### 

## 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, or select agents as defined in Title 42, Code of Federal

Regulations (42 CFR) 72.6, or animals) YES  NO

Will your research involve collection and/or handling of human specimens? YES  NO

If yes, please answer the following five questions regarding the personnel listed above:

1. Do all personnel have a VAMC or ETSU clinical appointment? YES  NO
2. Have all personnel received training in universal precautions from YES  NO

VAMC or ETSU infection control?

3) Have all research personnel received or been offered hepatitis B vaccine YES  NO

free of charge from Employee Health at the VAMC?

4) Will you be shipping specimens? YES  NO

5) If yes, have personnel received training in “Shipping of Specimens and YES  NO

Dangerous Goods”?

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 form 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 table below.

**Organism/Agent/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 of VHA Handbook 1200.8, *Safety of Personnel Engaged in Research*.)

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 *(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), please provide the Centers for Disease Control and Prevention (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:

Date of Last Inspection Biosafety Hood:

Date of Last Inspection of Chemical Fume Hood:

f. Described 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 known biohazard for lab personnel?

NA YES  NO

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

***Note:* *If these studies involve animals, the Animal Component of Research Protocol***

***(ACORP) must be completed*.**

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

d. Will you be shipping specimens or dangerous goods? NA YES NO

**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  NA

(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. It can be found at the Internet site http://www4.od.nih.gov/oba

(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** (MSDS website <http://siri.uvm.edu/msds>)

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*** <http://www.usdoj.gov/dea/pubs/schedule.pdf>

## 8. RADIOACTIVE MATERIALS

The purchase, handling, receipt and disposal of radionuclides must be performed as specified by the investigator’s license. The site where the work is being performed determines which license the investigator must use. Work performed at ETSU must be done under the authority of the ETSU (State of Tennessee) license. Work being performed at the VA must be done under the authority of the VA license.

Investigators working at ETSU with a State of TN license using VA funding to purchase radionuclides, must follow State of TN guidelines for radioactive materials. Purchasing will be done by ETSU to ensure delivery to ETSU (and not the VA warehouse). Appropriate arrangements must be made with the VA Research Office (Ext 2859) for a contract to reimburse ETSU for purchasing and disposal costs.

In all cases, projects utilizing radioactive materials must have budget line item for disposal costs.

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

If **YES,** provide the following:

a. Identity and activity of radioactive source (s):

b. Radiation Safety Officer/Ch, Radiation Safety Committee:

**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 review forms used locally are available from the Research Office.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Chair, Subcommittee on Research Safety Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Chair, Research & Development Committee Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Radiation Safety Officer (if applicable) Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Facility Safety Officer Date

**Appendix A**

**Hazardous Chemical List**

|  |  |  |  |
| --- | --- | --- | --- |
| **Chemical** | **Storage/**  **Location** | **Use/Disposal Location** | **Volume** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Minimum precautionary measures will be according to MSDS for each chemical.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# PI Signature

**Appendix B**

### Training Checklist

**All technical and incidental workers involved in this project will be aware of potential hazards and will receive instructions and annual training on the proper handling and use of chemical, radioactive and biohazardous materials. Training will include the universal precautions for blood-borne pathogens when human blood/tissue are used, and the appropriate personal protective equipment for each procedure involving biohazards.**

**Annual Training Institution providing training**

**a. Right-to-Know/Hazard Communication - MSDS procedures**  **VA**  **University**

**b. Radiation Emergency Procedures**  **VA**  **University**

**c. Laboratory Safety** **VA**  **University**

**d. Accident Reporting Procedures**  **VA**  **University**

**e. Blood-borne Pathogens/Universal Precautions**  **VA**  **University**

**f. Fire Safety**  **VA**  **University**

**g. Infection Control**  **VA**  **N/A**

**h. Research Chemical Hygiene Plan**  **VA**  **University**

**i. Disaster Plan/Evacuation Plan**  **VA**  **University**