RESEARCH PROTOCOL SAFETY SURVEY (RPSS)
COVER SHEET

All research performed at SFVAMC[1] 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, *do not* 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, *complete* 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)

- ☐ **Cryogens 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)

• 4-Dimethylaminoazobenzene	• Ethylene Glycol
• 5-Bromo-2'-deoxyuridine (BrdU)	• Formaldehyde
• Acetaldehyde	• Hydrazine and Hydrazine Sulfate
• Actinomycin D	• Hydrogen Sulfide
• Acrylamide	• Lead
• Benzene	• Minocycline hydrochloride
• Benzidine	• Naphthalene
• Bleomycin	• Nitrilotriacetic Acid
• Butanediol	• Nitrobenzene
• Carbon Tetrachloride	• Pentachlorophenol
• Carboplatin	• Phenolphthalein
• Chloramphenicol	• Propylene Oxide
• Chloroform	• Sodium fluoroacetate
• Cycloheximide	• Streptozotocin (Streptozocin)
• Diazomethane	• Tamoxifen
• Dichloroacetic acid	• Tetracycline
• Dimethyl Sulfate	• Thiourea
• Dimethylformamide	• Toluene
• Doxorubicin hydrochloride	• Urethane (Ethyl carbamate)
• Ethidium Bromide	

Table 2: Corrosives

• Glacial Acetic Acid	• Ammonium Hydroxide
• Formic Acid	• Barium Hydroxide
• Hydrochloric acid	• Calcium Hydroxide
• Hydrofluoric acid	• Phenol
• Nitric acid	• Potassium Hydroxide
• Perchloric acid	• Sodium Hydroxide
• Phosphoric acid	• Sodium Hypochloride
• Picric acid	• Sodium Sulfide
• Sulfuric Acid	• Silver Nitrate
• Trichloroacetic acid	
• N,N,N′,N′-Tetramethylethylenediamine (TEMED)	

Table 3: Flammables and Combustibles

• Acetaldehyde	• Methyl Methacrylate
• Acetone	• N,N,N′,N′-Tetramethylethylenediamine (TEMED)
• Acetonitrile	• Nitromethane
• Ethanol	• Petroleum Ether
• Benzene	• Picric Acid
• Ether (Ethyl Ether, Diethyl Ether)	• Propylene Oxide
• Hydrazine	• Silane
• Isopentane	• Toluene
• Isopropyl Alcohol (Propanol)	• Trimethylamine
• Methanol	• Xylene
• Methylamine	

Table 4: Irritants

• Acetone	• Ethanol
• Ammonia	• Formaldehyde
• Chlorine	• Glutaraldehyde
• Dichloromethane	• Halogens other than Chlorine
• Dimethylformamide	

Table 5: Reactive or Unstable Substances

• Acetaldehyde	• Hydroxylamine
• Ammonium Persulfate	• Isopropyl Ether
• Benzyl Alcohol	• Methyl Methacrylate
• Benzoyl Peroxide	• Perchloric acid
• Ether (Ethyl Ether, Diethyl Ether)	• Picric acid
• Hydrazine	• Tetrahydrofuran (THF)
• Hydrogen peroxide	• Sodium Azide

Table 6: Sensitizers

• Acrylates	• Isocyanates
• Ammonium Persulfate	• Nickel salts
• Chromium compounds	• Plicatic acid
• Epoxies	• Potassium Persulfate
• Ethylenediamine	• Trimellitic anhydride
• Glutaraldehyde	

Table 7: Specific Target Organ (STO) Toxicants

• 1-Methyl-4-phenyl-1,2,3,6-tetrahydropyridine hydrochloride (MPTP)	• Formaldehyde
• Benzene	• Hexane
• Carbon Monoxide	• Hydrazine and Hydrazine Sulfate
• Carbon Tetrachloride	• Hydrogen Sulfide
• Chloroform	• Lead
• Cyanide salts (Potassium Cyanide, Sodium Cyanide)	• Nitrobenzene
• Diazomethane	• Osmium Tetroxide
• Dimethyl Sulfate	• Silica
	• Sodium Azide
	• Toluene

Table 8: Select Agents (Permissible Amounts)

• Abrin (100 mg)	• Saxitoxin (100 mg)
• Botulinum neurotoxins (0.5 mg)	• Staphylococcal Enterotoxins (Subtypes A, B, C, D, E) (5 mg)
• Short, paralytic alpha conotoxins (100 mg)	• T-2 toxin (1000 mg)
• Diacetoxyscirpenol (DAS) (1000 mg)	• Tetrodotoxin (100 mg)
• Ricin (100 mg)	

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 <u>any</u> of these questions is YES, complete all sections of this survey that apply.

If <u>all</u> 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 ****

** 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)

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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?	☐ 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) _____

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**