

**JOHN D. DINGELL VA MEDICAL CENTER
R&D APPLICATION
For Renewal of Active Animal Project**

PLEASE SUBMIT COPY OF FORMS SUBMITTED TO IACUC

PLEASE SUBMIT DOCUMENTATION OF REQUIRED TRAINING

**Research Safety Hazard Assessment Survey
Research Safety Committee
JOHN D. DINGELL VA MEDICAL CENTER**

Principal Investigator:

Email Address:

Project Title:

**This form must be included with your application to the VA R&D Committee.
Please check all boxes that apply to your research protocol.
Give a brief summary for each item checked.**

- A.** Ionizing Radiation: radioactive materials generating equipment
- B.** Microbial/Viral Agents
- C.** Chemicals (toxic, flammable, explosive, corrosive, carcinogenic, neurotoxins)
- D.** Recombinant DNA
- E.** Other cell lines, pathogens, toxins, select agents
- F.** Poisonous, toxic, venomous animals/plants
- G.** Physical agents (UV light, Lasers, Radiofrequency or microwaves, electricity, trauma, etc.)
- H.** Controlled Substances
- I.** Animals (must submit VA ACORP form with WSU addendum)
- J.** Human tissue, blood, other body fluids (must submit VA Human Studies Application)

If you checked one or more boxes above, you must complete a Research Protocol Safety Survey (VAF 10-0398). The RPSS must be accompanied by the "work proposed" section of your research proposal. If your work involves **ONLY** collection of human tissue, blood or body fluids, complete the section below. You will not need to complete VA Form 10-0398.

- a. If collecting clinical samples, where will the samples be analyzed?

b. How will samples be transported (please describe the containers that will be used)?

NOTE: Federal regulations have established requirements for shipping materials of a potentially infectious nature. If samples will be shipped, the following requirements must be met:

- a. Shipping must be done only by personnel who have received approved training.
- b. Materials must be packaged in approved containers with required labeling.

Personnel: List the names of all personnel, co-investigators and collaborators who will work with the PI on this research proposal. List non-VA personnel only if working in a VA laboratory.	Has person received safety training specific for this project?	SRS Use Only
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
If NO to any personnel, please explain:		
PI Signature		Date
<input type="checkbox"/> Exempt from Safety Review <input type="checkbox"/> Full Safety Review Conducted <input type="checkbox"/> Reviewed by SRS Chair		
TIMOTHY HADDEN, PH.D. Research Biosafety/Chemical Hygiene Officer/SRS Chairperson		Date

RESEARCH PROTOCOL SAFETY SURVEY

This form must be accompanied by a copy of the “work proposed” section of your research proposal.

PRINCIPAL INVESTIGATOR (PI):
PROJECT TITLE:
DATE OF SUBMISSION:
VA FUNDED? (circle) YES NO
LIST VA AND NON-VA LOCATIONS WHERE THIS PROTOCOL WILL BE CONDUCTED:

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

- a. Biological Hazards
 - (1) Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6, YES NO
 - (2) 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 this research protocol 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>)

Have you reviewed this website?

Yes Date

No

(2) And 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:

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- 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 human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES NO

If yes, specify:

b. Will this study represent a potential biohazard for lab personnel? NA YES NO

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

c. Will personnel work with animals or animal blood? YES NO

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

d. If this study involves use of animals, 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

If NO, skip to next section.

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://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:

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(2) Biological source of DNA insert or gene:

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(3) Function of the insert or gene:

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

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

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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. Have you reviewed this list?  Yes Date _____ No

b. 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:

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

8. RADIOACTIVE MATERIALS

Does this 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
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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
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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

Conflict of Interest

The policy of the VA is to ensure that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Objectivity in research is a key component of any research project. One method for maintaining objectivity is to have **all** individuals involved in research design, development, or data evaluation/analysis disclose any potential and/or real financial conflict of interest. This includes all personnel working on this proposal.

Examples of relevant relationships for potential conflict of interest include but are not limited to:

- (1) receiving past, current, or expecting future income in the form of salary, stock or stock options/warranties, equity, dividends, royalties, profit sharing, capital gain, forbearance or forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor
- (2) receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel
- (3) serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation
- (4) inventor on a patent or copyright involving technology/processes/products licensed or expected to be licensed to the sponsor.

See HIC Policy and Procedures Institutional Review Board & Institutional and Individual Financial Conflict of Interest (COI) at www.research.wayne.edu/coi, MCNM 11R-4, Institutional Conflict of Interest (COI) in Research, and Research Service Policy #8, Conflict of Interest Policy.

If any response below is "yes," there must be a "Financial Conflict of Interest Detailed Disclosure Form" submitted to the R&D Committee at the time of this protocol submission and then annually or when changes occur; if this form is **not** submitted, the protocol **cannot** be approved.

The form and more information are available through the Research Office. For additional information please call 313-576-1000, x61046.

PRINCIPAL INVESTIGATOR:	
SIGNATURE:	
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources?	<input type="checkbox"/> No <input type="checkbox"/> YES
Are you aware of any potential and/or real financial conflict of interest with the sponsor of this project, involving your supervisor, service chief or the John D. Dingell VA Medical Center?	<input type="checkbox"/> No <input type="checkbox"/> YES
Are you aware of any potential and/or real financial conflict of interest with the sponsor of this project, involving co-investigators, other key personnel (which could include collaborators, fellows, residents, research assistants, etc.) and/or their spouses, domestic partners, or dependent children?	<input type="checkbox"/> No <input type="checkbox"/> YES