Please fill out the following form and e-mail it to aaelliott@mail.wvu.edu. For assistance, please call 3-7157, or aaelliott@mail.wvu.edu

**BIOSAFETY & rDNA PROTOCOL REGISTRATION**

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| Protocol Overview: Complete this section for all protocol submissions. |

Protocol Title:

## Principal Investigator

|  |  |  |
| --- | --- | --- |
| **Last Name:**       | **First Name:**       | **Title:**       |
| **Campus Mailing Address: PO Box**       | **Office Location (Bldg & Room #):**       |
| **Email Address:**       | **Office Phone:**       | **Department:**       |

Protocol Type (For amendment or renewal, please highlight changes)

[ ]  New Protocol [ ]  Renewal (IBC Protocol #     ) [ ]  Amendment (IBC Protocol #     )

## Summary of Project

Provide a brief overview of your project, including the goals and potential benefits of the research. Include a general overview of the biohazardous materials and methods used to conduct this research. This is an overview, specific methods and SOPs will be included in a following section.

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## Research Locations

Please list all rooms where biohazards or rDNA will be handled or stored. Include rooms in the animal facility, the greenhouse or other research cores (microscope facility, flow cytometry, pathology, clean room, etc.). Note: if work is occurring in shared research facilities, the cores will receive a copy of the approved biosafety protocol.

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| --- | --- | --- | --- | --- | --- |
| **Room & Building** | **BSL of Room** | **Shared** | **Secured** | **Use of Room** | **Biosafety Cabinet Certification Date** |
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## Personnel

Please include all personnel that will be participating in biohazard experiments or that have potential for exposure to biohazards.

| **Name** | **Position** | **Project Responsibilities** | **BBP/Biosafety training (Y/N)** | **HepB Vaccine (Y/N)** | **Fit Testing (Y/N)** | **Medical Monitoring (Y/N)** |
| --- | --- | --- | --- | --- | --- | --- |
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Please have all personnel fill out the Occupational Health Questionnaire before submitting this document.

<https://sole.hsc.wvu.edu/apps/occupationalhealthquestionnaire>

Please contact Ali Elliott (Biosafety Officer) 304-293-3757 or aaelliott@mail.wvu.edu for BBP training.

Please contact Veronica Cyphert in Occupational Medicine 304-293-3693 if you need information on medical monitoring, Hep B vaccines, or fit testing.

<http://wvuhealthcare.com/services/wvu-occupational-medicine/>

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| General Lab Safety Procedures: Complete this section for all protocol submissions.  |

Personal Protective Equipment (PPE): What PPE will be used? (Lab Coats, Safety Glasses, Shoe Covers, Gloves, Respirators, Surgical Mask, Hair Bonnets)

For reusable PPE such as lab coats & eye wear, please describe how they will be cleaned or laundered.

If respirators are used, have the personnel on this protocol been fit tested within the last year?       Date(s) of Testing

Biohazardous Sharps: What sharps will be used? (Needles, glass pipettes, scissors, scalpels, slides, other)

## Surface Disinfection

|  |  |  |  |
| --- | --- | --- | --- |
| **Disinfectant** | **Dilution** | **Contact Time** | **Shelf Life** |
|       |       |       |       |
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## Waste Disposal

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| **Type of Waste (Solid, liquid)** | **Autoclave** | **Call for Pickup** | **Chemical Disinfectant (10% bleach)** |
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For more information on waste disposal, and to fill out a hazardous waste pick-up form, please visit the EHS website: [www.ehs.wvu.edu](http://www.ehs.wvu.edu)

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| Does Your Project Involve Any of the Following: (Check all that apply) |

\_\_\_ Recombinant or Synthetic DNA (fill out pages 5-7)

\_\_\_ Human, animal, or plant pathogens (fill out page 8)

\_\_\_ Human tissue, serum, cell lines, other human derived samples (fill out page 9)

­­\_\_\_ Any animal work involving rDNA, human cells, pathogens, or toxins (fill out page 10)

\_\_\_ Work with wild animals (fill out page 11)

\_\_\_ Biologically active agents (toxins, allergens, poisonous plants, venoms) (fill out page 12)

\_\_\_ Exotic animals, plants, or microbes (not native to the area) (fill out page 13)

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| Recombinant or Synthetic Nucleic Acids: Complete this section if your research involves the use of recombinant or synthetic nucleic acid molecules, viral vectors, transgenic organisms or human gene therapy. |

* [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)

## **Description of Genes**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Gene Name** | **Gene Source** | **Function of Gene** | **Use of Construct** | **Potential Hazards (oncogenes, toxins)** | **Will the gene be expressed? (Y/N)** |
|        |        |        |       |        |  |
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## Vector Information:

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| --- | --- | --- | --- | --- |
| **Vector Name** | **Vector Type** | **Promoters** | **Host Strain/Species** | **Biosafety Level** |
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## Description of Viral Vectors:

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| **Type of Virus** | **System Generation** | **Other Safety Features** | **Targeted Genes** | **Helper Viruses or Packaging System** | **Use of viral vectors in vitro (Y/N)** | **Viral vectors in animals/humans (Y/N)** | **Virus-transfected cells in animals (Y/N)** |
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## Transgenic (Genetically modified) Organisms (vertebrates, invertebrates, Plants and Microorganisms)

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| --- | --- | --- | --- | --- |
| **Organism** | **Gene Name** | **Vector Name** | **How will rDNA be introduced?** | **ACUC Protocol #** |
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## Human Gene Therapy (Human somatic cell gene transfer)

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| --- | --- | --- | --- | --- |
| **Gene** | **Target Host Cells** | **Clinical application** | **Vector/gene delivery system** | **IRB Protocol # (or date of submission)** |
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Will organisms containing recombinant or synthetic nucleic acid molecules be produced on a large-scale (>10 liters of culture)?

## Risk Assessment:

For the genes and vectors described above, what would the health effect be if researchers were exposed to or injected with the construct? Address genome incorporation, replication risk and risk of tumorigenesis. Describe handling practices, PPE, vaccinations, etc intended to prevent exposure, and potential treatment should exposure occur.

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WHAT SECTION OF THE NIH GUIDELINES DOES YOUR PROJECT FALL UNDER? **Please check all that apply**

NIH Guidelines involving Recombinant and Synthetic Nucleic Acids

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| --- | --- |
| **\_\_\_ Section III-A** | Transfer of a drug resistance trait to a Risk group 2, 3, or 4 organism. Such transfer would affect the ability to control disease in humans, plants, animals. |
| **\_\_\_ Section III-B** | Using genes that code for a toxin molecule with LD50 of less than 100 nanograms/kg of body weight. |
| **\_\_\_ Section III-C** | Human Gene Transfer. |
| **\_\_\_ Section III-D-1** | Experiments involving the introduction of recombinant or synthetic nucleic acid into risk group 2, 3, or 4 agents. |
| **\_\_\_ Section III-D-2** | Experiments in which DNA from risk group 2, 3, or 4 agents is inserted into non-pathogenic organisms/systems. |
| **\_\_\_ Section III-D-3** | The use of infectious viruses, replication-defective viruses, or viral vectors with helper viruses. |
| **\_\_\_ Section III-D-4** | Administration of recombinant or synthetic nucleic acid molecules into animals requiring ABSL-2 or higher. |
| **\_\_\_ Section III-D-5** | Experiments with transgenic whole plants requiring BSL-2+, BSL3, or BSL4 -P. |
| **\_\_\_ Section III-D-6** | Experiments involving more than 10 liters of culture. |
| **\_\_\_ Section III-D-7** | Experiments involving Influenza Viruses. |
| **\_\_\_ Section III-E** | Experiments involving whole plants contained under BSL1 and BSL2-P. Creation of transgenic animals housed at ABSL-1. Formation of rDNA containing no more than 2/3 of an eukaryotic virus genome without the presence of helper viruses. Experiments which do not fall into any other category. |
| **\_\_\_ Section III-F** | Experiments involving rDNA outside of living or viral organisms. rDNA that can not replicate or be expressed in vivo. If the DNA source organism is the same as the host organism. E.coli K12 host-vector system, Saccharomyces host vector system, Bacillis subtilis or Bacilis licheniformis host-vector system. |

If you need help identifying the section that your project falls under, please contact the biosafety officer 3-7157, aaelliott@mail.wvu.edu

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| Human, Animal & Plant Pathogens: Complete this section for use of all pathogenic microorganisms (bacteria, fungi, parasites, rickettsias, viruses, prions, etc.). Do not include organisms that are usually non-pathogenic to a healthy host or viral vectors used solely for gene expression. |

* [CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)
* [Vaccine Recommendations of the ACIP](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html)

## Description of Microorganisms

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| **Species and Strain** | **Source** | **Infectious Dose** | **Highest Concentration Used** | **Will rDNA be introduced into pathogen? (Y/N)** | **Does pathogen produce toxins? (Y/N)** | **Is pathogen antibiotic resistant? (Y/N)** | **BSL** |
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## Risk Assessment:

For each microbe, describe the prophylactic & response procedures. Consider the consequences of an accidental exposure (mucosal splash, inhalation, ingestion, or inoculation) which might occur during experimental handling. What is the preferred antibiotic? What are the symptoms following infection? Is serum tested prior to and/or after exposure? Are immunizations required? If rDNA, toxin, or resistance boxes were checked above, please explain.

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| Bloodborne Pathogens & Other Potentially Infectious Materials:Complete this section for research using human-derived materials |

* [OSHA Standard for Bloodborne Pathogens and Needlestick Prevention](https://www.osha.gov/SLTC/bloodbornepathogens/index.html)

This section applies to all occupational exposure to blood or other potentially infectious materials including:

* Human blood, human blood components and products made from human blood
* Human body fluids (semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva, etc.)
* Any unfixed tissue or organ from a human (living or dead), including patient-derived tumor samples
* HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions
* All human- and primate-derived cell lines

## Description of Human-Derived Materials

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| **Samples/Cell Lines** | **Origin of Samples** | **Pathogens associated with sample or cell line** | **Patients in Isolation excluded?** **(Y/N)** | **IRB #** |
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## Risk Assessment

Describe treatment in the case of potential exposure, as well as symptoms of likely infections.

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| ANIMAL INFECTION WITH RECOMBINANT DNA, PATHOGENS, OR HUMAN CELLS: Complete this section for research involving animal infection with rDNA, synthetic nucleic acids, pathogens, toxins, human cells or tissues, or any other human derived material. |

<http://oric.research.wvu.edu/services/iacuc/acuc-faq>

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| --- | --- | --- | --- | --- |
| **Animal Species** | **rDNA, pathogen, toxin, human material** | **Route of Infection** | **Highest Concentration to be Used** | **ACUC #** |
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## Risk Assessment

Describe the response to an animal bite/scratch from an infected animal. Describe the procedures for an escaped animal. List any additional PPE required for working with infected animals. An agent specific risk assessment should be included in the corresponding section of this document (rDNA, BBP, pathogen page).

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| Field Collection Or Sampling Of Wild Animals: Complete this section for field research with wild species including mammals, fish, birds, insects, and amphibians. |

This section covers field research that involves the following:

* Trapping and handling of wild animals for surveillance of agents infectious to humans and/or animals designated at BSL-2 or higher
* Trapping and handling of wild animals that may transmit significant or life threatening zoonotic diseases (e.g. rabies, Hantavirus Pulmonary Syndrome) as determined by risk assessment of the target species and proposed procedures
* Laboratory processing of diagnostic samples collected from these studies

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| **Wild Animal Species** | **Pathogens Associated with Species** | **Transmission of Pathogens** | **Vaccinations** | **Venomous Organism? (Y/N)** |
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## Risk Assessment

Describe the treatment procedures for an accidental exposure (Animal scratch, bite, splash to mucous membranes, ingestion). What is the preferred antibiotic, or antidote? Describe the symptoms of potential infections.

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| Biologically-Active Agents: Complete this section for use of biologically-active agents such as biological toxins, allergens, poisonous plants and venoms. |

Biological toxins are toxic substances produced by plants, animals or microorganisms. This section should include work with the organism that produces the toxin (poison ivy plants, bacteria that make toxin, etc) as well as work with purified toxins.

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| **Agent** | **Source** | **Route of Exposure** | **Target Organ or System** | **LD50 (If Known)** | **Inactivation/Disposal** |
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## Risk Assessment

Describe the treatment procedures for an accidental exposure (Cutaneous exposure, splash to mucous membranes, ingestion). Is there an antidote? Describe the symptoms of potential infections. What safety precautions will you use when handling/collecting the agent?

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| Exotic Plants, Animals or Microbes: Complete this section for research using pests, noxious weeds and arthropods not indigenous to this area. |

* [US Plant Protection Act](http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/PPAText.pdf)
* [[A Practical Guide to Containment: Plant Biosafety in Research Greenhouses](http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/PPAText.pdf)](http://www.isb.vt.edu/Containment-guide.aspx)
* [[Arthropod Containment Guidelines](http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/PPAText.pdf)](http://www.liebertonline.com/doi/pdf/10.1089/153036603322163475)

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| **Animal Plant/Species** | **USDA/APHIS Permits** |
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| **Arthropod Species** | **Infection Status** | **Distribution** | **Transgenic (Y/N)** | **ACL** |
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## Risk Assessment

Describe the potential impact on local animal and plant populations in the event of an accidental release into the environment. What would be theprocedures following a release?

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## Materials And Methods

Please provide a detailed materials & methods/SOPs for experimental activities using the biohazardous materials described in the document. Include information on transporting samples to the lab, as well as specific procedures that will make use of these samples. If working with animals, describe the procedures for infecting animals, precautions taken when handling infected animals, how carcasses will be handled, what samples will be collected from necropsy, and what those samples will be used for.

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| **PRINCIPAL INVESTIGATOR'S ACKNOWLEDGEMENT OF REGULATORY REQUIREMENTS:** |

**As the principal investigator for this registration, I understand and acknowledge my responsibilities to:**

* Comply with WVU safety policies, as well as local, state, and federal regulations.
* Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
* Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection)
* Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.
* Report all spills, exposures, and other incidents involving biohazardous material to the biosafety officer.
* Remain in communication with the IBC throughout the length of the project.

**By Submitting This Form To The IBC, The PI Acknowledges These Responsibilities**