VA Pittsburgh Healthcare System (VAPHS)

Research and Development

Part II: Research Institutional Biosafety Committee Protocol Survey

(adapted from VHA Handbook 1200.08, Appendix G, and VA Form 10-0398)

## Principal Investigator/Program Director: Click or tap here to enter text.

##

## Project Title: Click or tap here to enter text.

##

## Submission Date: Click or tap to enter a date.

##

## Complete entire form by answering all questions in each section or mark the section as Not Applicable. (See Attachment A on the Research Safety and Security webpage for additional information)

## Does this research project involve the use of any of the following?

### 1. Human specimens collected from participants in VA Clinical Studies:  [ ] YES [ ] NO

* blood, urine, tissue, etc.

### 2. Biological Agents for Non-Clinical and/or Animal Studies [ ] YES [ ] NO

* Human and Non-human primate specimens (primary cells, tissues, blood, bodily fluids, established cell lines)
* Pathogens (bacteria, virus, fungus, parasites, rickettsiae) and microbial toxins (e.g., endotoxin/LPS)
* Select Agents and toxins (as defined in 42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331)

### 3. Recombinant or Synthetic Nucleic Acid Molecules [ ] YES [ ] NO

* vectors, probes, PCR, siRNA, etc

###

### 4. Chemicals: [ ] YES [ ] NO

* Toxic chemicals
* Flammable, explosive, or corrosive chemicals
* Carcinogenic, mutagenic, or teratogenic chemicals
* Toxic compressed gases
* Acetylcholinesterase inhibitors or neurotoxins

### 5. Animals [ ] YES [ ] NO

* animal blood, bodily fluids, organs, tissues, cell lines

### 6. Controlled Substances [ ] YES [ ] NO

### 7. Radiation: [ ] YES [ ] NO

* Ionizing
* Non-ionizing
* Ultraviolet light
* Lasers (Class 3b or 4)
* Radiofrequency or microwave sources

### 8. Physical Agents: [ ] YES [ ] NO

* Electricity or trauma
* Noise
* Extreme Cold/Heat (-80 freezer, liquid nitrogen, Bunsen burners, etc.)

# SECTION A:

## Using non-technical language, provide a detailed description of the work that will be performed as applicable for this study by providing an answer to the three sections below.

### 1. Does your research require research personnel to interact with human participants? [ ]  YES\* [ ]  NO

If YES, please provide a 2-3 sentence abstract describing the handling of clinical specimens by Research Personnel. Specimens would include identifiable or de-identified tissues. Please be sure to include specimen types (e.g., blood, urine) as described in section 3.5 of the ProSPECT submission (if different types of specimens are handled differently, please provide the information for each type of specimen separately):

Click or tap here to enter text.

\*Complete all parts of Section B and any other applicable Sections (Sections C-I)

### 2. Does your research require research personnel to work with animals? [ ]  YES\* [ ]  NO

###

If YES, please provide a 2-3 sentence abstract describing the work performed with animals (Please be sure to specify locations on-site and/or off-site): Click or tap here to enter text.

\*Complete Section F and any other applicable Sections (Sections C-I; Section B should be listed as not applicable)

### 3. Does your research require research personnel to work with biological agents and/or pathogens (human or animal) in the research lab? [ ]  YES\* [ ]  NO

###

If YES, please provide a 2-3 sentence abstract describing the type of wet laboratory research performed on-site and/or off-site (Please be sure to specify locations on-site and/or off-site): Click or tap here to enter text.

\* Complete Section C and any other applicable sections (Sections D-H; Section B should be listed as not applicable)

### 4.Does your research require research personnel to work with non-biological (e.g., chemicals, radioactive) materials in the research lab? [ ]  YES\*\* [ ]  NO

###

If YES, please provide a 2-3 sentence abstract describing the type of wet laboratory research performed on-site and/or off-site (Please be sure to specify locations on-site and/or off-site): Click or tap here to enter text.

\*\*Complete Section E, if chemicals will be used for this project and any other applicable sections (Sections F-I)

# SECTION B: CLINICAL STUDIES CHECK HERE IF NOT APPLICABLE [ ]

## The PI must ensure that Standard Precautions are used when handling human specimens. This section should only be completed if the study involves enrollment of Human Participants.

## Human Specimens:

### 1. Will Research Personnel be exposed to or collect Identifiable human blood, bodily fluids, organs, and tissue specimens? [ ]  YES [ ]  NO

 (NOTE: Individuals working with specimens that are identifiable must be listed on the IRB application.)

If yes, list what specimens will be used: Click or tap here to enter text.

### 2. Will Research Personnel be exposed to or collect De-identified specimens? [ ]  YES [ ]  NO

###

If yes, list what specimens will be used: Click or tap here to enter text.

List all Research Personnel below who will be working with the Identifiable or De-identified specimens:

Click or tap here to enter text.

### 3. Provide the location where human (identifiable or de-identified) specimens will be handled/processed:

 Building(s): Click or tap here to enter text.

 Room number(s): Click or tap here to enter text.

1. Describe any transport of the specimens: Click or tap here to enter text.

1. Describe how the specimens will be processed: Click or tap here to enter text.

1. Describe where and how the specimens are analyzed: Click or tap here to enter text.

1. Specify any potential hazards for working with the human specimens: Click or tap here to enter text.

1. Detail the precautions employed to protect Research Personnel. When listing personal protective equipment (PPE) used, please be specific (safety glasses, nitrile gloves, etc.):

Click or tap here to enter text.

# SECTION C: BIOLOGICAL AGENTS CHECK HERE IF NOT APPLICABLE [ ]

## FOR ALL USE OF BIOLOGICAL AGENTS: The PI must ensure that Standard Precautions are routinely used in laboratories. The PI must make certain that all lab personnel are provided with detailed instructions regarding the risks associated with the agents as well as proper handling/waste disposal procedures.

### 1. Human and Non-human primate specimens (PLEASE NOTE: All human or non-human primate blood, bodily fluids, organs, tissues, primary cells, and established cell lines are considered BSL-2 agents and should be handled using Standard Precautions).

1. Will Research personnel work with human or non-human primate blood, bodily fluids, organs, tissues, primary human cells, or established human cell lines? [ ] YES [ ] NO

If yes, specify what is used? Click or tap here to enter text.

 Please provide the location where human or non-human primate specimens will be handled/processed\*\*: Click or tap here to enter text.

 Building(s): Click or tap here to enter text.

 Room number(s): Click or tap here to enter text.

1. Describe the processes used: Click or tap here to enter text.

\*\*NOTE: All locations where BSL-2 agents are used/stored must be identified with appropriate biohazard signage.

1. Specify any potential hazards for working with the human or non-human primate specimens:

 Click or tap here to enter text.

1. Detail the precautions employed to protect lab personnel. When listing personal protective equipment (PPE) used, please be specific (safety glasses, nitrile gloves, etc.):

Click or tap here to enter text.

### 2. Pathogens (bacteria, virus, fungus, parasites, rickettsiae) and microbial toxins (e.g., endotoxin/LPS)

Using the table below, please list all pathogens and/or microbial toxins used in the project. See Attachment B on the Research Safety and Security webpage for assistance in determining the Biosafety Level (BSL).

|  |  |  |
| --- | --- | --- |
| Name of Agent | Biosafety Level | Location of use, handling, storage |
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### 3. Select Agents and Toxins

### Are any of the biological hazards listed classified as Select Agents or toxins by the Centers for Disease Control? \*\* [ ] YES [ ] NO

###

\*\* If Select Agents or toxins are used, a copy of the laboratory’s Standard Operating Procedure (SOP) for handling these materials must be attached.

If yes, please provide the following:

1. CDC Laboratory Registration Number: Click or tap here to enter text.
2. Date of last CDC/USDA Inspection: Click or tap here to enter text.

### 4. BSL-2 or Greater Human or Non-human primate Specimens, Pathogens, Select Agents or Toxins

### For each agent designated BSL-2 or above (in items 1, 2 or 3 above), please answer each of the items (a-h) below:

1. Is the specimen/agent potentially infectious to humans? [ ] YES [ ] NO

If yes, please describe the methods for preventing exposures: Click or tap here to enter text.

1. Is a biological safety (biosafety) cabinet used to handle the specimen/agent(s)? [ ] YES [ ] NO

If yes, please provide the following information:

|  |  |  |
| --- | --- | --- |
| Class of biosafety cabinet | Location | Date of certification  |
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Note: For a description of biosafety cabinets, see Attachment C on the Research Safety and Security webpage.

1. Is a containment centrifuge used? [ ] YES [ ] NO [ ] Not Applicable

If yes, please note the following:

Building(s): Click or tap here to enter text.

Room Number(s): Click or tap here to enter text.

1. Is antibiotic resistance expressed in the specimen/agent? [ ] YES [ ] NO [ ] Not Applicable

If yes, to which antibiotic(s): Click or tap here to enter text.

