University of Texas at San Antonio

**Institutional Biosafety Committee Application**

All IBC applications must be submitted by email as a MS Word Document to [ibc@utsa.edu](mailto: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.

# PROJECT DETAILS

|  |  |  |  |
| --- | --- | --- | --- |
| **PROJECT DIRECTOR** |  | **PHONE** |  |
| **DEPARTMENT** |  | **EMAIL** |  |

|  |  |
| --- | --- |
| **PROJECT TITLE** |  |

|  |
| --- |
| **PROJECT DESCRIPTION** (Please give a brief description of the project in non-technical terms) |
|  |

# TYPE OF APPLICATION

### Mark an ‘X’ in the box that best describes the type of application

|  |  |  |  |
| --- | --- | --- | --- |
|  | **RESEARCH APPLICATION** |  | |
|  | **TEACHING LABORATORY APPLICATION** | **COURSE NUMBER:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **NEW PROTOCOL** |  | |
|  | **RENEWAL OF EXISTING PROTOCOL** | **PROTOCOL NUMBER:** |  |
|  | **AMENDMENT OF EXISTING PROTOCOL** | **PROTOCOL NUMBER:** |  |

### Please indicate whether the project you are proposing uses any of the following materials and complete the corresponding section(s):

|  |  |
| --- | --- |
|  | **Microbial Agents or Infectious Agents – Section A** |
|  | **Toxins – Section B** |
|  | **Recombinant Nucleic Acids, Synthetic Nucleic Acids and/or Transgenic Organisms – Section C** |
|  | **Vertebrate Tissue or Fluids (including human or other primate cell lines) – Section D** |

Sections E, F, G, H, I and J must be completed for **every** application.

Project submissions are forwarded to the full Institutional Biosafety Committee (IBC) for review, comment, and approval. The IBC is composed of scientists and community representatives that *may not be experts in your particular field of research*. **Please tailor your responses on the registration form accordingly.** We must obtain sufficient information to determine required containment level, facilities, procedures, practices, and expertise/training necessary for the safe conduct of the project, therefore **please be thorough.** Insufficient information/incomplete forms will delay the approval process and the form will be returned to you for revision. **Please utilize the fillable document and type the form; hand written forms are not accepted. If you have any questions, please contact the Laboratory Compliance Manager 458-8515 or** [**ibc@utsa.edu**](file:///\\UTFILE\groups\IBC\04-01-15\ibc@utsa.edu)**.**

# CERTIFICATION

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 provisions and guidelines established by the NIH, CDC, and UTSA Institutional Biosafety Committee, that pertain to the research project described in this application.

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

**DATE:**

# OTHER COMMITTEES AND PERMIT DETAILS

Please complete all sections below.

# IACUC APPROVAL

If any part of the study described in the application uses vertebrates or vertebrate material and requires IACUC approval please complete the following questions:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is IACUC approval required for this project? |  | **YES** |  | **NO** |

### If YES, indicate the status of your IACUC protocol:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Not Submitted** |  | **Submitted** |  | **Approved** |

### IACUC Protocol Number:

### If the study generates transgenic animals indicate the status of your IACUC appendix B:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Not Submitted** |  | **Submitted** |  | **Approved** |

# IRB APPROVAL

If any part of the study described in the application uses human subjects or materials and requires IRB approval please complete the following questions:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is IRB approval required for this project? |  | **YES** |  | **NO** |

### If YES, indicate the status of your IRB protocol:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Not Submitted** |  | **Submitted** |  | **Approved** |

### IRB Protocol Number:

# USDA PERMIT

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is a USDA permit required for this project? |  | **YES** |  | **NO** |

### If YES, indicate the status of the USDA permit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Applied for** |  | **Approved** |  | **Not yet applied for** |

### USDA Permit Number:

# APHIS PERMIT

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is an APHIS permit required for this project? |  | **YES** |  | **NO** |

### If YES, indicate the status of the APHIS permit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Applied for** |  | **Approved** |  | **Not yet applied for** |

### APHIS Permit Number:

# CDC SELECT AGENT APPROVAL

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does this study make use of [Select Agents](http://www.selectagents.gov/SelectAgentsandToxinsList.html) or toxins |  | **YES** |  | **NO** |

### If YES, provide the CDC Select Agent Approval Number:

# SECTION A – MICROBIAL AGENTS OR INFECTIOUS AGENT

# 1. DESCRIPTION OF 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](mailto:Jose.LopezRibot@utsa.edu) or [ibc@utsa.edu](mailto:ibc@utsa.edu).

## List all agents:

|  |
| --- |
|  |

## Risk Group and Biosafety Level:

|  |  |  |  |
| --- | --- | --- | --- |
| **RISK GROUP** | | **BIOSAFETY LEVEL** | |
|  | **Risk Group 1** |  | **Biosafety Level 1** |
|  | **Risk Group 2** |  | **Biosafety Level 2** |
|  | **Risk Group 3** |  | **Biosafety Level 2+** |
|  |  |  | **Biosafety Level 3** |

## Is this agent classified as a [Select Agent](http://www.selectagents.gov/SelectAgentsandToxinsList.html) by the CDC?

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

## How will the agent be acquired (check all that apply)?

|  |  |
| --- | --- |
|  | **Already in the lab** |
|  | **Purchased from a commercial vendor** |
|  | **Acquired from a collaborator at UTSA** |
|  | **Acquired from a collaborator outside of UTSA** |
|  | **Other (explain)\*** |

**\* If OTHER, please explain:**

|  |
| --- |
|  |

## Will the agent be modified either at UTSA or at the point of origin?

|  |  |
| --- | --- |
|  | **YES** |
|  | **NO** |
| **If YES, explain the nature of the intended modification and complete Section C of the application.** | |
|  | |

## Will these genetic modifications increase the virulence or expand the host range of the agent?

|  |  |
| --- | --- |
|  | **YES** |
|  | **NO** |
| **If YES, describe and complete Section J of the application.** | |
|  | |

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

|  |  |
| --- | --- |
|  | **YES** |
|  | **NO** |
| **If YES, describe the method used to inactivate, and confirm inactivation of the samples. Detail where samples will be stored until decontamination has been confirmed.** | |
|  | |

# 2. USE OF MICROBIAL OR INFECTIOUS AGENTS IN VERTEBRATES

## Will the agent be administered (modified or unmodified) to animals?

|  |  |
| --- | --- |
|  | **YES** (If YES, please complete Section C and D of the application) |
|  | **NO** |

## List the animal species that will be infected:

|  |
| --- |
|  |

## How will the agent be administered?

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

**\* If OTHER, please explain:**

|  |
| --- |
|  |

## Does the procedure have a potential for generating aerosols?

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

## Where will infected animals be housed (building and room number)?

|  |
| --- |
|  |

## Describe the protocol (include any specific safety considerations):

|  |
| --- |
|  |

# 3. USE OF MICROBIAL OR INFECTIOUS AGENTS IN PLANTS

## Will the agent be administered (modified or unmodified) to plants?

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

## List the plant species that will be infected:

|  |
| --- |
|  |

## How will the agent be administered?

|  |
| --- |
|  |

## Does the procedure have a potential for generating aerosols?

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

## Where will the infected plants be housed (building and room number)?

|  |
| --- |
|  |

## Describe the protocol (include any special safety considerations):

|  |
| --- |
|  |

# 4. USE OF MICROBIAL OR INFECTIOUS AGENTS IN VERTEBRATE TISSUE

## Will the agent be administered (modified or unmodified) to vertebrate tissue?

|  |  |
| --- | --- |
|  | **YES** (If YES, please complete Section D of the application) |
|  | **NO** |

## What tissue will be used?

|  |
| --- |
|  |

## How will the tissue be acquired (check all that apply)?

|  |  |
| --- | --- |
|  | **Already in the lab** |
|  | **Purchased from a commercial vendor** |
|  | **Acquired from a collaborator at UTSA** |
|  | **Acquired from a collaborator outside of UTSA** |
|  | **Other (explain)\*** |

**\* If OTHER, please explain:**

|  |
| --- |
|  |

## How will the agent be administered?

|  |
| --- |
|  |

## Does the procedure have a potential for generating aerosols?

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

## Does the tissue contain any other known infectious agents?

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

**\* If YES, list all the agents present:**

|  |
| --- |
|  |

## Describe the protocol (include any special safety considerations):

|  |
| --- |
|  |

# SECTION B - TOXINS

# 1. DESCRIPTION OF TOXINS

## Name of Toxin:

|  |
| --- |
|  |

## LD50 and species determined in:

|  |
| --- |
|  |

## In what form will the toxin be obtained:

|  |  |
| --- | --- |
|  | **Liquid** |
|  | **Solid / Powder** |
|  | **Other\*** |

**\* If OTHER, please explain:**

|  |
| --- |
|  |

## If this is a Select Agent Toxin will the total, cumulative, amount held in the laboratory be an [exempt quantity](http://www.selectagents.gov/PermissibleToxinAmounts.html) ?

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

## If this is a Select Agent Toxin (in either exempt or non-exempt quantities) does the facility have secure storage?

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

## Will an accurate inventory of all toxins be maintained?

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

## Will needles or other sharps be used in the procedures involving toxins?

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

# 2. USE OF TOXINS IN ANIMALS

## Will you be administering the toxin to animals?

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

## If YES, what animal species will be used?

|  |
| --- |
|  |

## How will the toxin be administered?

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

**\* If OTHER, please explain:**

|  |
| --- |
|  |

## Does the procedure have the potential for generating aerosols?

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

## Where will the infected animals be housed (building and room number)?

|  |
| --- |
|  |

## Describe the protocol (include any special safety considerations):

|  |
| --- |
|  |

# SECTION C – USE OF RECOMBINANT NUCLEIC ACIDS, SYNTHETIC NUCLEIC ACIDS AND / OR TRANSGENIC ORGANISMS.

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

# 1. CATEGORIZATION OF EXPERIMENTS ACCORDING TO THE NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT AND / OR SYNTHETIC NUCLEIC ACIDS.

Please select the specific subsection(s) from Section III of the [NIH Guidelines](https://osp.od.nih.gov/biotechnology/nih-guidelines/) (e.g. III-D-3-a) under which you believe this research is covered

|  |
| --- |
|  |

# 2. DESCRIPTION OF RECOMBINANT / SYNTHETIC NUCLEIC ACIDS

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

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

## Is the source of the DNA / nucleic acids associated with alterations of normal cell cycle or cell growth (i.e. a potentially oncogenic or tumorigenic gene)?

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

**\* If YES, please describe:**

|  |
| --- |
|  |

## Will you use any nucleic acid that is replication competent or able to replicate in a living cell?

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

## Will any expressed proteins be a toxin known to affect vertebrates?

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

## Please provide the following information:

### Gene name(s) and acronym(s) if appropriate:

### Biological source / origin (mouse, virus, bacteria etc.):

### All pertinent biological activities of the products (normal function, oncogenic potential, toxicity etc):

|  |
| --- |
|  |

# 3. DESCRIPTION OF VECTORS

## Will the recombinant nucleic acid be inserted into a virus, replicon, bacterial plasmid, BAC or other vector system?

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

## Identify the vector:

|  |
| --- |
|  |

## What containment level will be used for experiments involving this vector?

|  |  |
| --- | --- |
|  | **Biosafety Level 1** |
|  | **Biosafety Level 2** |
|  | **Biosafety Level 2+** |
|  | **Biosafety Level 3** |

## If the vector is a virus, 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:

|  |
| --- |
|  |

# 4. CELL CULTURE HOSTS

## Will nucleic acids be inserted into a prokaryotic or eukaryotic host cell?

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

## Identify the host(s):

|  |
| --- |
|  |

## What containment level will be used for experiments involving this host?

|  |  |
| --- | --- |
|  | **Biosafety Level 1** |
|  | **Biosafety Level 2** |
|  | **Biosafety Level 2+** |
|  | **Biosafety Level 3** |

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

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

# 5. ANIMAL HOSTS

## Will nucleic acids be introduced into animals (i.e. as a recombinant virus or expression plasmid) or used to produce transgenic animals?

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

## Describe the procedure (include any special safety considerations):

|  |
| --- |
|  |

# 6. PLANT HOSTS

## Will nucleic acids be introduced into plants (i.e. as a recombinant virus or expression plasmid) or used to produce transgenic plants?

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

## Describe the procedure (include any special safety considerations):

|  |
| --- |
|  |

# 7. SPECIAL SAFETY CONSIDERATIONS

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

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

**\* If YES, please describe:**

|  |
| --- |
|  |

# SECTION D – USE OF VERTEBRATE TISSUE OR FLUIDS INCLUDING HUMAN OR OTHER PRIMATE CELL LINES.

**NOTE:** If the tissue contains a known infectious agent then Section A of this application must also be completed.

# 1. DESCRIPTION OF VERTEBRATE TISSUE OR FLUID

## Name the tissue, fluid or cell line to be used in the project and the species from which it is derived:

|  |
| --- |
|  |

## Does the tissue contain a known infectious agent?

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

## If YES, list all infectious agents:

|  |
| --- |
|  |

## How will the tissue be acquired (check all the apply)?

|  |  |
| --- | --- |
|  | **Already in the lab** |
|  | **Purchased from a commercial vendor** |
|  | **Acquired from a collaborator at UTSA** |
|  | **Acquired from a collaborator outside of UTSA** |
|  | **Collection in the field** |
|  | **Other (explain)\*** |

**\* If OTHER, please explain:**

|  |
| --- |
|  |

## What safety procedures should personnel take to protect themselves from this material?

|  |
| --- |
|  |

## Will universal safety precautions be taken?

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

# SECTION E – PERFORMANCE SITE

# 1. LOCATION OF WORK AND FACILITY SUITABILITY

## Identify the location of the research laboratories, common use facilities, and any other area in which the infectious agents, recombinant / synthetic nucleic acids, animals, vertebrate tissue or plants will be used.

|  |
| --- |
|  |

## Where will infectious agents, recombinant / synthetic nucleic acids, vertebrate tissue or plants be stored?

|  |
| --- |
|  |

## Are these facilities properly designed and equipped for performing research under the Biosafety Level conditions required for this research project?

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

## If NO, explain:

|  |
| --- |
|  |

# SECTION F – LABORATORY PERSONNEL

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **NAME** | **UTSA ID**  **(abc123)** | **POSITION** | **SA401** | **SA443.01** | **SA483**  **SA483r** | **PI SPECIFIC**  **TRAINING** | **PARTICIPATING IN THE PROJECT (Y/N)** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

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).

Check the **PI training** column if staff have received additional training specific to the project from the PI.

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

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

## If YES, explain immunization status and monitoring of laboratory personnel:

|  |
| --- |
|  |

# SECTION G – SHIPPING AND TRANSPORTING

## Will samples be shipped or transported to or from UTSA?

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

## Are items being shipped to UTSA only (i.e. from a commercial vendor)?

|  |  |
| --- | --- |
|  | **YES** (If YES, C below is not required) |

## If shipping samples from UTSA to other institutions / commercial 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 other sites by methods other than standard shipping 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\*** |
|  | **OTHER\*** |

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

## If applicable, describe any other special shipping / transportation conditions:

|  |
| --- |
|  |

# SECTION H – TERMINAL INACTIVATION AND WASTE DISPOSAL

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).

# 1. DISPOSAL OF LIQUID AND SOLID BIOLOGICAL WASTE (INCLUDING PLANTS)

**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\*** |

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

# 2. 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](mailto:larc@utsa.edu)**) for assistance with this process.**

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

## \*If NO or OTHER, explain:

|  |
| --- |
|  |

# 3. SPECIAL WASTE DISPOSAL REQUIREMENTS (If applicable)

**Please describe:**

|  |
| --- |
|  |

# SECTION I – 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).

# 1. PROJECT DESCRIPTION

## Description of the experimental goals:

|  |
| --- |
|  |

## Experimental Design and Procedures:

|  |
| --- |
|  |

## Assessment of Biohazard Potential:

|  |
| --- |
|  |

## Containment Conditions and Procedures:

|  |
| --- |
|  |

## P.P.E Worn

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Laboratory Coat** |  | | | | | |
|  | **Eye Protection** | **Splash Resistant** | |  | | **Impact Resistant** |  |
|  | **Gloves** |  | | | | | |
|  | **Respiratory Protection** | **Describe** (e.g. N95)**:** | | |  | | |
|  | **Other** | **Describe:** |  | | | | |

## Special Safety Considerations:

|  |
| --- |
|  |

# 2. HIGH-RISK PROCEDURES INVOLVING BIOLOGICAL MATERIALS

|  |  |  |  |
| --- | --- | --- | --- |
| **The procedures listed below could result in a exposure to biohazardous materials through:**   1. **Aerosols** 2. **Splashes / Sprays** 3. **Physical Injury (e.g. Needlestick)** | **Identify procedures performed by checking YES /NO** | | **Biohazardous materials used during these procedures.** |
|  | **YES** | **NO** |  |
| **Example: Centrifugation** | **X** |  | **Live Human Cells, Lentivirus** |
| **Centrifugation** |  |  |  |
| **Sonication** |  |  |  |
| **Vortexing** |  |  |  |
| **Homogenization** |  |  |  |
| **Flaming of inoculating loops** |  |  |  |
| **Use of a shaking incubator** |  |  |  |
| **Placing biohazardous materials under pressure** |  |  |  |
| **Use of needles** |  |  |  |
| **Use of sharps other than needles** |  |  |  |
| **Intranasal inoculation of animals** |  |  |  |
| **Necropsy of biohazardous animals** |  |  |  |
| **Fluorescence activated cell sorting / analysis (live cells only)** |  |  |  |
| **Use of stereotactic devices / specialty equipment** |  |  |  |
| **Imaging of live cells** |  |  |  |
| **Other\*** please specify below |  |  |  |

**\*Specify other high risk activity, if not listed above:**

|  |
| --- |
|  |

# SECTION J – DUAL USE RESEARCH OF CONCERN

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 [DURC NIH website](https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/).

## 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:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Enhance the harmful consequences of the agent or toxin | **YES** |  | **NO** |  |
| 1. Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification | **YES** |  | **NO** |  |
| 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 | **YES** |  | **NO** |  |
| 1. Increase the stability, transmissibility, or the ability to disseminate the agent or toxin | **YES** |  | **NO** |  |
| 1. Alter the host range or tropism of the agent or toxin | **YES** |  | **NO** |  |
| 1. Enhance the susceptibility of a host population to the agent or toxin | **YES** |  | **NO** |  |
| 1. Generate or reconstitute an eradicated or extinct agent or toxin | **YES** |  | **NO** |  |

**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** |