**BIOSAFETY PROTOCOL REGISTRATION FORM**

IBC Protocol # *(to be assigned by the IBC Office)*:

**I. BASIC PROTOCOL INFORMATION**

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| **1. APPLICATION TYPE** |
| New Application |
| Renewal |

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| **2. PROJECT & PERSONNEL INFORMATION** | | | |
| Project Title: | | | |
| **Principal Investigator:** | | **Title:** | |
| Dept.: | Bldg.: | | Office #: |
| Phone: | Fax: | | Email: |
| **Co-Investigator:** | | **Title:** | |
| Dept.: | Bldg.: | | Office #: |
| Phone: | Fax: | | Email: |
| **Lab Contact:** | | **Title:** | |
| Dept.: | Bldg.: | | Office #: |
| Phone: | Fax: | | Email: |

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| **3. QUALIFICATIONS & EXPERIENCE** | | |
| **Name & Degree** | **Role** | **Experience with Procedures Performed** |
|  | PI | Beginner Intermediate Advanced |
|  |  | Beginner Intermediate Advanced |
|  |  | Beginner Intermediate Advanced |
|  |  | Beginner Intermediate Advanced |
|  |  | Beginner Intermediate Advanced |
|  |  | Beginner Intermediate Advanced |

***Note****: For role in the project, state Co-Investigator (CI), Aide (A), or Technician (T).*

**II. PURPOSE & METHODOLOGY**

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| **4. PURPOSE & GOALS** |
| **Describe the purpose and goals of your research project:** |
| **Describe your plan of work, research methods, microbiological practices, and laboratory procedures** *(including the activities with respect to the biological agents used to accomplish the above purpose and goals)*: |

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| **5. HUMAN, ANIMAL, & PLANT USE** |
| **Will vertebrate animals be used?**  No  Yes, IACUC Protocol #: |
| **Will non-vertebrate animals be used?**  No  Yes |
| **Will human subjects be directly or indirectly (samples) used?**  No  Yes, IRB Protocol #: |
| **Will plants be used?**  No  Yes |

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| **6. BIOSAFETY CONTAINMENT LEVELS USED** | | | | |
| **Laboratory:** | BSL-1 | BSL-2 | BSL-3 | Other: |
| **Animal:** | ABSL-1 | ABSL-2 | ABSL-3 | Other: |
| **Plant:** | BSL1-P | BSL2-P | BSL3-P | Other: |

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| **7. FACILITIES** |
| **Provide the location of facilities where biological agents will be used** *(if applicable, include building, room number, biosafety level, animal species housed, and plant species housed)*: |

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| **8. STUDY CATEGORIES & SUPPLEMENTAL INFORMATION** | | |
| **Check either “Yes” or “No” for each of the following categories:** | | |
| **Infectious Agents** *(Animal/Human/Plant)* | No | Yes, *Complete Section III* |
| **Recombinant DNA** | No | Yes, *Complete Section IV* |
| **Human or Primate Blood, Bodily Fluids, Cells, Cell Lines and/or Tissues** | No | Yes, *Complete Section V* |
| **Transgenic Plants** | No | Yes, *Complete Section IV & VI* |
| **Transgenic Animals** | No | Yes, *Complete Section IV & VII* |
| **Select Agents or Toxins** | No | Yes, *Complete Section III & VIII* |

**III. INFECTIOUS AGENTS AND BIOLOGICAL TOXINS**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **INFECTIOUS AGENT AND BIOLOGICAL TOXIN INFORMATION** | | | | | | | | | | | |
| **Infectious Agent/Toxin:** | | | | | | | | | | | |
| Human Hazard?\* | | Animal Hazard? | | Plant Hazard? | | | Human Vaccine? | | BSL | | |
| Yes | No | Yes | No | | Yes | No | Yes | No | 1 | 2 | 3 |
| **Infectious Agent/Toxin:** | | | | | | | | | | | |
| Human Hazard?\* | | Animal Hazard? | | Plant Hazard? | | | Human Vaccine? | | BSL | | |
| Yes | No | Yes | No | | Yes | No | Yes | No | 1 | 2 | 3 |
| **Infectious Agent/Toxin:** | | | | | | | | | | | |
| Human Hazard?\* | | Animal Hazard? | | Plant Hazard? | | | Human Vaccine? | | BSL | | |
| Yes | No | Yes | No | | Yes | No | Yes | No | 1 | 2 | 3 |
| **Infectious Agent/Toxin:** | | | | | | | | | | | |
| Human Hazard?\* | | Animal Hazard? | | Plant Hazard? | | | Human Vaccine? | | BSL | | |
| Yes | No | Yes | No | | Yes | No | Yes | No | 1 | 2 | 3 |
| **Infectious Agent/Toxin:** | | | | | | | | | | | |
| Human Hazard?\* | | Animal Hazard? | | Plant Hazard? | | | Human Vaccine? | | BSL | | |
| Yes | No | Yes | No | | Yes | No | Yes | No | 1 | 2 | 3 |
| **Infectious Agent/Toxin:** | | | | | | | | | | | |
| Human Hazard?\* | | Animal Hazard? | | Plant Hazard? | | | Human Vaccine? | | BSL | | |
| Yes | No | Yes | No | | Yes | No | Yes | No | 1 | 2 | 3 |

***Note:*** *For definition of BSL classifications, refer to Biosafety in Microbiological Biomedical Laboratories (*[*BMBL*](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)*), or the* [*NIH Guidelines*](https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf) *for the use of recombinant DNA.*

***\*****If the organism is non-pathogenic to humans, check the “No” box.*

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| **SUPPLEMENTAL QUESTIONS REGARDING AGENTS AND TOXINS** |
| **Describe the experimental design and goals**: |
| **What is the source of the agent/toxin/potentially biohazardous material?** |
| **What is your assessment of the biohazardous potential? Include any necessary vaccines:** |
| **What methods will be used for transporting the material within and between facilities?** |
| **What is the method of terminal inactivation of the biological agent?** |
| **What is the disposal method for inoculated animals or plants?** |
| **List all materials that require federal permits & include copies with your application:** |

**IV. RECOMBINANT DNA**

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| **EXPERIMENTS COVERED BY THE NIH GUIDELINES** *(SELECT APPLICABLE):* |
| **Category III-A:** *NIH Director, RAC, & IBC Oversight* |
| Studies involving the deliberate transfer of drug resistance to microorganisms (not known to acquire the trait naturally) that can compromise the use of the drug to control the microorganism and its disease in humans, veterinary medicine, or agriculture. |
| **Category III-B:** *NIH/OBA & IBC Oversight* |
| Activities limited to cloning genes that encode for toxin molecules with LD-50<100 nanograms/kg body weight. Examples: botulinum, tetanus, diphtheria toxins |
| **Category III-C:** *RAC, IRB, & IBC Oversight* |
| Transfer of recombinant DNA, or DNA and RNA derived from recombinant DNA, into one or more human subjects. |
| **Category III-D:** *IBC Approval Prior to Study Initiation* |
| **D-1:** Experiments using Risk Group 2. Risk Group 3, Risk Group 4, or restricted agents as host-vector systems. |
| **D-2:** Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems. For cloning toxin molecules with LD-50 of less than 100 nanograms per kilogram body weight, check section III-B above. Section D-2 does not apply. |
| **D-3:** Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of a helper virus in tissue culture systems.  **1. Experiment is likely to enhance pathogenicity.**  Yes  No  **2. Experiment extends the host range.**  Yes  No |
| **D-4:** Experiments involving whole animals in which the animal’s genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line *(transgenic animals)*, and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. For the latter, other than viruses wich are only vertically transmitted, the experiments may not be conducted at BL1-N containment. A minimum containment of BL2 or BL2-N is required. *(See E-3 for BSL-1 transgenic rodent experiments).*  **1. Fraction of viral genome being utilized may lead to productive infection.**  Yes  No  **2. Recombinant DNA, or DNA or RNA molecules derived therefrom; source is greater than 2/3 eukaryotic viral genome.**  Yes  No |
| **D-5:** Experiments involving the generation of transgenic plants or use of recombinant microorganisms or recombinant insects in plants. *(For cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram bodyweight see section III-B above. Section D-5 does not apply.)* |
| **D-6:** Experiments involving cultures of 10L increments or greater. |
| **Category III-E:** *IBC Approval Simultaneous with Study Initiation* |
| **E-1:** Experiments involving less than 2/3 of a eukaryotic virus genome. All viruses from a single family being considered identical.  **1. Do cells contain helper viruses for family of viruses being used?** *(If, yes see III-D3)*  Yes  No |
| **E-2:** Experiments involving the generation of transgenic plants or use of recombinant microorganisms or recombinant insects in that plant. For those not described in III-A, III-B, III-C, III-D, or III-F. |
| **E-3:** Experiments involving the generation of transgenic rodents for BSL-1 only. (See III-D4 for experiments requiring BSL-2, 3 or 4). |
| **Category III-F:** *Protocol Submission Required* |
| **Exempt by NIH Guidelines.** Use the [NIH Guidelines](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Section_III-F._Exempt) to cite rationale for your exemption request: |

***Note:*** *NIH Review & Guidelines (See* [*Section III*](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276228) *for Categories, See* [*Section II-A-1*](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276224) *for Risk Groups)*

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| **SUPPLEMENTAL QUESTIONS REGARDING RECOMBINANT DNA** | | |
| **Yes/No** | **Statement** | |
| Yes  No | I am inserting foreign DNA or RNA into a vector or organism to clone or express it. | |
| **The DNA or RNA to be Cloned:** | | |
| Yes  No | Is from a Risk Group 3 agent. | |
| Yes  No | Represents more than two-thirds of the genome of Risk Group 1 or Risk Group 2 organisms. Represents more than two-thirds of the genome of a Risk Group 1 or 2 organism that has not been determined to be exempt by the [NIH Guidelines](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Section_III-F._Exempt). | |
| Yes  No | Encodes a known oncogene. | |
| Yes  No | Encodes a control element that may extend the host range. | |
| Yes  No | Encodes molecules known to be toxic to vertebrates at LD50 less than 100ng/kg. | |
| **The vector used for introducing foreign DNA or RNA into the host:** | | |
| Yes  No | Is from a Risk Group 3 agent. | |
| Yes  No | Is a Risk Group 1 or 2 virus that infects eukaryotic cells and contains more than two-thirds of the viral genome. | |
| Yes  No | The host into which I am introducing my foreign DNA or RNA is a cell or organism **other than** *E. Coli* K12 or its derivatives, *S. Cerevisiae, S. uvarum, B. subtilis, B. lichenformis*. | |
| **If you checked “Yes” for any of the above statements, complete the following recombinant DNA information** *(as applicable)*: | | |
| **Host(s), and if applicable, include plants to be transformed:** | | **BSL:**  1  2  3 |
| **Vector(s)\*:** | | **BSL:**  1  2  3 |
| **Gene(s) to be cloned:** | | **BSL:**  1  2  3 |
| **DNA/RNA Source(s):** | | **BSL:**  1  2  3 |

*\*List the type of vector systems used (plasmid, lentiviral, adenoviral, etc.) and provide vector names. If multiple vectors are used, provide a representative example of vector names.*

**V. HUMAN OR PRIMATE BLOOD, BODILY FLUIDS, CELLS, CELL-LINES/TISSUES**

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| **POTENTIALLY INFECTIOUS AGENTS** | | |
| **Indicate whether your protocol will include any of the following:** | | |
| **Blood** | Type: N/A | Vendor/Collaborator: |
| **Bodily Fluids** | Type: | Vendor/Collaborator: |
| **Cells/Tissues** | Type: | Vendor/Collaborator: |
| **Primary Cell Lines** | Type: | Vendor/Collaborator: |
| **Established Cell Lines** | Type: | Vendor/Collaborator: |

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| **USE OF CHARACTERIZED/SELECT AGENTS OR TOXINS** |
| **Do any cells, tissues, or cell lines have characterized/select agents or toxins?**  No  Yes *(Complete Section III)* |

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| **EXPOSURE CONTROL PLANNING** |
| **Use of human or primate blood, bodily fluids, cells, and/or tissues may require:**   1. Blood-Borne Pathogen Exposure Control Plan (ECP) 2. Blood-Borne Pathogen Training and 3. Offering Vaccinations to Personnel |
| **Has a BBP ECP been completed?**  Yes  No |
| **Has your BBP ECP been reviewed and approved by the Biosafety Officer/HR?**  Yes  No |
| **Are systems in place to ensure lab personnel BBP Training?**  Yes  No |
| **Are systems in place to ensure lab personnel are offered required Hepatitis-B Virus (HBV) vaccinations?** *(Not applicable for established cell lines except those of liver origin)*  Yes  N/A |

**Note:** *Depending on the nature of the study, the collection of human blood, bodily fluids, cells, or tissues, may require human subjects approval from the IRB.*

**VI. TRANSGENIC PLANTS**

Per the NIH Guidelines, transgenic plant activities must be reported to the IBC. If the transgenic plant project only requires BSL-1 containment, the study may begin simultaneously with the submission of this form to the IBC. All other transgenic plant projects require IBC approval prior to initiation.

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| **TRANSGENIC PLANT LOCATION AND USE** |
| **Please check “Yes” or “No” for each of the following categories, and fill in the appropriate boxes as indicated:** |
| **Transgenic whole plants will be maintained in the laboratory, greenhouse, or growth chamber:**  No  Yes |
| **Transgenic whole plants will be introduced into the field:**  No  Yes *(Complete the “Field Study” section below)* |

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| **TRANSGENIC PLANT—FIELD STUDY** |
| **If a pharmaceutical or bioactive industrial compound will be synthesized in a food or feed crop, state the reason for choosing that crop:** |
| **Describe information gained from lab and growth chamber or greenhouse experiments that would be relevant to assessing potential risks from field tests:** |
| **Describe procedures to monitor for and eliminate any volunteer plants:** |
| **How close is the field planting to other plants where gene flow or cross pollination could occur?**  Less than 100 feet  Less than one mile  Less than 100 yards  Greater than one mile  Not Applicable  Explain: |
| **Have bordering farms been made aware of the transgenic field release?**  No  Yes |
| **I agree to adhere to all federal guidelines as outlined in the attached copy of the APHIS approval/permit.**  No  Yes |
| **Has a planting map with GPS coordinates and bordering field planting information been attached?**  No  Yes |

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| **TRANSGENIC PLANT PROPERTIES** | | |
| **Is the recombinant plant a noxious weed?** | Yes | No |
| **Can the recombinant plant interbreed with weeds in the area?** | Yes | No |
| **Does the recombinant plant have recognized potential for detrimental environmental impact on managed or natural ecosystems?** | Yes | No |
| **Does the recombinant DNA work contain a complete genome of a non-exotic infectious agent?** | Yes | No |
| **Does the recombinant DNA work contain the genome of an exotic infectious agent?** | Yes | No |
| **Could this work reconstitute the genome of an infectious agent in a plant?** | Yes | No |
| **Does this work involve exotic infectious agents with potentially detrimental environmental impact?** | Yes | No |
| **Contains an exogenous toxin?**  No  Yes *(Describe)*: | | |

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| **CONTAINMENT & DECONTAMINATION** | |
| **What physical and/or biological containment strategies will be implemented?** | |
| **How will biological material be decontaminated or inactivated?** | |
| Steam | Desiccation |
| Chemical | Chopping/Mincing |
| Composting | Incineration |
| Other: | Other: |

**VII. TRANSGENIC ANIMALS**

This section is to be completed for any transgenic vertebrate or invertebrate animal(s).

***Exemption:*** *Projects involving the purchase, transfer, and use of transgenic rodents in BSL-1 experiments are not required to fill out this section. Breeding of BSL-1 rodent colonies within the same genetic lineage is also exempt if:*

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| **EXEMPTION CRITERIA** |
| **Both parental rodents can be housed under BSL-1 containment and neither parental transgenic rodent contains either of the following genetic modifications:** |
| Incorporation of more than one-half of the genome of a eukaryotic virus from a single family |
| **OR** |
| Incorporation of a transgene that is under the control of a gammaretroviral terminal repeat (LTR) |
| **AND** |
| The transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses. |

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| **DETERMINATION OF EXEMPTION STATUS** |
| This research utilizes only rodents that meet the above exemption criteria. |
| The exemption does not apply to this research, answer the questions below. |

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| **TRANSGENIC ANIMAL RESEARCH** |
| **Source of animal(s):** |
| **Method of animal decontamination upon termination of experiment:**  Incineration  Other: |
| **If breeding BSL-1 rodent colonies with other genetic lines, describe the genetic makeup of both lineages that will be used for breeding:** |

**VIII. SELECT AGENTS AND TOXINS**

Select agents require special registration with the CDC or APHIS in order to laboratories and PIs to be approved for research utilizing these agents.

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| **HHS NON-OVERLAP SELECT AGENTS AND TOXINS** |
| **Indicate below the select agents and toxins used in your lab** *(above the exempt amount)***:** |
| Abrin (<100mg) |
| Botulinum neurotoxins |
| Botulinum neurotoxin producing species of Clostridium |
| Conotoxins (<100mg) |
| Coxiella burnetii |
| Crimean-Congo hemorrhagic fever virus |
| Diacetoxyscirpenol |
| Eastern Equine encephalitis virus |
| Ebola viruses |
| Francisella tularensis |
| Lassa fever virus |
| Lujo virus |
| Marburg virus |
| Monkeypox virus |
| Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of eight gene segments *(Reconstructed 1918 influenza virus)* |
| Ricin (<100mg) |
| Rickettsia prowazekii |
| SARS-associated coronavirus (SARS-CoV) |
| Saxitoxin (<100mg) |
| South American hemorrhagic fever viruses: |
| *Chapare* |
| *Guanarito* |
| *Junin* |
| *Machupo* |
| *Sabia* |
| Staphylococcal enterotoxins (A,B,C,D,E, subtypes) |
| T-2 toxin |
| Tetrodotoxin (<100mg) |
| Tick-borne encephalitis complex (flaviviruses) |
| Far Eastern tick-borne encephalitis |
| Siberian subtype |
| Kyasanur Forest disease virus |
| Omsk hemorrhagic fever virus |
| Variola major virus (Smallpox virus) |
| Variola minor virus (Alastrim) |
| Yersinia pestis |

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| **HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/SELECT AGENTS** *(OVERLAP AGENTS)* |
| Bacillus anthracis |
| Bacillus anthracis Pasteur strain |
| Brucella abortus |
| Brucella melitensis |
| Brucella suis |
| Burkholderia mallei *(formerly Pseudomonas mallei)* |
| Burkholderia pseudomallei *(formerly Pseudomonas pseudomallei)* |
| Hendra virus |
| Nipah virus |
| Rift Valley fever virus |
| Venezuelan equine encephalitis virus |

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| **USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS** *(NON-OVERLAP AGENTS AND TOXINS)* |
| African horse sickness virus |
| African swine fever virus |
| Avian influenza virus *(highly pathogenic)* |
| Classical swine fever virus |
| Foot and mouth disease virus |
| Goat pox virus |
| Lumpy skin disease virus |
| Mycoplasma capricolum/M.F38/M.mycoides Capri *(contagious caprine pleuropneumonia)* |
| Mycoplasma mycoides mycoides *(contagious bovine pleuropneumonia)* |
| Newcastle disease virus *(velogenic)* |
| Peste Des Ptits Ruminants virus |
| Ridnerpest virus |
| Sheep pox virus |
| Swine vesicular disease virus |

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| **LISTED PLANT PATHOGENS** |
| Peronosclerospora philippinesis |
| Phoma glycinicola *(formerly Pyrenochaeta glycines)* |
| Ralstonia solanacearum race 3, biovar 2 |
| Rathayibacter toxicus |
| Schlerophthora rayssiae var. zeae |
| Synchytrium endobioticum |
| Xanthomonas oryzae |

**PI Certification Statement:**

*By signing below, I certify that I have read the following statements and agree that I and all listed participants will abide by them:*

1. Personnel have received or will receive necessary and appropriate training in safe laboratory practices and procedures for this study before any work begins and as required thereafter.
2. Follow health surveillance practices as required in the biosafety laboratory manual and inform those working on the protocol about appropriate emergency assistance information applicable to their location(s).
3. Inform the IBC of any research-related accidents or illnesses as soon as possible after occurrence. Depending on the nature of the incident, HR should also be notified.
4. Submit in writing a request for approval from the IBC for any significant modifications to the study protocol, facilities, or procedures.
5. Adhere to all applicable federal, state, and local regulations and guidelines as well as the policies set forth by the University.

Signature of Principal Investigator:        
Date: