Principal Investigator/Program Director:

Project Title:

Submission Date:

Does this research project involve the use of any of the following? See Attachment A on the Research Safety and Security webpage for additional information.

|  |  |
| --- | --- |
| 1. **Human specimens collected from participants in VA Clinical Studies:** (blood, urine, tissue, etc.) | **YES NO** |
| 1. **Biological Agents for Non-clinical and/or Animal Studies**     * + 1. Human and Non-human primate specimens (primary cells, tissues, blood, bodily fluids, established cell lines)        2. Pathogens (bacteria, virus, fungus, parasites, rickettsiae) and microbial toxins (e.g., endotoxin/LPS)        3. Select Agents and toxins (as defined in 42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331) | **YES NO** |
| 1. **Recombinant or Synthetic Nucleic Acid Molecules** **(vectors, probes, PCR, siRNA, etc.)** | **YES NO** |
| 1. **Chemicals:** 2. Toxic chemicals 3. Flammable, explosive, or corrosive chemicals 4. Carcinogenic, mutagenic, or teratogenic chemicals 5. Toxic compressed gases 6. Acetylcholinesterase inhibitors or neurotoxins | **YES NO** |
| 1. **Animals (animal blood, bodily fluids, organs, tissues, cell lines)** | **YES NO** |
| 1. **Controlled Substances** | **YES NO** |
| 1. **Radiation:**    * + 1. Ionizing        2. Non-ionizing 2. Ultraviolet light 3. Lasers (Class 3b or 4) 4. Radiofrequency or microwave sources | **YES NO** |
| 1. **Physical Agents:**    * + 1. Electricity or trauma        2. Noise        3. Extreme Cold/Heat (-80 freezer, liquid nitrogen, Bunsen burners, etc.) | **YES NO** |
| **\*Complete entire form by answering all questions in each section or mark the section as Not Applicable.** | |

**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):

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

1. **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):

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

1. **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):

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

**If NO**, please describe the laboratory research and whether it requires research personnel to work with non-biological (eg. chemicals, radiation) materials in the research lab.

**\*\*Complete Section C, if chemicals will be used for this project and any other applicable sections (Sections D-H; Sections A and B should be listed as not applicable)**

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| **SECTION A: 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)***

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| **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:     1. Will Research Personnel be exposed to or collect **De-identified** specimens?   **YES  NO**  If yes, list what specimens will be used:    \*List all Research Personnel below who will be working with the Identifiable or De-identified specimens:    3. Provide the location where human (identifiable or de-identified) specimens will be handled/processed:  Building(s):  Room number(s):  4. Describe any transport of the specimens:  5. Describe how the specimens will be processed:  6. Describe where and how the specimens are analyzed:  7. Specify any potential hazards for working with the human specimens:  8. Detail the precautions employed to protect Research Personnel. When listing personal protective equipment (PPE) used, please be specific (safety glasses, nitrile gloves, etc.): |

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| **SECTION B: 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).**  |  |  |  | | --- | --- | --- | | a. Will Research personnel work with human or non-human primate blood, bodily fluids, organs, tissues, primary human cells, or established human cell lines?  If yes, specify what is used? | **YES NO** | | | b. Please provide the location where human or non-human primate specimens will be handled/processed\*\*:  Building(s):  Room number(s):   1. Describe the processes used:   **\*\*NOTE: All locations where BSL-2 agents are used/stored must be identified with appropriate biohazard signage.** | |  | | d. Specify any potential hazards for working with the human or non-human primate specimens: | |  | | e. Detail the precautions employed to protect lab personnel. When listing personal protective equipment (PPE) used, please be specific (safety glasses, nitrile gloves, etc.): | |  | |  |  | |  1. **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** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  |  1. **Select Agents and Toxins**  |  |  | | --- | --- | | Are any of the biological hazards listed classified as Select Agents or toxins by the Centers for Disease Control?\*\*  If yes, please provide the following:   1. CDC Laboratory Registration Number: 2. Date of last CDC/USDA Inspection:   \*\* If Select Agents or toxins are used, a copy of the laboratory’s Standard Operating Procedure (SOP) for handling these materials must be attached. | **YES NO** |  1. **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?   If yes, please describe the methods for preventing exposures: | **YES NO** | | 1. Is a biological safety (biosafety) cabinet used to handle the specimen/agent(s)?   If yes, please provide the following information : | **YES NO** |  |  |  |  | | --- | --- | --- | | **Class of biosafety cabinet** | **Location** | **Date of last certification** | |  |  |  | |  |  |  | |  |  |  | |  |  |  |   Note: For a description of biosafety cabinets, see Attachment C on the Research Safety and Security webpage.   |  |  |  | | --- | --- | --- | | c. Is a containment centrifuge used?  If yes, please note the following:  Building(s):  Room Number(s): | **YES NO**  **Not Applicable** | | | d. Is antibiotic resistance expressed in the specimen/agent?  If yes, to which antibiotic(s): | **YES NO**  **Not Applicable** | | | e. What is the largest volume of the organism that will be used?  Liters:  Highest concentration: | **Not Applicable** | | | f. Specify methods of specimen/agent concentration: **☐ Not Applicable**        Centrifugation       Precipitation        Filtration       Other (please specify): | |  | | g. Specify method(s) of specimen/agent decontamination:        Heat (autoclave)       Chemical (please specify):        Radiation       Other (please specify):   |  |  | | --- | --- | | h. Will the BSL-2 agents (including human and non-human primate specimens) be transported?  If yes, specify how the samples will be packaged and the method of transport: | **YES NO** | | |  | |

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| **SECTION C: 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 i. and ii, If No, Skip to b. | | 1. Are rDNA procedures limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? | **YES  NO** | | 1. 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** | | 1. Creation or use of cDNA/genomic/expression libraries? | **YES  NO** | | 1. Cloning and vector construction in bacteria and/or yeasts? | **YES  NO** | | 1. Cloning of toxin molecule genes or proteins? | **YES  NO** | | 1. Use of or cloning of gene from or into a Risk Group 2, 3, 4, or restricted agent? | **YES  NO** | | 1. Cloning greater than 2/3 of genome of any eukaryotic virus? | **YES  NO** | | 1. Expression of rDNA products into cultured cells? | **YES  NO** | | 1. Propagating culture volumes exceeding 10 Liters? | **YES  NO** | | 1. Use of vectors derived from a eukaryotic virus? | **YES  NO** | | 1. Transfer of rDNA molecules into humans (i.e., gene transfer protocol)? | **YES  NO** | | 1. Transfer of rDNA molecules into live (intact) animals or whole plants? | **YES  NO** | | 1. Transfer of purified peptides or proteins into live (intact) animals or whole plants? | **YES  NO** |  1. 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. 2. NIH classification and brief description for rDNA studies: 3. Biological source of DNA insert, gene, or peptide: 4. Function of insert, gene or peptide: 5. Vector(s) used for cloning (e.g., pUC18, pCR3.1): 6. Host cells and/or virus used for cloning (e.g., bacterial, yeast or viral strain, cell line): 7. Identify appropriate biosafety level (see Attachment B on Research Safety and Security webpage):  |  |  | | --- | --- | | 1. Does the project involve the use of replication-defective viruses?   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: | **YES  NO** | | 1. Does the project involve replication-competent or wild-type viruses?   If yes, please provide details: | **YES  NO** | |

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| **SECTION D: CHEMICALS CHECK HERE IF NOT APPLICABLE** |
| Investigators using chemicals must complete and attach a chemical matrix, containing all chemicals, radiochemicals, and controlled substances used in this study. The matrix can be accessed on the [VAPHS Research Safety and Security webpage](http://www.pittsburgh.va.gov/Research/Research_Safety_and_Security.asp).   |  |  | | --- | --- | | 1. Has the use of chemicals been reviewed by the Institutional Biosafety Committee in the past 12 months through submission of a chemical inventory?   \*\*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. | **YES**  **\*\*NO** | | 1. Have all lab personnel been trained regarding any special hazards posed by chemicals used in the laboratory? | **YES  NO** | | 1. Does the research involve any of the following: 2. Toxic chemicals (including heavy metals) 3. Flammable/explosive/corrosive materials 4. Carcinogenic/mutagenic/teratogenic chemicals 5. Toxic compressed gases (includes chlorine gas, phosgene, ammonia; does **NOT** include carbon dioxide) 6. Acetylcholinesterase inhibitors/neurotoxins | **YES  NO**  **YES  NO**  **YES  NO**  **YES  NO**  **YES  NO** |   Reminder: Safety Data Sheets (SDSs) may be obtained utilizing the [VHA Center for Engineering and Occupational Safety and Health (CEOSH)](http://vaww.ceosh.med.va.gov/ceosh/MSDS.shtml).  **Investigators Certification (This is to be signed ONLY if Section C is applicable):**  By signing below, I certify that 1) a chemical matrix containing all chemicals, radiochemicals, 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.    Principal Investigator (signature) Date |

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| **SECTION E: 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** | |  |  | |  |  | |  |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | | 1. Will animals be experimentally or naturally exposed to any biological agents?   List all biological agents: | **YES  NO**  If yes, list all biological agents. | | | | 1. Will animals be experimentally exposed to any hazardous chemical agents? Examples of hazardous chemicals that are used in animals include tamoxifen, streptozotocin, etc.   List all chemical agents: | **YES  NO**  If yes, list all chemical agents. \*Ensure all chemical agents are listed on the Appendix 3 and Chemical Matrix. | | | | 1. Will these substances (biological and/or chemical) represent a potential hazard for lab personnel? If yes, specify the hazards and detail the precautions used to protect lab personnel. Be specific when listing PPE (safety glasses, gloves, etc.): | **YES  NO** | | | | 1. 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) | |  | | | 1. 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[[1]](#footnote-1). 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** | |

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| **SECTION F: 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** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |
| **SECTION G: RADIATION CHECK HERE IF NOT APPLICABLE** |
| If radioactive materials are used (in animal or lab procedures) or if radiation generating equipment is used, “PART V: Request for Use of Radioactive Materials in Research” must also be completed and approved before work can begin. Contact the Radiation Safety Officer (412-360-3221) for assistance.  **IONIZING RADIATION**   |  |  |  | | --- | --- | --- | | 1. Will this project use radioactive materials? | **YES  NO**  If Yes, complete the table below. | | | |  |  |  |  | | --- | --- | --- | --- | | **Radionuclide** | **Max Amount in Lab** | **Use in Animals** | **Location** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | |  | | 1. List all authorized personnel that will work with radioactive materials:  |  | | --- | | **Name** | |  | |  | |  | |  | | |  | | 1. Provide the date of Radiation Safety Committee Approval for radioactive materials use: |  | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | 1. Will this project use radiation generating equipment? | **YES  NO**  If yes, complete the table below: | | | |  |  | | --- | --- | | **Name of equipment** | **Location of Use (Bldg and Room #)** | |  |  | |  |  | |  |  | |  |  | | |  | |  |  | | | 1. Provide the date of Radiation Safety Committee approval for radiation generating equipment use: |  | | |  |  | | |  |  | |   Studies involving human research participant exposure to non-standard of care ionizing radiation will require approval by the VAPHS Radiation Safety Committee (RSC). Contact Mitch Belanger ([Mitchell.Belanger@va.gov](mailto:Mitchell.Belanger@va.gov)) for additional information regarding review and approval procedures.  **NON-IONIZING RADIATION**   |  |  | | --- | --- | | 1. Will this project include the use of the following? 2. Ultraviolet light (UV crosslinker, transilluminator, germicidal lights) 3. Lasers (Class 3B or 4) 4. Radiofrequency or microwave sources | **YES  NO**  **YES  NO**  **YES  NO** | |
| **SECTION H: 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?   If yes, please explain: | | **YES  NO** | | 1. If you are using extreme cold or heat, does the research involve any of the following: 2. Use of liquid nitrogen 3. Use of -80 freezer 4. Use of dry ice 5. Use of heated materials including use of Bunsen burner, touch-plate burner, or items that are heated in a microwave. 6. Additional extreme cold or heat hazard not yet listed. Please explain: | **Not Applicable**  **YES  NO**  **YES  NO**  **YES  NO**  **YES  NO**  **YES  NO** | | | 1. Have all lab personnel been trained on the proper PPE to wear when exposed to the additional hazards present in the laboratory? Please list specific PPE worn: | **YES  NO** | | |

**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 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.

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| Principal Investigator | Date |

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| --- | --- | --- | --- | --- |
| ***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 |  |  | | |
|  | Paula Clemens, M.D. | |  | Date |
| Radiation Safety Officer:  *(if applicable)* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |  |
|  | Mitch Belanger | |  | Date |
| 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)* | Christian Lewis | |  | Date |
|  |  | |  |  |
| Chair, R&D Committee: | | | | |
|  | Gretchen Haas, Ph.D. | |  | Date |
|  |  | |  |  |

1. Personnel working with unfixed animal tissues and/or anesthetic gases must enroll in an Animal Exposure Program (the AEPMP at the VAPHS, the AESP at the University of Pittsburgh, or other approved comparable program). [↑](#footnote-ref-1)