**Institutional Biosafety Committee (IBC)**

**University of Vermont**

**Research Protections Office**

**213 Waterman Bldg., 85 South Prospect Street**

**Burlington, VT 05405**

**Protocol Form**

|  |
| --- |
| PROTOCOL NUMBER: |
|  |
| **\*\*TYPE ONLY. Answer all questions. For not-applicable questions type N/A or check NO.** |
| **Section 1: General Information** |
|  |
| **1.1** Principal Investigator |  | Department |  |
|  |
|  Faculty Sponsor (if applicable) |  |
|  Project Title |  |
| Is this project equivalent to a project that has previously been approved by the IBC? |  | Yes |  | No |
| If you believe that this new project is equivalent, list the previous IBC protocol number here  |  |
| If yes, please explain any differences that would require changes in biosafety practices. If none, state so. |
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| **1.2** Funding Source |  | InfoEd # |  |
|  | Project Start Date |  | Project End Date: |  |
|  |
| **1.3** Contact Person for IBC correspondence and inquires  |
|  | Name |  | Email |  |
|  |
| **1.4** | Location(s) of laboratory, clinic or treatment area, core facility, or greenhouse where project will be conducted: | Building: |  | Room#(s): |  |
| Building: |  | Room#(s): |  |
| Building: |  | Room#(s): |  |
|  |  |  |
| **1.5** | Other Approvals:Indicate other committees required to approve this project |  | Committee |  Date Submitted: |  | Committee Assigned Number |
|  | RAC |  |  |  |
|  | IACUC |  |  |  |
|  | IRB |  |  |  |
|  | Other  |  | List other: |  |
|  |  |  |
| **1.6a** | Research Material:(check all that apply) |  | Animals (live animals only) |  | Humans Subjects |
|  | Biotoxins Recombinant nucleic acid moleculesSynthetic nucleic acid molecules\*Human Derived Materials *(primary tissue or cell lines, established cell line, blood)* Other Describe below |  | Infectious Agent *(e.g. bacteria, fungi, parasites, virus)* Viral Vector *(e.g. retrovirus, lentivirus, adenovirus)*Plants |
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|   |
| \*Only check when used in combination with other hazardous materials. Cell use alone does not require review. |
| **1.6b**  | \*DURC Select Agents or Toxins(check all that apply)  |  | Avian Influenza Virus (highly pathogenic) |  | Marburg virus |
|  | Bacillus anthracis |  | Reconstructed 1918 Influenza virus |
|  | Botulinum neurotoxin |  | Rinderpest Virus |
|  | Burkholderia malleiBurkholderia pseudomallei |  | Toxin producing strains of Clostridium botulinum |
|  |
|  | Ebola Virus |  | Variola major virus |
|  | Foot-and-mouth disease virus |  | Variola minor virus |
|  | Francisella tularensis |  | Yersinia pestis |

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| \*If any select agents or toxins are selected in 1.6b, please continue with this current form and then complete the corresponding Appendix at the end. |

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| **1.7** | Lay Abstract: Provide a brief non-technical abstract of the project including safety procedures:(please do not exceed one single-spaced 8 ½x 11” page) |  |
|  |  |  |
|  **1. 8** | Fully describe how recombinant DNA and or infectious agents will be used. Do not reference an attached grant as this document must stand alone. |  |
|  |  |  |
|  **1.9** | Are written standard operating procedures in place?  |  | For work **with** infectious agents or viral vector systems such as lentivirus or adenovirus or biotoxins attach a formal SOP. |
|  |
|  | BSL1 or work with human derived materials, describe below.  |
|  | Risks to personnel |
|  |  |
|  | Safety Practices |
|  |  |
|  | Emergency Plan |
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| **Section 2: Infectious Agents**  |
|  |  |  |  |
| **2.1** | Are infectious agents used in this study? |  | Yes |
|  | No If no, proceed to **Section 3**. |
|  |
| **2.2** Infectious Agent(s) *NOTE: Each infectious agent requires its own Standard Operating Procedure. Our forms page has multiple template versions of the most common of the infectious agents. Please indicate under “Source” below if a commercial system versus an investigator-developed noncommercial system.* |
| Name/Strain\* | SelectAgent*Y/N* | Indicate Specific Source | Is the organism or viral vector used attenuated or inactivated? *Y/N* If yes, describe below. | Risk Group[NIH Guide](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf) | Biosafety Level[BMBL Guide](http://www.cdc.gov/biosafety/publications/bmbl5/) | Route of Potential Exposure |
|  |  |  |  |  |  |  |
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| *\*If the only infectious agent is human blood, body fluids, or fresh tissue or other potentially infectious materials be sure to also complete section 7.*  |
| **2.2.a** If a select agent is being used, provide the quantity and whether a USDA or CDC permit is required below. *(Attach verifying documents)* |
|  |
| **2.2b** If applicable, describe the attenuation or inactivation of the organism or viral vector. |
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| **Section 3: Biotoxins** |
|  |
| **3.1** | Are biological toxins used in this study? |   | Yes |
|  | No If no, proceed to **Section 4**. |
|  |
| **3.2** |
| a. List Toxin | b. Total Quantity/ Concentration | c. Where was toxin obtained? | d. How much is used per experiment? |
|  |  |  |  |
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| **Section 4: Recombinant DNA Molecules (NIH Guidelines for Research Involving Recombinant DNA)** |
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|  **4.1** | Are recombinant DNA Molecules used in this project?  |  | Yes  |
|  | No If no, proceed to **Section 5.** |

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|  |  |  |  |
| **4.2** | a. Host Cells  |  | Bacteria | Name & Strain |  |
|  |  | Fungi | Name & Strain |  |
|  |  | Established human cell line | Designation |  |
|  |  | Primary human cells | Source & Type |  |
|  |  | Established animal cell line | Designation |  |
|  |  | Primary animal cells | Source & Type |  |
|  |  | Animals | Describe |  |
|  |  | Plants | Describe |  |
|  |  |  |  |  |
| b. Vectors |  | Bacterial Plasmid | Plasmid Name |  |
|  |  | Baculovirus | Name & Strain |  |
|  |  | Adenovirus | Name & Strain |  |
|  |  | Lentivirus | Name & Strain |  |
|  |  | Other Retrovirus | Name & Strain |  |
|  |  |  | Other Vector | Explain |  |
|  |  |  |  |
|  | c. Is a helper virus used? |  | Yes Strain: |  |
|  |  | No |
|  |  If yes, evidence helper virus removal by purification |  |
|  |  |  |  |
|  | d. Is the viral vector used replication-incompetent? |  | Yes *(provide documented evidence in SOP)* |
|  | No |
|  | e. Are whole organisms to be exposed to the recombinant? |  | Yes |
|  |  |  | No |
|  |  If yes, list |  |
|  |  |  |  |
| **4.3** | Identify the Biosafety Level (BSL) recommended for working with these materials (established in the “NIH Guidelines for Research Involving  |  | BSL-1 |  | BSL-3 |
|  | BSL-2 |  | BSL-4 |
|  | Recombinant DNA Molecules” <http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf#page=72&zoom=auto,55,427> |
|  |  |  |  |  |  |
|  **4.4** | a. Source(s) of recombinant materials:(check all that apply) |  | Commercial |  | Plant |
|  | Animal tissue |  | Virus |
|  | Bacteria |  | Other: list |
|  |  |  | Human tissue |  |
|  | b. List genes to be expressed | Is this gene known to be oncogenic? Yes or No |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  **4.5** | Does the insert represent more than 2/3 of the viral genome? |  | Yes |
|  | No |
|  |  |  |  |
|  **4.6** | Will the foreign gene be expressed in the cloning vehicle? |  | Yes  |
|  | No |
|  | If yes, name proteins expressed |  |
|  |  |  |  |
|  **4.7** | Are maximum working quantities of cultures: |  | Less than 10L?  |  | Greater than 10L? |
|  |  |  |  |

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| **Section 5: Plant Use** |
|  |  |
| **5.1** | Will plants be used in this research? |  | Yes |
|  | No If no, proceed to **Section 6.** |
|  |  |  |
| **5.2** | Will transgenic plants be used or created for this work? |  | Yes |
|  |  |  | No |
|  |  |  |
| **5.3** | Explain procedure for disposal of plants and related materials |  |
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| **Section 6: Use of Live Animals** |
|  |  |  |  |
| **6.1** | Will live animals be used in this research? |  | Yes |
|  | No If no, proceed to **Section 7.** |
| If yes, list: |  |
|  |  |  |  |
| **6.2** | List IACUC Protocol number, if available: |  |
|  |  |  |  |
| **6.3** | Where will animals be housed? | Building |  |
|  |  | Room # |  |
|  |  |  |  |
| **6.4** | Will live animals be used or accessed outside of filter top cages and outside of the Biosafety Cabinet (i.e. upon a countertop)? |  | Yes |
|  | No |
| If yes, explain here: |  | N/A |
|  |
| **6.5** | Are there needs to remove live animals from the housing biocontainment area? |  | Yes  |
|  | No |
|  |  | N/A |
|  | If yes, how long and rationale: |  |
|  |  |  |  |  |  |
| **6.7** | What properties of this site and accompanying safety practices allow biohazard research to be conducted at the appropriate level? Reference: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> |  | BSL-1 |  | BSL-2 |
|  | BSL-3 |  | BSL-4 |
|  |  |  |  |
| **6.8** | Method of decontamination of equipment (e.g., cages) being used in and to be removed from the biocontainment area? | Equipment |  |
|  |  |
| Method |  |
|  |  |  |  |
| **6.9** | Explain procedures for disposal of contaminated animals. |  |
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| **Section 7: Human Derived Materials** \*Only complete when used in combination with other hazardous materials. Cell use alone does not require review. |
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|  **7.1** | Does this study involve the analysis of, or experimentation, with sera, blood products, cell lines or primary tissue? |  | Yes |
|  | No, If no proceed to **Section 8**. |
|  |  |
|  **7.2** | Where are you obtaining the materials from? |
|  |  | Collaborators |  | Purchasing |  | Human Subjects |
|  |  |
|  **7.3** | If obtaining from human subjects, what specimens will be collected? (note: you must obtain prior IRB approval of the collection of these specimens for research purposes) |
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| **Section 8: Human Subjects** |
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|  **8.1** Will human subjects be included in this research? |  | Yes |
|  | No, If no proceed to **Section 9**. |
|  **8.2** | Indicate the type of study:  |
|  | a. Introduction of Recombinant DNA (plasmids) or gene transfer vectors (including virus vectors) into humans |
|  |
|  | b. Introduction of genetically engineered mirco-organisms into humans |
|  | c. Infectious agents or toxins, deliberately introduced into humans (including live vaccines if they are experimental in nature and/or not FDA-approved for use in the specific study population) |
|  |
|  | d. Introduction of live human cells (e.g. stem cells) |
|  |
|  **8.3** | Describe the study agent and biosafety level recommended by the sponsor or federal government. |
|  |  |
|  **8.4** | Does this study agent contain small informational polymers based on DNA, RNA (including antisense, RNAi/siRNA), or mimetics of DNA or RNA (PNA, LNA, etc.)? |
|  |  |
|  **8.5** | Do you expect these molecules to functionally suppress expression of the cognate gene? (if yes, describe which genes will be regulated and the expected outcome) |
|  |  |
|  **8.6** | Who is the study pharmacy contact? |
|  |  |
|  **8.7**  | Administration of the agent.  |
|  | a. How will the study agent be administered?  |
|  |  |
|  | b. Describe the route of exposure. |
|  |  |
|  | c. Who is the contact person for the administration of the agent? |
|  |  |
|  | d. Where will the administration take place? |
|  |  |
|  | e. Where will the agent be prepared? |
|  |  |
|  **8.8** Attach one copy of the following documents for protocol review: |
|  | Clinical Trial Protocol |  | FDA Determination (as applicable) |
|  | Informed Consent (draft) |  | Standard Operating Procedures for Constitution and Handling |
|  | Human Subjects Common Cover Form |  | For gene therapy protocols also include the following:  |
|  | Investigational Drug Brochure |  | Responses to NIH Guidelines Appendices M-II through M-V |

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| **Section 9: Personal Protective Equipment, Containment, Other Equipment, and Emergency Response**  |
|  |  |  |  |
| **9.1** | Personal Protective Equipment (PPE) (check all that apply) | When is this required? |
|  | a) Eye protection: |  | Goggles |  |
|  |  | Face Shield |  |
|  |  | Safety Glasses |  |
|  |  |  |
| b) Respiratory protection |  | Disposable particulate (N-95) |  |
|  |  | Cartridge Respirator (Half or Full face)  |  |
|  |  | Powered Air Purifying Respirator (PAPR) |  |
|  |  |  |
| c) Body protection |  | Lab coat - non-disposable |  |
|  | Lab coat - disposable |  |
|  |  |  |
| d) Hand protection: |  | Nitrile Gloves |  |
|  | Other: list |  |
|  |  |  |
| e) Foot protection  |  | Shoe covers |  |
|  |  |  |
| f) Other PPE |  | Specify below: |
|  |
|  |  |  |  |
| **9.2** | Biological Safety Cabinets (BSC)Identify all BSC used for this work  | Class of BSC | Location | Date of Certification |
|  |  |  |
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|  |  |  |
|  |  |  |  |
| **9.3** | How is biological waste managed | Equipment/Method | Building/Location |  | Room # |
|  | Autoclave |  |  |  |
|  | Boxed waste system |  |  |  |
|  | Chemical Disinfection | List: |  |
|  |  |  |
| **9.4** | Other Information:Additional information or comments pertinent to the Institutional Biosafety Committee review of this Proposal |  |
|  |  |  |
| **Section 10: Personnel Roster and Training** |

Include names of all individuals involved with biohazards at time of initial submission. Additionally, if you would like to appoint a primary contact person to receive all protocol correspondence for this protocol, please indicate that person’s name below.**PLEASE DO NOT INCLUDE INDIVIDUALS WHO HAVE NOT COMPLETED THE REQUIRED TRAINING.** All key personnel are required to complete the appropriate online training modules and, if applicable, in-class training. Please visit the [CITI resource](http://www.uvm.edu/rpo/?Page=citi.html) page for more information

|  |  |  |  |
| --- | --- | --- | --- |
| Name | UVM NetID | Role | Years of Experience |
| PI: |  |  |  |
| Contact: |  |  |  |
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\*NOTE: All training records will be reviewed when labs are inspected.

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| **PRINCIPAL INVESTIGATOR ASSURANCE** |
|  |  |  |  |
| **1.** | I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities recommended for the Biosafety level (indicated by CDC/NIH) applicable to this project. I agree all faculty, staff, and students working on this project will follow these recommendations as a condition of the Institutional Biosafety Committee approval of this project. |
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| **2.** | I agree to comply with the requirements specified by the NIH Guide for Grants and Contracts Pertaining to Shipment and Transfer of Recombinant DNA Materials, including requirements specified by the IATA Guide for Shipment of Infectious Substances and/or Diagnostic Specimens. |
|
|
| **3.** | I agree to accept responsibility for training and safety of all the laboratory workers involved in the project and assure that all research personnel are familiar with and understand the potential biohazards and relevant biosafety practices, protective equipment and techniques, and emergency procedures. |
|
|
| **4.**  | If applicable, I have read and understand the [United States Government Policy](http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf) for Oversight of Life Sciences Dual Use Research of Concern (DURC). |
|  |  |  |  |
|  | Signature of the Principal Investigator |  | Date |
|  |
|  |
| **Biosafety Risk Assessment Review** |
|  | Risk Assessment Not Required | Why Not? |  |
|  |
| Containment Level: |  | BL1 |  | BL2 |  | BL2 Enhanced |  | BL3 |
|  |  |  |
| Risk Group: |  |  |
|  |
| Review Recommendation based on risk: |
|  |  | Full Board |  | Full Simultaneous |  | Designated |  | Exempt |
| Findings/Items that are not resolved at time of submission to IBC: |
|  |
| Do these findings/items need to be resolved prior to release of IBC approval? |
|  |  | Yes |  | No |
|  |
| Required [CITI](https://about.citiprogram.org/en/homepage/) Training Courses: | Required Classroom Training: |
|  |  | BSL-1 |  | BSL-2 |
|  |  | BSL-2 |
|  |  | Animal Biosafety |  | BSL-3 |
|  |  | Nanotechnology |
|  |  | Select Agents/DURC |
|  | Signature below indicates protocol review. |
|  |  |  |  |
|  | Jeff Labossiere, Biological Safety Officer |  | Date |

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| **\*DURC Appendix: Assessment by the PI for Experimental Effects**  |
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| PIs are required to assess whether any research directly involving unattenuated forms of one or more of the listed agents produces, aims to produce, or is reasonably anticipated to produce one or more of the experimental effects listed in Section 6.2.2 of the [Supplement to the USG Policy for Institutional Oversight.](http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf)   |

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| --- | --- | --- |
| A.1Enhances the harmful consequences of the agent or toxin? |   | Yes If yes, please explain below.No |
|  |  |
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| --- | --- | --- |
| A.2Disrupts immunity or the effectiveness of an immunization against  the agent or toxin without clinical or agricultural justification? |   | Yes If yes, please explain below.No |
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| A.3Confers to the agent or toxin resistance to clinically or agriculturally  |   | Yes If yes, please explain below.No |
|  useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies? |  |
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| A.4Alters properties of the agent or toxin in a manner that would |   | Yes If yes, please explain below.No |
|  enhance its stability, transmissibility, or ability to be disseminated? |  |
|  |

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| --- | --- | --- |
| A.5Alters the host range or tropism of the agent or toxin? |   | Yes If yes, please explain below.No |
|  |  |
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| --- | --- | --- |
| A.6Enhances the susceptibility of a host population to the agent or toxin? |   | Yes If yes, please explain below.No |
|  |  |
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| --- | --- | --- |
| A.7Generates or reconstitutes an eradicated or extinct agent or toxin  |   | Yes If yes, please explain below.No |
|  listed in Section 1.6 of this form?  |  |
|  |