1. What is the largest volume of the organism that will be used? [ ]  Not Applicable

Liters: Click or tap here to enter text.

Highest concentration: Click or tap here to enter text.

1. Specify methods of specimen/agent concentration: [ ]  Not Applicable

 [ ]  Centrifugation [ ]  Precipitation

 [ ]  Filtration [ ]  Other (please specify): Click or tap here to enter text.

1. Specify method(s) of specimen/agent decontamination:

 [ ]  Heat (autoclave) [ ]  Chemical (please specify): Click or tap here to enter text.

 [ ]  Radiation [ ]  Other (please specify): Click or tap here to enter text.

1. Will the BSL-2 agents (including human and non-human primate specimens) be transported?

[ ] YES [ ] NO

If yes, specify how the samples will be packaged and the method of transport: Click or tap here to enter text.

# SECTION D: RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES

# CHECK HERE IF NOT APPLICABLE [ ]

### 1. Does the research involve any of the following:

1. Use of recombinant DNA (rDNA) molecules for detection purposes (probes, PCR, etc.)?

[ ]  YES [ ]  NO

If Yes, complete items below. If No, Skip to b.

* Are rDNA procedures limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? [ ]  YES [ ]  NO
* Are rDNA procedures limited to commercially purchased oligonucleotides?

[ ]  YES [ ]  NO

1. Use of synthetic nucleic acid molecules that can base pair with naturally occurring nucleic acid molecules (e.g., siRNA)? [ ]  YES [ ]  NO
2. Creation or use of cDNA/genomic/expression libraries? [ ]  YES [ ]  NO
3. Cloning and vector construction in bacteria and/or yeasts? [ ]  YES [ ]  NO
4. Cloning of toxin molecule genes or proteins? [ ]  YES [ ]  NO
5. Use of or cloning of gene from or into a Risk Group 2, 3, 4, or restricted agent? [ ]  YES [ ]  NO
6. Cloning greater than 2/3 of genome of any eukaryotic virus? [ ]  YES [ ]  NO
7. Expression of rDNA products into cultured cells? [ ]  YES [ ]  NO
8. Propagating culture volumes exceeding 10 Liters? [ ]  YES [ ]  NO
9. Use of vectors derived from a eukaryotic virus? [ ]  YES [ ]  NO
10. Transfer of rDNA molecules into humans (i.e., gene transfer protocol)? [ ]  YES [ ]  NO
11. Transfer of rDNA molecules into live (intact) animals or whole plants? [ ]  YES [ ]  NO
12. Transfer of purified peptides or proteins into live (intact) animals or whole plants? [ ]  YES [ ]  NO

### 2. Please answer the following questions for each specific rDNA or peptide: (attach separate pages if necessary). Refer to the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules for additional assistance.

1. NIH classification and brief description for rDNA studies: Click or tap here to enter text.

1. Biological source of DNA insert, gene, or peptide: Click or tap here to enter text.

1. Function of insert, gene or peptide: Click or tap here to enter text.

1. Vector(s) used for cloning (e.g., pUC18, pCR3.1): Click or tap here to enter text.

1. Host cells and/or virus used for cloning (e.g., bacterial, yeast or viral strain, cell line): Click or tap here to enter text.

1. Identify appropriate biosafety level (see Attachment B on Research Safety and Security webpage):

Click or tap here to enter text.

### 3. Does the project involve the use of replication-defective viruses? [ ]  YES [ ]  NO

If yes, provide the upper limit (in pfu) of the replication-competent virus in the viral stocks and the methodology used to determine this number: Click or tap here to enter text.

### 4. Does the project involve replication-competent or wild-type viruses? [ ]  YES [ ]  NO

If yes, please provide details: Click or tap here to enter text.

# SECTION E: CHEMICALS CHECK HERE IF NOT APPLICABLE [ ]

## Investigators using chemicals must complete and attach a chemical matrix, containing all chemicals, radioactive materials, and controlled substances used in this study. The matrix can be accessed on the VAPHS Research Safety and Security webpage.

### 1. Has the use of chemicals been reviewed by the Institutional Biosafety Committee in the past 12 months through submission of a chemical inventory? [ ]  YES [ ]  \*\*NO

\*\*If the answer is No, then you must provide a complete chemical inventory to the Biosafety Officer for review before the project can be approved.

### 2. Have all lab personnel been trained regarding any special hazards posed by chemicals used in the laboratory? [ ]  YES [ ]  NO

### 3. Does the research involve any of the following:

1. Toxic chemicals (including heavy metals) [ ]  YES [ ]  NO
2. Flammable/explosive/corrosive materials [ ]  YES [ ]  NO
3. Carcinogenic/mutagenic/teratogenic chemicals [ ]  YES [ ]  NO
4. Toxic compressed gases (includes chlorine gas, phosgene, ammonia; does NOT include carbon dioxide) [ ]  YES [ ]  NO
5. Acetylcholinesterase inhibitors/neurotoxins [ ]  YES [ ]  NO

Reminder: Safety Data Sheets (SDSs) may be obtained utilizing the VHA Center for Engineering and Occupational Safety and Health (CEOSH).

**Investigators Certification (This is to be signed ONLY if Section E is applicable):**

By signing below, I certify that 1) a chemical matrix containing all chemicals, radioactive materials, and controlled substances used in this protocol is visibly posted in the laboratory and 2) a complete laboratory chemical inventory and associated SDSs are maintained in my lab and these materials are readily available to lab personnel and Safety/Biosafety Committee personnel as required.


# SECTION F: ANIMALS CHECK HERE IF NOT APPLICABLE [ ]

## Investigators working with animals must also complete PART IV ACORP and it must be approved by the Institutional Animal Care and Use Committee (IACUC) before work can begin.

Provide information on all species and strains, if applicable.

|  |  |
| --- | --- |
|  Species | Strain, if applicable |
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### 1. Will animals be experimentally or naturally exposed to any biological agents? [ ]  YES [ ]  NO

If yes, list all biological agents: Click or tap here to enter text.

### 2. Will animals be experimentally exposed to any hazardous chemical agents? Examples of hazardous chemicals that are used in animals include tamoxifen, streptozotocin, etc. [ ]  YES [ ]  NO

If yes, list all chemical agents. (Ensure all chemical agents are listed on the Appendix 3 and Chemical Matrix)

 Click or tap here to enter text.

### 3. Will these substances (biological and/or chemical) represent a potential hazard for lab personnel? [ ]  YES [ ]  NO

If yes, specify the hazards and detail the precautions used to protect lab personnel. Be specific when listing PPE (safety glasses, gloves, etc.): Click or tap here to enter text.

### 4. Will lab personnel work with animals, animal blood, bodily fluids, organs, tissues, or cell lines, even if not listed on an ACORP? [ ]  YES [ ]  NO

###

If yes, specify location(s): [ ]  VAPHS Animal Research Facility

 [ ]  University of Pittsburgh Division of Laboratory Animal Resources

[ ]  Investigator’s laboratory at the VA

[ ]  Other (e.g., Investigator’s laboratory at Pitt)

### 5. Will lab personnel work with Anesthetic Gases? [ ]  YES [ ]  NO

If yes, specify location(s): [ ]  VAPHS Animal Research Facility

 [ ]  University of Pittsburgh Division of Laboratory Animal Resources

[ ]  Investigator’s laboratory at the VA

[ ]  Other (e.g., Investigator’s laboratory at Pitt)

If items 4 or 5 are answered yes, please complete the table below. Enrollment is verified before the project can be approved. Contact the Research Office at 412-360-2382 for any questions.

|  |  |  |
| --- | --- | --- |
| Name | Working with Unfixed Animal Tissues? | Working with Anesthetic Gas? |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |
|  | [ ]  YES [ ]  NO | [ ]  YES [ ]  NO |

# SECTION G: CONTROLLED SUBSTANCES CHECK HERE IF NOT APPLICABLE [ ]

## Controlled substances used for animal surgeries must be included. See Attachment D on the Research Safety and Security webpage for a list of controlled substances.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Controlled Substance | Location of Storage (Bldg and Room #) | Method of Storage (double-locked box) | Safety Precautions (appropriate PPE, use in fume hood, etc) | Disposal |
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# SECTION H: RADIATION CHECK HERE IF NOT APPLICABLE [ ]

## The purpose of this section is to identify potential radiation hazards to Research Personnel.

Radiation use for human clinical studies: If Research Personnel will conduct studies that involve ionizing radiation exposure to human study participants (e.g., nuclear medicine scans, CT, DEXA, fluoroscopic imaging), then this work must be reviewed and approved by the VAPHS Institutional Biosafety Committee (IBC). If all studies that involve ionizing radiation exposure are performed by clinical personnel, then IBC review and approval is not required.

Radiation use for non-human animal or lab procedures: If radioactive materials are used or if radiation generating equipment is used, then this work must be reviewed and approved by the VAPHS IBC. In addition, “PART V: Request for Use of Radioactive Materials/Radiation Generating Equipment in Research” must be completed and approved by the Radiation Safety Committee before work can begin. Contact the Radiation Safety Officer (412-360-3221) with any questions.

##  Ionizing Radiation

### 1. Will this project involve Research Personnel using radioactive materials? [ ]  YES [ ]  NO

If Yes, complete the 2 tables below.

|  |  |  |  |
| --- | --- | --- | --- |
| Radionuclide | Max Amount in Lab | Use in Animals  | Location |
|  |  | [ ]  YES [ ]  NO |  |
|  |  | [ ]  YES [ ]  NO |  |
|  |  | [ ]  YES [ ]  NO |  |

Please list all authorized Research Personnel that will be working with radioactive materials:

Click or tap here to enter text.

### 2. Will this project involve Research Personnel using radiation generating equipment? [ ]  YES [ ]  NO

If yes, complete the 2 tables below:

|  |  |
| --- | --- |
| Name of equipment |  Location of Use (Bldg and Room #) |
|  |  |
|  |  |
|  |  |

Please list all authorized Research Personnel working with radiation generating equipment: Click or tap here to enter text.

### 3. For lab or animal research radioactive material or radiation generating equipment exposure, please provide Radiation Safety Committee approval date of the PI’s PART V Form: Click or tap to enter a date.

## Non-ionizing Radiation

### 1. Will this project include the use of the following?

1. Ultraviolet light (UV crosslinker, transilluminator, germicidal lights) [ ]  YES [ ]  NO
2. Lasers (Class 3B or 4) [ ]  YES [ ]  NO
3. Radiofrequency or microwave sources [ ]  YES [ ]  NO

# SECTION I: PHYSICAL HAZARDS CHECK HERE IF NOT APPLICABLE [ ]

1. Does this protocol involve additional/unusual physical hazards such as electricity/trauma, noise, or extreme cold or heat? [ ]  YES [ ]  NO

If yes, please explain: Click or tap here to enter text.

2. If you are using extreme cold or heat, does the research involve any of the following: [ ]  Not Applicable

1. Use of liquid nitrogen [ ]  YES [ ]  NO
2. Use of -80 freezer [ ]  YES [ ]  NO
3. Use of dry ice [ ]  YES [ ]  NO
4. Use of heated materials including use of Bunsen burner, touch-plate burner, or items that are heated in a microwave. [ ]  YES [ ]  NO
5. Additional extreme cold or heat hazard not yet listed. Please explain: [ ]  YES [ ]  NO

3. Have all lab personnel been trained on the proper PPE to wear when exposed to the additional hazards present in the laboratory? [ ]  YES [ ]  NO

 Please list specific PPE worn: Click or tap here to enter text.

# Investigator Acknowledgement of Responsibility

With regard to any of the potential hazards identified in this form, specific training will be provided to laboratory staff. This will include:

(1) Required participation in safety training: I certify that staff will complete all applicable safety training including but not limited to:

• Research Laboratory Safety Training (web-based)

• Fire Safety (web-based)

• Radiation Safety Training (web-based)

• Bloodborne Pathogens Training (web-based)

(2) Practices and techniques required to ensure safety: I certify that I have prepared Standard Operating Procedures (SOPs) and these SOPs are available in the laboratory, and personnel are knowledgeable of and will adhere to these SOPs. Safety Data Sheets (SDSs) are available for all chemicals used in this project. The current version of the Laboratory and Clinical Research Safety/Biosafety Manual and Chemical Hygiene Plan is also present in the laboratory providing additional safety information, precautions, and procedures to be followed when using hazardous chemicals, radioisotopes, biohazards and physical hazards. This information is an integral and important component of mandatory training and orientation. The manual will be reviewed by employees on an annual basis.

Furthermore, I certify that no research procedures will be initiated until I have received written notification from the Associate Chief of Staff for Research and Development (ACOS/R&D) that this project has been reviewed and approved by the Institutional Biosafety Committee (IBC), as well as all other appropriate subcommittees of the R&D, other appropriate VA Committees, and the Research & Development Committee.

I further 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 used in this proposal is included in this survey.



For Office Use Only

The Research Office will secure the following signatures on your behalf.

Certification of IBC 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, IBC:

Radiation Safety Officer (If applicable):

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.

Industrial Hygienist/

Facility Safety Officer

(if applicable)

Chair, R&D Committee: