

**INSTITUTIONAL BIOSAFETY COMMITTEE**

**PROTOCOL APPLICATION**

**☐ NEW ☐ RENEWAL ☐ AMENDMENT**

**I. GENERAL INFORMATION**

|  |  |
| --- | --- |
| Principal Investigator |  |
| Co-PI (If applicable) |  |
| Department |  |
| Phone Number |  |
| E-Mail Address |  |
| Location of Project (Bldg/Rm#) |  |
| ***\*if this is another researcher’s lab, please annotate that here\**** |  |
| Project Title |  |

**Application type (Check all that apply)**

☐ Research Application

☐ Instructional Laboratory Application

Course Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Location of Teaching Lab: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ If Renewal or Amendment include Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_

**Description of Research Activity (Provide a brief, non-technical summary of the research project)**

**Description of Instructional Activity (Provide a brief, non-technical summary of biological material that will be handled. Common or scientific names for materials can be used)**

***Biological material brought into a classroom or teaching lab, that is being used for demonstrational purposes only, DOES NOT require IBC oversight.
Students registered for the course and/or instructional lab, DO NOT require IBC training.
Only PI/Faculty members who are the teacher of record, and the lab TA’s, require the appropriate IBC training that corresponds with the designated biosafety level.***

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**Materials used in this project (Check all that apply)**

☐ Vertebrate Tissue or Fluids

☐ Plant(s)

☐ Toxins

☐ Microbial Agents and/or Infectious Agents

☐ Recombinant Nucleic Acids, Synthetic Nucleic Acids and/or Transgenic Organisms

**Indicate the Biosafety Level at which this project will be conducted:**

☐ Biosafety Level 1 Low risk agents (generally risk group 1), special containment equipment not required

☐ Biosafety Level 2 Moderate risk agents (generally risk group 2), biosafety cabinets, and restrictions to research areas.

**Indicate the Personal Protective Equipment (P.P.E) required for this protocol**

☐ Laboratory Coat

☐ Splash Resistant Eye Protection

☐ Gloves

☐ Closed-Toe Shoes

☐ Respiratory Protection *(Users must be trained and medically cleared in accordance with the OSHA standard. Contact EHSREM.)*

 Type:

☐ Other

*\*If OTHER, please describe below*:

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**Permits: Please identify all permits required for this study to begin**

☐ USDA Permit

 Number:

☐ APHIS Permit

 Number:

☐ CDC - Import Permit

 Number:

☐ Other

 Type:

 Number:

**Select Agent Use – does this protocol make use of select agents or toxins**

☐ Yes

☐ No

**Committee Approvals: Indicate if this study requires IACUC and/or IRB review**

☐ IACUC

 Protocol Number:

☐ IRB

 Protocol Number:

**Certification**

*Please read the following statements and indicate your agreement by checking each statement.*

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| ☐ *I certify that, to the best of my knowledge, the information provided in this application is complete and correct. I am familiar with, and agree to abide by the University’s policies for research with potentially biohazardous materials, the* [*BMBL 6th Edition*](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf) *and guidelines established by the NIH, CDC, and USDA that may pertain to the research project detailed in this application*. |
| ☐ *I will ensure all personnel under my supervision are provided with an initial lab orientation and any additional training, instruction, and/or supervision needed to work safely with the biological agents and materials associated with this project.* |
| ☐ *I understand that I am responsible for immediately reporting any violations of the NIH Guidelines, problems with containment, and / or any research related accidents or illnesses to EHSREM (x3616) and the IBC.* |
| ☐ *I agree to notify the IBC of changes in the project described herein and will submit an IBC amendment form to the committee for review.* |

**II. WASTE DISPOSAL AND TERMINAL INACTIVATION**

*Please read the waste disposal statements below. Please check if you will be following the standard waste disposal methods. If your project requires special waste treatment, please give details below.*

* **Disposal of Liquid and Solid Biological Waste**

I agree to follow the waste disposal methods described below, where appropriate:

* Chlorine bleach will be added to all liquids to a final concentration of 10% bleach and left for a minimum of 20 minutes contact time prior to disposal down the drain. Bleach solution will be made daily.
* All contaminated solids will be placed in an appropriately labeled biohazard bag or sharps container, as appropriate. Bags will be placed in an appropriate biohazard waste container, meeting guidelines, provided by EHSREM. When ¾ full EHSREM will be notified to pick up the container(s) for proper waste disposal. Samples requiring autoclaving will be processed prior to collection by EHSREM.
* All work surfaces and equipment will be cleaned, after use, with an appropriate disinfectant.

☐ Yes

☐ No\*

☐ N/A

*\*If NO, please explain how contaminated waste (liquid or solid) will be decontaminated and disposed:*

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* **Disposal of infected Animal Waste and Animal Carcasses**

I agree to follow the waste disposal methods described below, where appropriate:

* All waste vertebrate tissue will be sealed in a bag appropriate to the biosafety level and placed in a freezer/refrigerator dedicated to, and labeled, for this purpose. Waste will then be collected by EHSREM and processed for proper waste disposal. Contact EHSREM (ehs@txstate.edu) for assistance with this process.

☐ Yes

☐ No\*

☐ N/A

*\*If NO, please explain:*

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**III. SHIPPING AND TRANSPORTATION
*\*Only fill out if you plan to ship from Texas State or transport materials to other locations on campus***

**1. Will samples be shipped from Texas State University to other institutions?**

☐ Yes

☐ No

If shipping samples from Texas State University to other entities, please read the statement below and check the appropriate response. If you will be following different shipping procedures, please give details below:

* I agree that shipping will follow appropriate guidelines for packaging, labeling, and shipping that conform to Federal and International regulations (International Air Transport Association (IATA) Dangerous Goods Regulations). Briefly, the labeled samples are packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling and transportation in a way that contents should not leak to the outside of the shipping container, even if leakage of the primary container occurs. All shipping will be processed by fully trained and approved shippers at Texas State University.

☐ Yes

☐ No\*

☐ N/A

*\*If NO, please explain:*

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**2. If transporting samples to or from Texas State or to other sites on campus please read the statement below and check the appropriate response. If you will be following different transportation procedures, please give details below:**

* I agree that all biological samples will be transported in a sealed secondary container that can withstand leakage of contents, shocks and other conditions incident to ordinary handling and transportation in a way that contents should not leak to the outside of the secondary container, even if leakage of the primary container occurs. If the contents are biohazardous the secondary container will be clearly labeled with a biohazard label.

☐ Yes

☐ No\*

☐ N/A

*\*If NO, please explain method of transport:*

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**IV. BIOLOGICAL TOXINS
*\*Only fill out this section if it applies to your research, if not, please skip and continue to the next section.***

List of toxins of a biological origin in this section.

1. **Toxin Name**

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## LD50 and species determined in (For example, E. coli K-12of DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 nanograms to 100 micrograms per kilogram body weight).

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## In what form will the toxin be obtained?

☐ Liquid

☐ Solid / Powder

☐ Other\*

*\*If OTHER, please explain:*

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## Will sharps be used in procedures involving toxins?

☐ Yes\*

☐ No

*\*If YES, please provide details below:*

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## Will you be administering the toxin to animals?

☐ Yes

☐ No

## How will the toxin be administered?

☐ Intravenous ☐ Aerosol

☐ Intranasal ☐ Subcutaneous

☐ Intraperitoneal ☐ Intramuscular

☐ Other\*

*\*If OTHER, please explain:*

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## Is this a Select Agent Toxin?

☐ Yes\*

☐ No

*\*If Yes, read and check the following statements*

7a. Will the toxin be kept in exempt quantities?

☐ Yes

☐ No

7b. Will the toxin be kept in secure storage?

☐ Yes

☐ No

*\*If YES, please explain how it will be stored and where it will be stored:*

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7c. Will an accurate inventory of all toxins be maintained?

☐ Yes

☐ No

**V. USE OF VERTEBRATE OR INVERTEBRATE TISSUE OR FLUIDS (INCLUDES CELL LINES)
*\*Only fill out this section if it applies to your research, if not, please skip and continue to the next section.***

**1. List the tissue, fluid or cell line and the species from which it is derived**

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**2. Does the tissue contain a known infectious agent?**

☐ Yes\*

☐ No

*\*If Yes,* *please list all known infectious agents – cell lines from commercial sources may contain known viruses that should be included here. Please check with the vendor to verify (e.g. HeLa cells contain strains of HPV):*

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## 3. What safety procedures should personnel take to protect themselves from this material? Include both collection and research if applicable.

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**VI. MICROBIAL OR INFECTIOUS AGENTS
*\*Only fill out this section if it applies to your research, if not, please skip and continue to the next section.***

Use of some common microbes such as *Escherichia coli* K-12, *Saccharomyces cerevisiae,* and *Bacillus subtilis*, in routine procedures may be exempt from NIH Guidelines, but the use of these microbes in many applications are regulated by the NIH and such experiments do require approval from the IBC before being initiated. Researchers are advised to consult the current version of the NIH Guidelines to determine if their experiments require IBC approval or if they are exempt. Questions may also be directed to the IBC chair or Research Integrity and Compliance.

**1. List all agents (including *E. coli* strains and viral vectors used in cloning)**

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**2. Risk Group (Note: The Risk Group may not always correspond to the Biosafety Level)**

☐ Risk Group 1 Agents are NOT associated with disease in healthy humans.

☐ Risk Group 2 Agents are associated with human disease that is rarely serious.

 There are often preventative or therapeutic interventions available.

☐ Risk Group 3 Agents are associated with serious or lethal human disease for which preventative or therapeutic interventions *MAY* be available.

**3. Will the agent be grown in volumes of 10L or more (in a single vessel)?**

☐ Yes

☐ No

**4. Are any of the agents listed classified as Select Agents?**

☐ Yes

☐ No

**5. Will the agent be genetically modified either at Texas State or at the point of origin? (If YES, complete section VI)**

☐ Yes

☐ No

**6. List any plant species or cell lines that will be infected with this agent**

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**7. Where will infected plants be housed? (Include building and/or Room Number)**

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**8. Describe any special safety considerations for handling the agents, infected plants or materials associated with infected plants:**

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**9. Will the agent be administered to animals? (This includes invertebrates such as Drosophila and C. elegans)**

☐ Yes

☐ No

**10. How will the agent be administered?**

☐ Intravenous ☐ Aerosol

☐ Intranasal ☐ Subcutaneous

☐ Intraperitoneal ☐ Intramuscular

☐ Other\*

*\*If Other, please explain:*

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**11. Describe any special safety considerations for administering the agent to animals and for handling infected animals or materials associated with infected animals:**

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**12. Will the agent be used to infect vertebrate tissue (cell lines)? If YES, please make sure Section V is completed.**

☐ Yes

☐ No

**VII. USE OF RECOMBINANT OR SYNTHETIC NUCLEIC ACIDS AND / OR TRANSGENIC ORGANISMS
*\*Only fill out this section if it applies to your research, if not, please skip and continue to the next section.***

 **NOTE:** *If this protocol generates material that has the potential to be infectious, then* ***Section VI*** *of this application must also be completed. If the product of any recombinant work produces a toxin* ***Section IV*** *of this application must also be completed.*

**1. Categorization of experiments according to the NIH Guidelines for research involving recombinant or synthetic acids and / or transgenic organisms.**

*Please select the specific subsection(s) from Section III of the* [*NIH Guidelines*](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) *(e.g. III-D-3-a) under which you believe this research is covered. Refer to Section III-F for exemption qualifications.*

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**2. Will this project use CRISPR or related technologies?**

☐ Yes (If Yes, please attach Appendix A with this application)

☐ No

**3. Will proteins or regulatory RNA’s be expressed?**

☐ Yes

☐ No

**4. Is the source of nucleic acids associated with alterations of normal cell cycle or cell growth? (e.g. oncogenic or tumorigenic)**

☐ Yes\*

☐ No

*\*If Yes,* *please provide more details below:*

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**5. Will the nucleic acid be replication competent or able to replicate in a living cell?**

☐ Yes

☐ No

**6. Will any expressed proteins be a toxin known to affect vertebrates? (If YES, complete Section IV)**

☐ Yes

☐ No

**7. Will the recombinant nucleic acid be inserted into a vector?**

☐ Yes\*

☐ No

*\*If Yes,* *what vector system will be used and is it replication competent?*

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**8. Will a packaging or helper system be used?**

☐ Yes\*

☐ No

*\*If Yes,* *describe the packaging/helper system to be used:*

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**9. Will nucleic acids/modified vectors be inserted into a prokaryotic or eukaryotic host?**

☐ Yes\*

☐ No

*\*If Yes,* *please describe:*

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**10. Description of recombinant / synthetic work:**

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| --- | --- | --- |
| **GENE NAME** | **BIOLOGICAL SOURCE (mouse, bacteria, virus etc.)** | **BIOLOGICAL ACTIVITIES OF THE PRODUCT** |
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**11. Please provide any additional information regarding your target genes below, you may use this section if your target genes are unknown or their function is unknown**

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**12. Will recombinant organisms be grown in volumes of 10L or more (in a single vessel)?**

☐ Yes

☐ No

**13. Will nucleic acids be introduced into animals or be used to produce transgenic animals? (Including invertebrates such as Drosophila or C. elegans)**

☐ Yes\*

☐ No

*\*If Yes,* *provide details including any special safety procedures:*

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**14. Will nucleic acids be used to produce transgenic plants?**

☐ Yes\*

☐ No

*\*If Yes,* *provide details including any special safety procedures:*

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**15. Does significant potential exist for the sexual or asexual reproductive structures of the transgenic plants to be released from the experimental areas?**

☐ Yes\*

☐ No

*\*If Yes,* *provide details including any special safety procedures:*

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**16. Are the transgenic plants an agricultural crop with the potential to outcross with plants being grown under commercial production?**

☐ Yes\*

☐ No

*\*If Yes,* *provide details including any special safety procedures:*

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**17. Are the transgenic plants noxious weeds or do they have the potential to outcross with noxious weeds?**

☐ Yes\*

☐ No

*\*If Yes,* *provide details including any special safety procedures:*

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**18. Are there any further special safety considerations associated with any of the recombinant or synthetic nucleic acids, gene products, vectors or hosts used in this research project?**

☐ Yes\*

☐ No

*\*If Yes,* *please describe:*

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**SECTION VIII. PERSONNEL AND TRAINING REQUIREMENTS**

*All laboratory personnel must be listed and complete the training below whether participating in the project or not.* ***FOR INSTRUCTIONAL LABS:*** *Students registered for the course and/or instructional lab, DO NOT require IBC training. Only PI’s/Faculty members who are the teacher of record, and the lab TA’s, require the appropriate IBC training that corresponds with the designated biosafety level.*

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| --- | --- | --- | --- | --- | --- | --- |
| **NAME** | **NetID** | **POSITION** | **GENERAL BIOSAFETY (For BSL-1 Done through EHSREM)****OR CITI Basic Biosafety** | **BLOODBORNE PATHOGEN*****If applicable* (Done through EHSREM)** | **BSL- 2*****If applicable* (Done through EHSREM)** | **PROJECT/LAB****SPECIFIC TRAINING *(CHOSEN BY THE LAB PI)*** |
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All laboratory personnel must complete the following Texas State Safety Training Courses offered on SAP before participating in laboratory research:

* Hazardous Waste Generator Training
* Hazard Communication and Laboratory Safety

**1. Has your facility had a satisfactory biosafety inspection by Environmental Health, Safety, Risk and Emergency Management (EHSREM) within the past 12 months** (including the resolution of any corrective action items)**? *\*Please note a biosafety inspection is different than quarterly inspections. \****

☐ Yes

☐ No

*\*If Yes,* *was it determined all personnel need to enroll and complete all requirements in the Occupational Health and Safety Program? (Only applies to personnel working with animals)*

☐ Yes

☐ No

**SECTION IX. PROJECT SUMMARY AND SAFETY PRECAUTIONS**

Describe the research project(s) in which the infectious agents, recombinant nucleic acids, plants, or vertebrate tissue will be used. The project summary should be written using non-technical terms and presented in a manner that be fully understood and evaluated by individuals outside of the researcher’s area of expertise. (Use additional pages as necessary).

## Description of the experimental goals:

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## Experimental design and procedures:

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## High risk procedures using biological materials listed in the protocol:

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| --- | --- | --- |
|  | **YES** | **NO** |
| Centrifugation |  |  |
| Sonication |  |  |
| Vortexing |  |  |
| Homogenization |  |  |
| Flaming inoculating loops |  |  |
| Use of a shaking incubator |  |  |
| Placing biological material under pressure (including in a syringe) |  |  |
| Use of needles or other sharps |  |  |
| Flow cytometry with live cells |  |  |
| Infection by means of aerosolization |  |  |
| Use of stereotaxic devices |  |  |
| Other\* |  |  |

\*If other, please describe below:

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## Assessment of biohazard potential and special safety considerations:

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## Containment conditions and procedures *(indicate Biosafety Cabinet Type, and last inspection date):*

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## ****Principal Investigator Certification****

 **As the Principal Investigator, I attest that the information in this application is complete and accurate. I agree that this study will be conducted in accordance with Texas State IBC Guidelines, NIH Guidelines, and the BMBL 6th Edition. I will request IBC approval before making any modification to the research procedures or forms. I understand that research will not be initiated until final IBC approval is received. I will notify the IBC of any unexpected or otherwise significant adverse events and general problems within one week of the incident.**

**I accept responsibility for the safe use of all potentially infectious organisms and have informed all personnel of the risks of exposures while working with these organisms and/or toxins. All personnel have been informed of potential risks, and proper laboratory practices for working safely with bloodborne pathogens and have had or have been given the opportunity for vaccination.**

**I understand that if these conditions are not met, this may result in suspension or termination of this research and/or not be recognized by Texas State University.**

**PI Signature:**

**PI Printed Name:**

## FOR OFFICIAL USE ONLYTo be filled out by RIC ONLY

Type of Review:

Reviewers assigned to the protocol:

Date of approval:

Expiration Date: