: none"> • Ethylene Glycol • Formaldehyde • Hydrazine and Hydrazine Sulfate • Hydrogen Sulfide • Lead • Minocycline hydrochloride • Naphthalene • Nitrilotriacetic Acid • Nitrobenzene • Pentachlorophenol • Phenolphthalein • Propylene Oxide • Sodium fluoroacetate • Streptozotocin (Streptozocin) • Tamoxifen • Tetracycline • Thiourea • Toluene • Urethane (Ethyl carbamate)
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Table 2: Corrosives

<ul style="list-style-type: none"> • Glacial Acetic Acid • Formic Acid • Hydrochloric acid • Hydrofluoric acid • Nitric acid • Perchloric acid • Phosphoric acid • Picric acid • Sulfuric Acid • Trichloroacetic acid • N,N,N',N'-Tetramethylethylenediamine (TEMED) 	<ul style="list-style-type: none"> • Ammonium Hydroxide • Barium Hydroxide • Calcium Hydroxide • Phenol • Potassium Hydroxide • Sodium Hydroxide • Sodium Hypochloride • Sodium Sulfide • Silver Nitrate
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Table 3: Flammables and Combustibles

<ul style="list-style-type: none"> • Acetaldehyde • Acetone • Acetonitrile • Ethanol • Benzene • Ether (Ethyl Ether, Diethyl Ether) • Hydrazine • Isopentane • Isopropyl Alcohol (Propanol) • Methanol • Methylamine 	<ul style="list-style-type: none"> • Methyl Methacrylate • N,N,N',N'-Tetramethylethylenediamine (TEMED) • Nitromethane • Petroleum Ether • Picric Acid • Propylene Oxide • Silane • Toluene • Trimethylamine • Xylene
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Table 4: Irritants

<ul style="list-style-type: none"> • Acetone • Ammonia • Chlorine • Dichloromethane • Dimethylformamide 	<ul style="list-style-type: none"> • Ethanol • Formaldehyde • Glutaraldehyde • Halogens other than Chlorine
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Table 5: Reactive or Unstable Substances

<ul style="list-style-type: none"> • Acetaldehyde • Ammonium Persulfate • Benzyl Alcohol • Benzoyl Peroxide • Ether (Ethyl Ether, Diethyl Ether) • Hydrazine • Hydrogen peroxide 	<ul style="list-style-type: none"> • Hydroxylamine • Isopropyl Ether • Methyl Methacrylate • Perchloric acid • Picric acid • Tetrahydrofuran (THF) • Sodium Azide
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Table 6: Sensitizers

<ul style="list-style-type: none"> • Acrylates • Ammonium Persulfate • Chromium compounds • Epoxies • Ethylenediamine • Glutaraldehyde 	<ul style="list-style-type: none"> • Isocyanates • Nickel salts • Picatic acid • Potassium Persulfate • Trimellitic anhydride
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Table 7: Specific Target Organ (STO) Toxicants

<ul style="list-style-type: none"> • 1-Methyl-4-phenyl-1,2,3,6-tetrahydropyridine hydrochloride (MPTP) • Benzene • Carbon Monoxide • Carbon Tetrachloride • Chloroform • Cyanide salts (Potassium Cyanide, Sodium Cyanide) • Diazomethane • Dimethyl Sulfate 	<ul style="list-style-type: none"> • Formaldehyde • Hexane • Hydrazine and Hydrazine Sulfate • Hydrogen Sulfide • Lead • Nitrobenzene • Osmium Tetroxide • Silica • Sodium Azide • Toluene
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Table 8: Select Agents (Permissible Amounts)

<ul style="list-style-type: none"> • Abrin (100 mg) • Botulinum neurotoxins (0.5 mg) • Short, paralytic alpha conotoxins (100 mg) • Diacetoxyscirpenol (DAS) (1000 mg) • Ricin (100 mg) 	<ul style="list-style-type: none"> • Saxitoxin (100 mg) • Staphylococcal Enterotoxins (Subtypes A, B, C, D, E) (5 mg) • T-2 toxin (1000 mg) • Tetrodotoxin (100 mg)
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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 (IACUC)-approved Animal Component.

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**
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

** 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:

e. Describe the containment equipment (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

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

NOTE:
must be completed

If these studies involve animals, the Animal Component of Research Protocol (ACORP)

c. Specify precautions employed to protect personnel working in the laboratory:

5. RECOMBINANT DNA

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

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

(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://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>

(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 12 months? YES NO

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

- | | | | |
|---|-----------------------------|------------------------------|-----------------------------|
| (1) Carcinogens? | <input type="checkbox"/> NA | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (2) Teratogens and Mutagens? | <input type="checkbox"/> NA | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (3) Toxic gases? | <input type="checkbox"/> NA | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (4) Neurotoxins? | <input type="checkbox"/> NA | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| (5) Reactive and potentially explosive compounds? | <input type="checkbox"/> NA | <input type="checkbox"/> YES | <input type="checkbox"/> 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)

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 <https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.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

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