University of Texas at San Antonio

Institutional Biosafety Committee – Protocol Application

All IBC applications must be submitted by email as a MS Word Document to ibc@utsa.edu. Further information can be found on the [IBC webpage](http://research.utsa.edu/research-funding/institutional-biosafety-committee-ibcnew/) or by contacting the IBC office at 210-458-8515.

# ADMINISTRATIVE INFORMATION AND CERTIFICATIONS

|  |  |
| --- | --- |
| Principal Investigator |  |
| Co-PI (If applicable) |  |
| Department |  |
| Phone Number |  |
| E-Mail Address |  |
| Location of Project (Bldg / Room #) |  |
| Project Title |  |

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

|  |
| --- |
|  |

**Application type**

|  |  |
| --- | --- |
|  | Research Application |
|  | Teaching Laboratory Application | Course Number: |  |
|  | NEW |  | RENEWAL |  | AMENDMENT | Protocol Number  |  |

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

|  |  |
| --- | --- |
|  | Vertebrate tissue or fluids |
|  | Toxins |
|  | Microbial agents and 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 |
|  | Biosafety Level 2 |
|  | Biosafety Level 2+ |
|  | Biosafety Level 3 |

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

|  |  |
| --- | --- |
|  | Laboratory Coat |
|  | Splash Resistant Eye Protection |
|  | Gloves |
|  | Respiratory Protection | Type |  |
|  | Other \* |
| \* If OTHER, please describe below |
|  |

**Permit details – please indicate if any of the following permits are required for this study to proceed**

|  |  |  |  |
| --- | --- | --- | --- |
|  | USDA Permit | Permit Number |  |
|  | APHIS Permit | Permit Number |  |
|  | Other (Specify) | Permit Number |  |

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

|  |  |
| --- | --- |
|  | YES |
|  | NO |

**Committee Approvals – please indicate if IACUC and / or IRB approval is required for this study to proceed**

|  |  |  |  |
| --- | --- | --- | --- |
|  | IACUC | Protocol Number |  |
|  | IRB | Protocol Number |  |

**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 (e.g. for BSL-3 users, describe your waste disposal protocol).

* **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.
* 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 EHSRM. When ¾ full EHSRM will be notified to pick up the container(s) for proper waste disposal. Samples requiring autoclaving will be processed prior to collection by EHSRM.
* All work surfaces will be cleaned, after use, with an appropriate disinfectant.

|  |  |
| --- | --- |
|  | YES |
|  | NO\* |
|  | OTHER\* (BSL-3 users should describe additional waste disposal protocols below) |

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

* **Disposal of Animal Waste for LARC Users**

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 associated with each of the LARC vivaria. Waste will then be collected by EHSRM and processed for proper waste disposal. Contact LARC (larc@utsa.edu) for assistance with this process.

|  |  |
| --- | --- |
|  | YES |
|  | NO\* |
|  | OTHER\* (BSL-3 users should describe additional waste disposal protocols below) |

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

**Shipping and Transportation**

## Will samples be shipped from UTSA to other institutions?

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |

If shipping samples from UTSA 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 UTSA.

|  |  |
| --- | --- |
|  | YES |
|  | NO\* |
|  | OTHER\* |

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

## If transporting samples to or from UTSA 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 shipping 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\* |
|  | Not Applicable |
|  | OTHER\* |

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

**Certification**

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

|  |
| --- |
| [ ]  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 5th Edition](https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf) and guidelines established by the NIH, CDC 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 the Biosafety Officer (x6101) 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. |

Date: Click or tap to enter a date.

# SECTION A – BIOLOGICAL TOXINS

List of toxins of a biological origin in this section.

## Toxin Name

|  |
| --- |
|  |

## LD50 and species determined in

|  |
| --- |
|  |

## What form will the toxin be obtained in

|  |  |
| --- | --- |
|  | Liquid |
|  | Solid / Powder |
|  | Other\* |
| \*If other provide details below |
|  |

## Will sharps be used in procedures involving toxins?

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |
| \* If yes provide details below |
|  |

## Will you be administering the toxin to animals?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## How will the toxin be administered

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Intravenous |  | Intraperitoneal |  | Subcutaneous |  | Other\*  |
|  | Intranasal |  | Aerosol |  | Intramuscular |  |  |

\* If OTHER, please explain:

|  |
| --- |
|  |

## Is this a Select Agent Toxin?

|  |  |
| --- | --- |
|  | YES\*  |
|  | NO |

**\* If YES, please read and check the following statements**

Will the toxin be kept in exempt quantities?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

Will the toxin be kept in secure storage?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

Will an accurate inventory of all toxins be maintained?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

# SECTION B – USE OF VERTEBRATE OR INVERTEBRATE TISSUE OR FLUIDS (INCLUDES CELL LINES)

## List the tissue, fluid or cell line and the species from which it is derived

|  |
| --- |
|  |

## Does the tissue contain a known infectious agent?

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |
| \*If YES, list all known infectious agents – cell lines from commercial sources may be contain known viruses that should be included here. Please check with the vendor to verify (e.g. HeLa cells contain strains of HPV) |
|  |

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

|  |
| --- |
|  |

# SECTION C – MICROBIAL OR INFECTIOUS AGENTS

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. Supervisors 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 ibc@utsa.edu.

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

|  |
| --- |
|  |

## Risk Group (Note: the Risk Group may not always correspond to the Biosafety Level)

|  |
| --- |
| **RISK GROUP** |
|  | Risk Group 1 |
|  | Risk Group 2 |
|  | Risk Group 3 |

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

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## Are any of the agents listed classified as Select Agents?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## Will the agent be modified either at UTSA or at the point of origin? (If YES, complete section D)

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## If the agent is a BSL-3 agent will any biological material be removed from the BSL-3 facility?

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |
| \*If YES, describe the method used to inactivate the sample and the method used to confirm the inactivation. |
|  |

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

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |
| \*If YES, list the species |
|  |

## How will the agent be administered?

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Intravenous |  | Intraperitoneal |  | Subcutaneous |  | Other\*  |
|  | Intranasal |  | Aerosol |  | Intramuscular |  |  |

\* If OTHER, please explain:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

## Will the agent be used to infect vertebrate tissue (cell lines)? If YES, complete Section B

|  |  |
| --- | --- |
|  | YES |
|  | NO |

# SECTION D – USE OF RECOMBINANT OR SYNTHETIC NUCLEIC ACIDS AND / OR TRANSGENIC ORGANISMS

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

## 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](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html) (e.g. III-D-3-a) under which you believe this research is covered

|  |
| --- |
|  |

## Will this project use CRISPR or related technologies?

|  |  |
| --- | --- |
|  | YES (**If YES please attach Appendix A with this application**) |
|  | NO |

## Will proteins or regulatory RNA’s be expressed?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## 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, provide details |
|  |

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

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## Will any expressed proteins be a toxin known to affect vertebrates? (If YES, complete Section A)

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## Will the recombinant nucleic acid be inserted into a vector

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## What vector system will be used?

|  |
| --- |
|  |

## Is the vector replication competent?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## Will a packaging or helper system be used?

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## Describe the packaging / helper system to be used:

|  |
| --- |
|  |

## Description of recombinant / synthetic work:

Please complete, a separate spreadsheet may be attached if necessary.

|  |  |  |
| --- | --- | --- |
| **GENE NAME** | **BIOLOGICAL SOURCE (mouse, bacteria, virus etc.)** | **BIOLOGICAL ACTIVITIES OF THE PRODUCT** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## 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

|  |
| --- |
|  |

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

|  |  |
| --- | --- |
|  | YES |
|  | NO |

## 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 |
|  |

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

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |
| \*If YES please describe: |
|  |

# SECTION E – PERSONNEL

All laboratory personnel must be listed and complete the training below whether participating in the project or not.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **NAME** | **UTSA ID** **(abc123)** | **POSITION** | **SA401** | **SA443.01** | **SA483****SA483r** | **PROJECT SPECIFIC** **TRAINING** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

All laboratory personnel must complete the following UTSA Safety Training Courses before participating in laboratory research:

* **SA 401**  Hazardous Waste Generator’s Training
* **SA 443.01** Hazard Communication and Laboratory Safety
* **SA 483** Biosafety and Bloodborne Pathogens Training (must be renewed once every 12 months, which can be accomplished by taking **SA 483r**, the refresher course. The full **SA 483** should be taken initially, the refresher in the following years).

## Is prior immunization required to work with the material in this project?

|  |  |
| --- | --- |
|  | YES\* |
|  | NO |
| \*If YES, provide details of the immunizations and how personnel will be monitored |
|  |

# SECTION F – 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:

|  |
| --- |
|  |

## Experimental design and procedures:

|  |
| --- |
|  |

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

|  |  |  |
| --- | --- | --- |
|  | **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 is selected please describe below:

|  |
| --- |
|  |

## Assessment of biohazard potential and special safety considerations:

|  |
| --- |
|  |

## Containment conditions and procedures:

|  |
| --- |
|  |

# SECTION G – DUAL USE RESEARCH

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.  The United States Government’s oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research. For further information visit the [NIH website](http://osp.od.nih.gov/sites/default/files/resources/EducationalBrochureDualUseResearch.pdf).

Please read the questions below and answer. NOTE: If the answer to any of the questions below is ‘YES’ further guidance must be sought from NIH, please contact the IBC office immediately at 210-458-8515.

Will the project:

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| 1. Enhance the harmful consequences of the agent or toxin
 |  |  |
| 1. Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.
 |  |  |
| 1. Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies
 |  |  |
| 1. Increase the stability, transmissibility, or the ability to disseminate the agent or toxin
 |  |  |
| 1. Enhance the susceptibility of a host population to the agent or toxin
 |  |  |
| 1. Generate or reconstitute an eradicated or extinct agent or toxin
 |  |  |
| 1. Alter the host range or tropism of the agent or toxin
 |  |  |

I agree to abide by all the measures laid out in the University of Texas at San Antonio’s Dual Use Research of Concern Policy. In the event that the project or results change in any way as to alter the DURC status the research will cease and the IBC Chair will be notified immediately.

|  |  |
| --- | --- |
|  | I agree |

**IBC OFFICE USE ONLY**

**DATE RECEIVED:** Click or tap to enter a date.

**REVIEW DATE:** Click or tap to enter a date.

**SCORE:** Choose an item.

**REVISIONS RECEIVED:** Click or tap to enter a date.

**APPROVAL DATE:** Click or tap to enter a date.

**EXPIRATION DATE:** Click or tap to enter a date.