# Cover Page

|  |
| --- |
| FOR INTERNAL USE ONLY |
| IBC #: IBC # |
| AUP # (if applicable): AUP # |
| IRB # (if applicable): IRB # |

 **Principal Investigator/Instructor Information**

PI Last Name: Last name PI First Name: First name

PI Department: Select department

Title of the Project: Enter project tile

Project Description: Enter a brief, non-technical project description

Requested BSL: Select BSL being requested

Office

Building: Select building Room: Enter room number

Phone numbers

Office: Enter office phone number Laboratory: Enter lab phone number Cell: Enter cell phone number

Email: Enter A&M-SA email address (Please provide your official university email.)

**Collaborators** (to add another, mouse over any area between “Last Name” and “Email”, click in the grey box, then click the blue “+” sign)

Last Name: Last name First Name: First name

Department: Select department

Office

Building: Select building Room: Enter room number

Phone numbers

Office: Enter office phone number Laboratory: Enter lab phone number Cell: Enter cell phone number

Email: Enter A&M-SA email address (Please provide their official university email.)

|  |
| --- |
| **Type of application (check all that apply)** |
| [ ]  Research |
| [ ]  Teaching | Course name and number: Course name and number |
| [ ]  New application |
| [ ]  Amendment of existing protocol | IBC protocol number: IBC number |

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# PART I: Application for IBC Permit

## Section 1 Principal Investigator/Instructor Assurances

Initials • I attest that the information contained in this registration is accurate and complete.

Initials • I agree to comply with all Texas A&M University-San Antonio (A&M-SA) Institutional Biosafety Committee (IBC) requirements regarding research involving biohazardous and/or recombinant materials.

Initials • I agree not to initiate any research subject to IBC approval without prior approval from the IBC.

Initials • I agree to notify the IBC via email at ibc@tamusa.edu immediately of accidents or spillages involving biohazardous and/or recombinant agents. (Definition of agent: [click here](#G._Agent_Characteristics.__Does_this_pro).)

Initials • I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the latest version of the *NIH Guidelines available here:* <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>

Initials • I have the knowledge, experience, and training required to safely handle the materials described in this application.

Initials • I agree to train all of my laboratory personnel according to the designated biosafety level (BSL) of the laboratory, submit and maintain documentation of training, and enroll everyone in a health assessment, if appropriate.

Initials • Entry doors to the laboratory will be monitored and closed when laboratory personnel are present and locked when the laboratory is unattended.

Initials • I agree to provide all personnel working in the laboratory notification, information, and training on the hazards, laboratory security, emergency policies, required personal protective equipment (PPE), and procedures associated with working in my laboratory. **I agree to inform all personnel working in the laboratory that potentially all microorganisms can be pathogens under certain conditions. When necessary, work procedures and protocols are in place to prevent aerosols and exposure to microorganisms. All personnel are provided training in sterile techniques, the use of automatic pipetters, if necessary, and the proper disposal of biohazardous materials. All personnel are advised that if they are in an immunocompromised/immunosuppressed condition that they are at risk for infection from the general environment and susceptible to infections that would normally not be a problem for an immunocompetent individual. All personnel are further advised that working in a laboratory that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health.**

***All signatures are required prior to submission.***

Select dateEnter PI’s Name

Signature of PI Date Typed/Printed Name

Select dateEnter Chair’s Name

Signature of Department Chair Date Typed/Printed Name

## Section 2 Application for IBC Permit

Research involving any of the agents listed below must be approved by the Texas A&M University-San Antonio IBC **prior to initiation**:

* Pathogens and potential pathogens of humans, animals, or plants;
* Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines, and environmental samples that may contain biohazardous agents or substances.);
* Recombinant DNA (and RNA) including the creation or the use of transgenic plants and animals;
* Select agents and toxins (see <http://www.selectagents.gov>) including strains and amounts exempted from the select agent regulations;
* Any material requiring a CDC import license or a USDA permit.

The Principal Investigator (PI) or the course Instructor is responsible for completing all appropriate parts of this registration document and for notifying the IBC when information submitted in this document changes, such as personnel, laboratory location, procedures, funding, etc. If such changes occur, the PI/Course Instructor will be required to fill out an Amendment Form (located online).

Protocols are currently approved for the duration of three (3) years with annual renewals and laboratory inspections.

**Only typed forms will be accepted**. For your convenience, each required form is available electronically. Only the most current forms will be accepted and reviewed; therefore we ask that you access our website for all submissions [https://www.tamusa.edu/graduate-studies- research/research/institutional-biosafety-committee/forms.html,](https://www.tamusa.edu/graduate-studies-%20research/research/institutional-biosafety-committee/forms.html) Prior to initiation of research, the application must be approved by the IBC. The application must be complete, which includes signatures of all appropriate personnel, and submitted to the IBC via email (ibc@tamusa.edu) for approval. At the time of submission, you are asked to also submit all (if applicable) grant proposals pertaining to your research. If the application for an IBC permit is for research, the application will be compared administratively to the grant proposal to ensure the research activities described in both documents align with one another. A course syllabus is required if the permit is for teaching a laboratory course. Failure to provide all information requested, including requested signatures, will lead to a delay in processing your application. If further instructions are necessary, please contact the IBC at ibc@tamusa.edu or call (210) 784-2344.

**INITIAL SUBMISSION ONLY:** please submit a signed copy of Part I (PI and Dep. Chair) as a PDF in addition to the working Word document.

**Resubmissions:** Revisions must be submitted within 30 days of receiving feedback. Failure to respond will result in withdrawal of the permit application. PI’s may resubmit an application and will undergo *de novo* review. PI’s may request a one-time, 30-day extension. Written extension requests are to be submitted to the Office of Research Compliance (ibc@tamusa.edu). Requests will be evaluated on a case-by-case basis and are subject to approval by the IBC Chair. All future resubmissions are to be Word documents ONLY with the “track changes” function enabled. **Failure to enable track changes will result in the application being returned to the PI without further review** until a version with that feature enabled has been submitted.

**Checklist and Table of Contents for Institutional Biosafety Protocols**

The following is a table of contents of the items included in an application for an IBC permit. In order for research to be approved, you must provide all applicable sections to the IBC, and a copy of the grant proposal and/or course syllabus. **Please check and attach all items that apply to your research or laboratory course, if applicable.**

Parts I, II, IV, and the Risk Assessment forms are required for every submission. Risk assessments must be completed and submitted for every biological agent listed in this application. Part III, proof of enrollment in the Occupational Health Program, a Shared Space Form, a Shipping and Transportation Form, and a copy of the grant proposal or course syllabus should be completed and submitted as applicable. **Only typed and complete applications (including training documentation) will be processed for review.**

Please send completed applications for IBC permits to the **Office of Research Compliance.**

The office may be contacted at (210) 784-2344 or by email at ibc@tamusa.edu.

Please allow sufficient time for processing your application.

**It may take 60-90 days to obtain IBC approval.**

Your protocol will not be forwarded for review if it is incomplete.

|  |
| --- |
|[ ]  [Part I:](#_PART_I:_Application) Application for IBC Permit (required for **all applications**, including signature of department chair) |
|[ ]  [Part II:](#_PART_II:_Agent) Agent Information (required for **all applications**) |
|[ ]  [Part III:](#_PART_III:_Viral) Viral Vectors (required **if applicable**) |
|[ ]  [Part IV:](#_PART_IV:_Personnel) Personnel Information (required for **all applications**) and confirmation of training |
|[ ]  Proof of enrollment in the Occupational Health Program. Information found at [Research and](https://www.tamusa.edu/graduate-studies-research/research/research-academic-environmental-health-safety-office/occupational-health-program.html) [Academic Environmental Health & Safety Office - Occupational Health Program](https://www.tamusa.edu/graduate-studies-research/research/research-academic-environmental-health-safety-office/occupational-health-program.html) (required for **BSL-2 and above applications ONLY**) |
|[ ]  [Risk Assessment Form(s):](#_PI_Risk_Assessment) Complete a separate form for each Agent listed in Part II Table A. (required for **all applications**) |
|[ ]  [Shared Space Form](#_Shared_Space_Form) (If applicable. Required if PI shares lab space with another faculty member or if work will be conducted in another faculty member’s lab including the teaching labs.) |
|[ ]  [Shipping and Transportation Form](#_Shipping_and_Transportation) (**if applicable,** an ORC form ([available here](https://www.tamusa.edu/graduate-studies-research/research/institutional-biosafety-committee/forms.html)) must be approved by the Office of Research Compliance before samples can be transported.) |
|[ ]  Grant Proposal (and approval letter, **if applicable**) or Course Syllabus (required **if applicable**) |

## Protocol Information

### Funding Source.

Please check all that apply and include it with your application.

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  NIH |  [ ]  NSF | [ ]  DOD |  [ ]  USDA |
| [ ]  A&M-SA Enter source  | [ ]  Other Enter source  |

### Grant Proposal or Course Syllabus. (if applicable)

Please include a copy of all grants associated with this IBC permit. The submission should include all sections of the grant that contain information pertaining to the research.

PI (if different from this application’s PI): Grant PI if different than the PI submitting this application

Grant title(s): Enter grant title

Instructor name if course-related: Enter the instructor of the course

Course number and name: Enter course name and number

Frequency the course is offered: [ ]  every semester, [ ]  once per year, [ ]  other (please explain)

|  |
| --- |
| Enter explanation for “Other” |

### Non-technical description of the project.

In the space below, in terms understandable to a **non-scientist**,please provide a brief summary of this project or course and describe its broader purpose, goal(s), methodology, and the use of biohazardous and/or recombinant material. The appropriate reading level for this summary is approximately at the 8th-grade level. This level can be determined by activating the readability statistics option in Microsoft Word. This section should not be copied from a proposal (e.g. the introduction).

|  |
| --- |
| Enter description |

### Technical description of the project.

Please provide a technical description in the space below. Provide information detailed enough so that IBC members can perform a risk assessment of your protocol. This section needs to focus on any biohazards that your procedures may involve, and should not simply be a list of the experiments you plan to do (i.e. do not copy-and-paste from a grant proposal) and to include the overall goal of the experiments/project. For example, it is not sufficient to say that proteins will be harvested from cell line XYZ. An example that provides sufficient detail for the IBC to evaluate biosafety procedures is below:

*Proteins from cell line XYZ obtained from Vendor ABC will be harvested using ultrasonic dismembration. RISK: aerosolization. Mitigation strategy: Ultrasonic dismembration will be performed in a biosafety cabinet using lower power and longer dismembration times. Risk: Cell line XYZ is known to contain the following viruses: Virus 1, Virus 2, and Virus 3. Mitigation strategy: Proteins will be harvested into a 50% guanidinium thiocyanate solution (4:1 buffer-to-sample ratio). Following dismembration, samples will be incubated in this solution at 25° C for 20 min to inactivate any viruses present.*

Applications lacking sufficient detail to assess biosafety protocols will be returned without full committee review, delaying the approval process.

Include the following information in the technical description:

* A technical overview of the project.
* Procedures, practices, and manipulations involving biohazardous or recombinant agents, and biosafety procedures (e.g. cloning of genes into *E. coli* for sequencing; creation of transgenic mice by means of lentiviral vectors; isolation of bacteria from sewage- may include human pathogens).
* Identify all manipulations that may increase the risk to personnel or the environment and describe how these risks will be mitigated (e.g. all manipulations involving agents listed in this protocol will be conducted in a biosafety cabinet; transgenic plants will be grown in locked growth chambers and will not be allowed to flower). Include sufficient detail so that biosafety risks and mitigation strategies can be assessed.
* Briefly describe your experience with the manipulations described in this section (e.g. I have used identical methodology to generate transgenic mice over 100 times in the last 10 years; I have never used this method to isolate proteins from pathogenic bacterial before, however, Dr. White, who developed this method 7 years ago, has agreed to assist me for the first 3 runs.).
* Decontamination (including exposure times) and waste disposal methods.
* Include a biosafety training plan for all personnel, including hands-on training for students.

|  |
| --- |
| Project Overview.  |
| **Pertinent PI Expertise to the Project Described in this Application.**  |
| Briefly describe expertise of the PI here |
| **Detailed description of procedures, potential biosafety risks, and mitigation steps.** |
| Describe and discuss procedures and biosafety risks. Use the table below to guide this section |

|  |  |  |
| --- | --- | --- |
| **The procedures listed below could result in 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 |[ ] [ ]   |
| 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 |[ ] [ ]   |

\* Please describe Other.

|  |
| --- |
| Enter description of “Other” |
| **Containment and decontamination procedures.** |
| Describe containment and decontamination procedures |
| **Laboratory-specific biosafety plan.** |
| Discuss biosafety training |

### Agent Use and Storage Locations.

Enter building name and room number. Pick campus, room use, current biosafety level, and shared lab status. If the laboratory is shared, please indicate the Principal Investigator.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **\*Location ID** | **Campus** | **Building** | **Room** | **Room use (pick one or both)** | **Lab’s Current Biosafety Level** | **\*\*Shared Lab?****Y/N****If yes, list other PI(s)** |
| **Storage** | **Use** |
| **\*#**  | Campus | Select building | Enter room | Enter location ID | Enter location ID | Select BSL | Select Y/NEnter PI(s) |

To add another row: Click on a row, then click the blue plus sign on the right.

\* use location ID (for example, ONLY write; 1, 2, etc. in **Part II: Agent Information** under “List location…used/stored” column)

**\*\*** If yes, submit a **Shared Space Form** ([click here](#_Shared_Space_Form_1)) with this application.

### Protocol Subjects.

Does this protocol involve:

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|[ ] [ ]  Human Subjects?If Yes, enter the Institutional Review Board (IRB) approval date Select date and ID: Enter approval number |
|[ ] [ ]  Live vertebrate animals?If Yes, enter the Institutional Animal Care and Use Committee (IACUC) approval date Select date and ID: Enter approval number |
|[ ] [ ]  Live invertebrate animals? (e.g. Drosophila) |
|[ ] [ ]  Plants? |
|[ ] [ ]  Importing agents or biological samples from another state within US? |
|[ ] [ ]  Importing agents or biological samples from another country? |

### Agent/Sample Characteristics.

*(An agent is defined as* Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing— (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment)

Does this protocol involve the use or storage of:

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|[ ] [ ]  Agents or samples that may contain agents that potentially affect humans? |
|[ ] [ ]  Agents or samples that may contain agents that potentially affect animals? |
|[ ] [ ]  Agents or samples that may contain agents that potentially affect the environment? |
|[ ] [ ]  Other materials potentially containing human pathogens (including human cell lines, human blood, unfixed human tissue(s))? |
|[ ] [ ]  Biological toxins? |
|[ ] [ ]  Select agents\* and toxins\* (including exempt strains and exempt quantities of toxins)? |
|[ ] [ ]  Any material requiring a CDC or USDA permit?  |

\*Select agents and toxins are defined by the NIH as “biological agents and toxins that could pose a severe threat to public health and safety, to animal health, or to animal products.” A list of such agents can be found here: <https://www.selectagents.gov/sat/list.htm>

**If you answered “yes” to any of the above questions, enter the agent name(s) or sample type(s) and information into Table A of Part II.**

### Recombinant DNA.

Does this protocol involve:

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|[ ] [ ]  The use of recombinant agents created elsewhere? |
|[ ] [ ]  The creation of recombinant bacteria or yeast non-pathogenic to humans, other vertebrates, invertebrates, plants, or the environment? |
|[ ] [ ]  The creation of recombinant bacteria or yeast potentially pathogenic to humans, other vertebrates, invertebrates, plants, or the environment? |
|[ ] [ ]  The use of viral vectors? |
|[ ] [ ]  The generation of transgenic animals? |
|[ ] [ ]  The generation of transgenic plants? |
|[ ] [ ]  The use of transgenic animals or plants (excluding the use of commercially obtained transgenic rodents kept at BSL-1) |

**If you answered “No” to all of the above questions, skip to Section K below.**

**If you answered “Yes” to any of the above questions, you must enter the requested information into Tables A and B of Part II, then continue with Question I:**

* **Enter host (target) name (e.g. *Mus musculus*) and information into Table A of Part II;**
* **Enter vector, if used, name (e.g. adeno-associated virus (AAV)) and information into Table A of Part II;**
* **Enter information regarding the cloned DNA insert (e.g. insulin) into Table B (Part II).**

### Viral Vectors Characteristics.

**If viral vectors are used, complete a separate Part III for each vector.**

### Insert Characteristics.

Please answer the following questions regarding the inserts listed in Part II.

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|[ ] [ ]  From a Risk Group (RG) 2\* Agent? ([Click here](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf#page=46) for RG 2 agents.) |
|[ ] [ ]  From a Risk Group 3\* or 4\* Agent? ([Click here](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf#page=49) for RG 3 agents. [Click here](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf#page=51) for RG 4 agents) |
|[ ] [ ]  From an animal or plant pathogen not affecting humans? |
|[ ] [ ]  From a Select Agent or coding for a Select Toxin? |
|[ ] [ ]  Encodes for a known or suspected oncogene? |
|[ ] [ ]  Encodes for a toxin molecule (whole or partial)? If yes, please describe the LD50 of the toxin and whether the insert will code for an active toxin. Enter LD50 and toxin information  |
|[ ] [ ]  Will antibiotic resistance be transferred to microorganisms? |

[\* Click here](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf#page=15) for definitions of the various risk groups.

**If “yes” to the previous question:**

* Describe what antibiotic resistance genes will be transferred to which biological agents noted in the above checkboxes for Section J.

|  |
| --- |
| Enter description. |

* Explain why this action would not fall under Section III-A-1-a of the *NIH Guidelines*. Include relevant references.

|  |
| --- |
| Explain why not on section III |

### Sections covered by the [*NIH Guidelines*](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)

Which sections of the [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)\* cover the research described in this protocol? (Select all that apply for each agent. Add lines to the table as needed)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table A ID** | **Agent, Genus, Species** | **Strain** | **BL/****ABSL/****BL-P** | **Section of the *NIH Guidelines* the covers experiments (pick all that apply)** |
| **A-**Example | *Salmonella enterica* | *S. enteriditis* | 2 | Section III-D-1-a |
| **A-#** | Enter agent/genus/species | Enter strain | Select level | Enter NIH Guidelines section |

To add another row: Click on a row, then click the blue plus sign on the right.

**\*Rules pertaining to Sections III-A, III-B, III-C, III-D, III-E, and III-F of the *NIH Guidelines* can be found at:**

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019) <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>

### Risk Assessment.

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|[ ] [ ]  Will any experimental procedures result in acquisition of new characteristics, such as enhanced virulence, infectivity, or a change in host range? |
|[ ] [ ]  Will any procedures with the agent be conducted outside of a biological safety cabinet? |
|[ ] [ ]  Will any of the agents be transported outside of the laboratory? |
|[ ] [ ]  Will more than 1 liter of the agent be generated at any one time? |
|[ ] [ ]  Will any of the agents be administered to animals? If yes, please describe the experiment in detail (e.g. animal species, how is the agent administered, how long will the animal be observed) |
|[ ] [ ]  Does this project involve the environmental release of recombinant/genetically engineered material? |
|[ ] [ ]  Does this project involve the environmental release of pathogenic or potentially pathogenic material (other than recombinant agents)? |
|[ ] [ ]  Will human tissue or cells be transplanted into animals? |
|[ ] [ ]  Will animal tissue or cells be transplanted into a different species of animal? |
|[ ] [ ]  Do any of the agents you intend to work with require pre-project serum samples, immunization, medical monitoring, and/or health surveillance? |
|[ ] [ ]  Will the deliberate aerosolization of any agent occur? |

If you answered **“Yes”** to any of the above questions, **please explain in the space below**.

 **Be sure to include any additional information not included in the risk assessment appendix.**

|  |
| --- |
| **Risk Assessment Explanation.** |
| Enter risk assessment |

### Medical Risks.

Describe health risks associated with the use of all agents or samples used in your laboratory and list the symptoms/disease(s) that may occur.

|  |  |
| --- | --- |
| **Agent ID** | **Health risks/symptoms/disease/target organ(s)/treatment** |
| A-Example | Symptoms of infection: diarrhea, fever, and stomach cramps. Symptoms usually begin six hours to six days after infection and last four to seven days.Sites of infection include infection in urine, blood, bones, joints, or the nervous system (spinal fluid and brain) and can cause severe disease.Treatment: Most people recover from Salmonella infection within four to seven days without antibiotics. People who are sick with a Salmonella infection should drink extra fluids as long as diarrhea lasts.Antibiotic treatment is recommended for: people with severe illness, people with a weakened immune system, such as from HIV infection or, chemotherapy treatment, and adults older than 50 who have medical problems, such as heart disease |
| A-**#** | Enter health risks |

To add another row: Click on a row, then click the blue plus sign on the right.

### Medical Treatment.

What treatment options/plans are available in case of a potential exposure to pathogens? Provide

a reference.

|  |
| --- |
| Describe medical treatment plan |

### Exposure Control.

Indicate the personal protective equipment you will use. Please check the applicable boxes.

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  Face mask | [ ]  Gloves | [ ]  Shoe covers | [ ]  Head covers |
| [ ]  Boots | [ ]  N95 (HEPA)\* | [ ]  Eye protection | [ ]  Double gloves |
| [ ]  Lab coats | [ ]  Face shield | [ ]  Disposable outers/lab coats | [ ]  P100 (HEPA)\* |
| [ ]  PAPR (HEPA)\* |  |  |  |
| [ ]  Other\*\*  |  |  |  |

\*\* If Other, please explain.

|  |
| --- |
| Enter information for “Other” |

**\***Please contact the Research and Academic Environmental Health and Safety Office

(RAEHS) for Occupational Health Program enrollment information (vpantusa@tamusa.edu)

or (210) 784-2822.

### Biological Safety Cabinet.

Indicate the type of Biological Safety Cabinet(s) (BSC) you intend to use. Please check the applicable boxes and enter the location IDs:

[ ]  Class II A (recirculating) Location ID Select building Enter room number

[ ]  Class II B1 (70% exhausted – ducted outside) Location ID Select building Enter room number

[ ]  Class II B2 (100% exhausted – ducted outside) Location ID Select building Enter room number

[ ]  None

[ ]  Other (Specify:)

|  |
| --- |
| Enter information for “Other” |

Is the biological safety cabinet(s) certified annually?

[ ]  No.

[ ]  Yes. Provide date(s) of most recent certification. Select date

[ ]  N/A.

Note: Cabinet certification is through A&M-SA Facilities Services. Contact Facilities at

(210) 784-2100 or facilities@tamusa.edu for further information.

## Section 3 Disposal/Decontamination of Laboratory Facilities

**The following materials must be sterilized, decontaminated, or inactivated before disposal**:

* **As per *NIH Guidelines***: All materials containing recombinant DNA (or items potentially exposed to recombinant DNA, such as, but not limited to, pipette tips, tubes, and gloves). This includes any recombinant DNA containing cell cultures, microorganisms, plants, animals (vertebrate, invertebrate, protists); **All** materials containing infectious agents (including materials potentially exposed to infectious agents, for example, gloves);
* All biological toxins (or materials potentially exposed to biological toxins);
* Blood (human, non-human primate, animal) or other potentially infected bodily fluids.

Decontamination or inactivation procedures must also be in place for working surfaces (benchtops)

 and equipment that may become contaminated with infectious agents, recombinant DNA, bodily fluids, or biological toxins.

1. **Materials Sterilization/Decontamination/Disposal Methods.**

Indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste. We define liquids as including cell culture and bacterial culture materials, blood, and other potentially infected bodily fluids. We define solids as including, but not limited to, petri dishes, agar, and other solid materials (gloves, paper towels, pipettes, tips, etc.) contaminated or potentially contaminated with infectious agents.

If bleach is used for decontamination in lieu of autoclaving, the decontaminated material is disposed of by pouring it down the drain. Under no circumstance is material containing bleach to be autoclaved.

See **Section C** below for suggested autoclave temperatures and exposure times.

If using chemical disinfection, indicate the final concentration of disinfectant and contact time required to achieve decontamination. Please refer to Appendix B[, BMBL (6th edition)](https://www.cdc.gov/labs/BMBL.html).

|  |
| --- |
| 1. **Surface/Equipment Decontamination:**
 |
| * [ ]  Bleach, [ ]  Ethanol [ ]  Other\* (describe below) method will be used for decontamination.
* Bleach or ethanol will be added to all liquids to a final concentration of 10% bleach or 70% ethanol and left for a minimum of 20 minutes contact time prior to disposal down the drain. (Bleach solutions must be prepared within 24 hours of use.)
* All contaminated solids will be placed in an appropriately labeled biohazard bag or a sharps container, as appropriate. Bags will be placed in an appropriate biohazard waste container meeting the guidelines provided by RAEHS.
* All work surfaces will be cleaned after use with an appropriate disinfectant (10% bleach or 70% ethanol, or other method, please explain in the box below), minimum contact time of 10 minutes.

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

|  |  |  |
| --- | --- | --- |
| [ ]  Yes | [ ]  No\* | [ ]  Other\* |
|  |  |  |

\*If No or Other, explain:

|  |
| --- |
| Enter information for “Other” |

 |

1. **Disposal, Autoclave Testing, Autoclave Efficacy, and Recordkeeping:**

Note: suggested temperatures and exposure times for autoclaving from NIH Biohazards Guidelines are:

[ ]  *Yes* [ ]  *No* [ ]  *Other\* Liquids: 121°C (250°F) for 1 hour, each gallon)*

[ ]  *Yes* [ ]  *No* [ ]  *Other\* Laundry: 121°C (250°F) for 30 minutes*

[ ]  *Yes* [ ]  *No* [ ]  *Other\* Solids: 121°C (250°F) for 1 hour*

[ ]  *Yes* [ ]  *No* [ ]  *Other\* Glassware: 121°C (250°F) or 160°C (320°F) for 1 hour to 4 hours (dry heat)*

*\*Other*

|  |
| --- |
| Enter information for “Other” |

1. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.

[ ]  I give assurance that the method(s) indicated above will be used.

[ ]  Other (*Please attach an explanation and include scientific rationale for the use of alternate conditions, i.e.: time, temperature, etc*. Use the table below to provide procedures.)

|  |
| --- |
| Enter information for “Other” |

1. Autoclaves should be tested before being placed into service and then periodically for effectiveness.
2. [ ]  The autoclave is departmentally maintained.

|  |  |  |  |
| --- | --- | --- | --- |
| Contact  | Contact name | Phone | Contact phone number |
| Building  | Select building | Room | Enter room number |

Indicate testing frequency:

[ ]  Minimum - 1 time every other week (BSL-2)

[ ]  Minimum - 1 time per month (BSL-1)

A commercially available test indicator kit that uses bacterial spores (*Bacillus stearothermophilus*) is the **required** method of testing autoclave efficiency.

1. [ ]  The autoclave is individually operated (supervised by Principal Investigator)

|  |  |  |  |
| --- | --- | --- | --- |
| Building | Choose building | Room | Enter room number |

Indicate testing frequency:

[ ]  Minimum - 1 time every other week (BSL-2)

 [ ]  Minimum - 1 time per month (BSL-1)

A commercially available test indicator kit that uses bacterial spores (*Bacillus stearothermophilus*) is the **required** method of testing autoclave efficiency.

C. [ ]  Other

Please include the following information: whether the autoclave is departmentally operated or is individually operated, contact information (phone number, office building and room) for the party responsible for the operation of the autoclave, location (Building and Room number) of the autoclave, and the testing frequency of the autoclave (every other week for BSL-2 or once per month for BSL-1)

|  |
| --- |
| Enter information for autoclaves not covered immediately above by A or B of this section |

[ ]  I give assurance that the method indicated above will be used for the individually operated autoclave.

1. The IBC requires that the treatment of each load of biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment and cycle number, and the printed name and initials of the person performing the treatment. Charts or printout strips will be kept as documentation on file with RAEHS. Additionally, documentation of the date and results of all verification tests using biological indicators are required.

[ ]  I give assurance that the documentation indicated above will be used.

 Select date Enter PI’s Name

Signature of PI Date Typed/Printed Name

1. **Disposal of Animal Remains and Waste.**

Carcasses, recognizable animal parts, or tissues, (whether or not they have been in contact with infectious agents) are subject to incineration. **Containers and instructions to collect waste for incineration can be obtained from RAEHS (contact Victor Pantusa,** vpantusa@tamusa.edu**).** The following wastes will be sent off-site for disposal via medical waste incineration by Stericycle.

Please indicate below if your protocol includes any of the following.

[ ]  *Yes* [ ]  *No* *Pathological waste – recognizable human or animal parts, tissues, or specimens*

[ ]  *Yes* [ ]  *No* *BSL-3, Infectious Category A, and select agent waste*

[ ]  *Yes* [ ]  *No* *Waste that contains trace chemotherapeutic drugs*

[ ]  I give assurance that I will alert RAEHS to dispose of waste destined for incineration as indicated above.

 Select date Enter PI’s Name

Signature of PI Date Typed/Printed Name

If you have specific questions on the proper disposal of hazardous materials or wastes, contact Research and Academic Environmental Health and Safety Office (RAEHS) at vpantusa@tamusa.edu or call (210) 784-2822.

1. **Disposal of Contaminated Sharps.**

I agree that contaminated sharps will be placed in a biohazard sharps container, filled to no more than ¾ full, sealed, and placed in a designated waste area in the laboratory for collection and disposal by RAEHS (contact Victor Pantusa: vpantusa@tamusa.edu)

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  Yes | [ ]  No\* | [ ]  Other\* | [ ]  Sharps will not be used in the work described in this application. |

\*If No or Other, explain:

|  |
| --- |
| Enter information for “Other” |

1. **Other Waste Disposal.**

If the waste disposal method is not described above, please describe the method(s) to be used below.

|  |
| --- |
| Describe other waste disposal methods |

# PART II: Agent Information

## Table A: Agent/Sample Type/Vector/Host Characteristics

* In the table below, list each agent, vector (e.g. plasmid), host, or sample type that will be used. Note the ID of the listing for later use in your application.
* If the agent is recombinant, list “Yes” in the appropriate cell and insert information into Table B.
* Note that if a vector is used to generate a recombinant host, both the vector and host need to be entered into Table A.
* If the agent is to be used with animals or plants, give the species, otherwise enter “No”.
* For samples only: known pathogens in the sample should be included here; potential pathogens in the sample do not need to be included here, but they should be addressed in the main technical description.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ID** | **Genus/Species** | **Strain** | **Risk Group** | **Biosafety Level** | **Animal Biosafety Level** | **Recombinant?****(Yes/No)** | **List location(s) where agent will be****(From Part 1 Sec. E)** | **Used in animals/plants****(list species)** |
| **Used** | **Stored** |
| A-100 | Example- *E. coli* | K-12 | RG-1 | BSL-1 | N/A | Yes | 1 | 1, 2, 3 | NA |
| # | Enter genus/species | Enter strain | Select RG | Select BSL | Select ABSL | Select Y/N | Enter location | Enter location | Enter species |

To add another row: Click on a row, then click the blue plus sign on the right.

##  Table B: Insert Characteristics

* In the table below, enter information about each **DNA insert expressed/cloned**.
* Enter the appropriate Host ID from Table A to indicate which host will contain the insert.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ID** | **Host ID****(Table A)** | **Source of Insert (e.g. human)** | **Insert Source Risk Group** | **Insert Name (e.g. insulin)** | **Insert Characteristic of Function (e.g. hormone)** |
|  | **Example** | Human | RG-1 | Insulin | Hormone |
| **B-#** | **A-#** | Enter insert source | Select RG | Enter insert name | Enter insert function |

To add another row: Click on a row, then click the blue plus sign on the right.

# PART III: Viral Vector Information

(To add another assessment sheet: Click in the form, then click the blue plus sign at the bottom.)

|  |
| --- |
|[ ]  This work uses viral vectors (fill out a separate table for each Agent listed in Part II Table A). |
|[ ]  This work does not use viral vectors. |
|

|  |  |  |
| --- | --- | --- |
| [ ]  Yes | [ ]  No | Will your lab be involved in way in constructing and producing the infectious virus? |
| If ‘no’ please indicate source from where you will be receiving the infectious virus.Enter source of virus here if it does not originate for your lab |

 |
| Note: An MTA may be required. |

|  |
| --- |
| 1. Agent ID from Part II, Table A Agent ID |
| 2. Is the virus replication competent or replication deficient?

|  |
| --- |
|[ ]  Competent |
|[ ]  Deficient |

 |
|

|  |
| --- |
| If the virus is replication deficient, please provide verification in the box below. |
| Verification that the virus is replication deficient |

3. Will assay systems used to measure the titer of replication competent viruses that may be present?

|  |
| --- |
|[ ]  Yes |
|[ ]  No |

If yes, please describe: Describe |
| 4. What is the host range of the viral vector?Describe |
| 5. Will the vector facilitate the insertion of a gene encoding for toxins or an oncogene? If yes, the toxin or oncogene must be described in detail in the risk assessment.

|  |
| --- |
|[ ]  Yes |
|[ ]  No |

 |
| 6. What percent of the original viral genome remains in the vector?Describe |
| 7. Describe the genome organization of the viral vector. Include information about what genes or genome regions have been removed.Describe |
| 8. The possibility of homologous recombination with endogenous viruses exists. Indicate the reversion rate and the recombination event of such a possibility. Describe methods you will use to ensure that replication competent viruses are excluded.Describe |
| 9. Will helper viruses be used?  [ ]  Yes [ ]  NoIf yes:* List in Part I, Section 2 Table E & Table K;
* List in Part II Table A & Table B;
* Complete risk assessment for each helper virus.
 |
| 10. Laboratory HazardsRisks include direct contact with skin and mucous membranes of the eye, nose and mouth, parenteral inoculation, ingestion.Will your work with viral vectors involve any of the following:

|  |  |  |
| --- | --- | --- |
| [ ]  Yes | [ ]  No | High energy-creating activities (centrifugation, sonication, high pressure systems, vortexing, tube cap popping) |
| [ ]  Yes | [ ]  No | Handling of sharps (needles, scalpels, microtome blades, broken glass, etc.) |
| [ ]  Yes | [ ]  No | Splash/droplet-creating activities (shaking incubators, liquid culturing, mechanical pipetting) |
| [ ]  Yes | [ ]  No | Equipment contamination |
| [ ]  Yes | [ ]  No | Exposed skin/uncovered wounds/broken or chapped skin |
| [ ]  Yes | [ ]  No | Other |

If you checked yes to any of the above, please address those items in your technical description (Part I, Section 2D) and discuss mitigation strategies. |

# PART IV: Personnel Information

**Personnel List.** All A&M-SA employees and students (graduate or undergraduate) who work in the lab space included in this application must be listed here, even if they are not on this project. (Please note if someone listed is not active on this protocol.) In the case of shared lab space with another faculty member, an IBC Shared Space form must also be included.

***Note****: Students in a teaching lab course will complete training given by the instructor and sign a lab safety agreement to be kept by the teaching lab manager.*

***Note:*** *Students enrolled in a laboratory course (i.e. teaching application) do not need to be listed in the table below. PI’s, instructors, and teaching assistants need to be listed as well as all personnel working in the shared space.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **First Name** | **Last Name** | **UIN or J/K number** | **Associated with an AUP\*#** | **List all sample types\*\* personnel will have access to.** | **Lab****Buildings** | **Lab****Rooms** | **Position Title** | **Email** **address** | **Active on this protocol?** |
| First name | Last name | UIN | Select Y/N | Enter organisms | Select building | Enter room | Enter position/title | Enter University email | [ ]  Yes | [ ]  No |

To add another row: Click on a row, then click the blue plus sign on the right.

\*AUP – Animal Use Protocol (from IACUC)

\*\* Sample types include, but are not limited to: pathogens, toxins, r/sNA, human and non-primate fluids and tissues, environmental samples.

# Check “Y” only if the AUP is applicable to the work described in this application.

**Training**

All CITI training must be completed before an application for an IBC permit will be forwarded to the full committee for review. Completion of training will be verified by the RCC. CITI training requirements can be found here: [https://www.tamusa.edu/graduate-studies-research/\_links/training-requirements-for-biosafety-research.pdf#Biosafety%20Research%20Training%20Requirements](https://www.tamusa.edu/graduate-studies-research/_links/training-requirements-for-biosafety-research.pdf%23Biosafety%20Research%20Training%20Requirements)

In addition to CITI training modules, during full-committee discussion, the IBC may require other specific types of training on an as-needed basis. Satisfactory proof of completion will be required before approval. For example, if a PI does not have demonstrable experience with BSL-2 samples, the Committee may require the PI find a mentor and become competent at handling those samples.

# PI Risk Assessment Form

(To add another assessment sheet: Click in the form, then click the blue plus sign at the bottom.)

|  |
| --- |
| APPENDIX LETTERAppendix letter |
| AGENT or SAMPLE TYPENumber: Number from Part II Table AName: Agent/Sample name |
| ASSESSMENT of the AGENT |
| 1. Is there a Risk Group (RG) description for this species provided by the NIH guidelines (mark one):

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |

If yes, please include information provided by the NIH guidelines: |
| NIH Guidelines information |
| 1. If the NIH guidelines do not address the RG for this species, does the BMBL 6th edition provide an RG for this organism?

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |

If yes, please include the information provided by the BMBL 6th edition.(The BMBL only provides guidance and suggestions in the use of human and non-human primate cell lines and tissues. It also recommends BSL-2 precautions when handling cell lines of unknown origins. If there is a suspected human pathogen present, then the appropriate RG and corresponding BSL should be used.)  |
| BMBL information |
| 1. If the BMBL 6th edition does not address the RG for this species, does the Health Canada Pathogen Safety Datasheet [(https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html)](https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html) provide information regarding the RG for this species?

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |

 |
| Health Canada information |
| 1. If none of the above sources provide information regarding the RG for this species, please provide information from the primary literature that supports designation of a Risk Group for this species.
 |
| Additional information |
| 1. Is this species considered a pathogen in healthy adult humans?

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |

Based on the above sources of information, the principal investigator proposes that the Risk Group designation of this species be:

|  |  |
| --- | --- |
|[ ]  Risk Group 1 |[ ]  Risk Group 2 |

 |
| ASSESSMENT of the PROCEDURES and PRECAUTIONS |
| Please describe the laboratory procedures in which this agent will be used that might create risk (e.g. concentration of the agent, volumes used, potential for aerosolization, use of sharps etc.)

|  |  |  |
| --- | --- | --- |
| * Agent concentration
 | [ ]  N/A or | Provide agent concentration |
| * Suspension volume
 | [ ]  N/A or | Provide suspension volume |
| * Risk of aerosol or airborne droplet formation (both equipment and procedure generated)
 | [ ]  N/A or | List procedures/equipment |
| * Use of sharps
 | [ ]  N/A or | List sharps |
| * Other (list)
 | [ ]  N/A or | List other procedures with elevated risk |

 |
| 1. Describe any precautions (personal protective equipment, procedure modifications, and special equipment such as a biosafety cabinet) that will be used to mitigate any risks described in the procedures above.
 |
| Describe precautions that will be taken |
| Based on the above descriptions of procedures and precautions, the principal investigator proposes that the agent be handled at:

|  |  |
| --- | --- |
|[ ]  BSL-1 |[ ]  BSL-2 |

 |
| PROFICIENCY of the PRINCIPAL INVESTIGATOR and other PERSONNEL/STUDENTS |
| 1. Please describe the expertise of the Principal Investigator.
 |
| PI expertise |
| 1. Please describe the expertise of the personnel/students who will work with this agent.
 |
| Other personnel expertise |
| 1. Have all personnel received appropriate biosafety level training for working with this agent?

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |

 |
| 1. Describe below how any deficiencies in lab-specific training are being addressed prior to beginning the work:
 |
| Describe deficiencies and training plan |
| All required biosafety training at the appropriate level (BSL-1 or BSL-2) must be completed and documented with the IBC prior to obtaining a final approval and registration. Please be sure to initiate these trainings as soon as possible to avoid any further delay to a protocol. |

# Shared Space Form

*This document may be used to indicate if the space assigned to the PI is already shared or if the PI is proposing to share an additional space. All PIs must become aware of the IBC-approved research in the shared space. Signatures on this document represent an agreement between the PI(s) responsible for the shared space and the applicant PI regarding the space or their equipment to be shared.*

Name of PI who is submitting the application for IBC: Name of submitting PI

Department: PI’s department Chair of the Department: PI’s Chair

Name(s) of PI(s) who is/are responsible for the assigned space in this request: PI(s) responsible for requested shared space

 *If the space is assigned to two or more PIs, please indicate the names of all PIs on the space above.*

Building and room number(s) of the assigned space to be shared: Building and room number

Equipment to be shared: Equipment shared

Title of Study: Title of study

Project Start Date: Start date Project End Date: End date

**Assurances by the person submitting the IBC application: (initial below)**

Initials I am aware of all recognized safety hazards in the lab space and will be responsible for training my personnel. I will inform the DRC and the faculty member(s) sharing the space of additional hazards my research may cause and report any safety-related incidents that occur in the space to DRC and the faculty member(s) sharing that space.

Initials I understand that use of the research space and/or equipment is contingent upon availability as determined by the assigned faculty who is responsible for the space/equipment.

Initials I am aware that misuse of the equipment or research space could result in revocation of user privileges.

Initials I understand that I am responsible for purchasing and supplying my own consumables, PPE, and/or other items required for use of the equipment/or research space.

|  |  |  |
| --- | --- | --- |
| Name of applicant |  | Date |
|  Printed Name of IBC Applicant  |  Signature | Date |
| PI(s) charged with oversight of lab space/equipment or who shares assigned space with the IBC applicant: The investigator and I have discussed the proposed research, and I grant permission authorizing the use of the resources in question by the investigator and/or their designees.  |
| Name of member sharing space |  | Date |
|  Printed Name of faculty member sharing the space | Signature | Date |
| Chair in charge of shared space |  | Date |
|  Printed Name of Department Chair with the space | Signature | Date |

# Shipping and Transportation Form

*This part of the application is required only if potentially biohazardous materials are being transferred to or from A&M-SA.*

1. Are items being shipped to A&M-SA only?

|  |
| --- |
|[ ]  Yes (If Yes, B below is not required) |

1. If shipping samples from A&M-SA 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 A&M-SA. Contact RAEHS (Victor Pantusa* *vpantusa@tamusa.edu**) for training requirements and scheduling training.*

|  |  |  |
| --- | --- | --- |
| [ ]  Yes | [ ]  No | [ ]  Other |

\*If No or Other, please explain:

|  |
| --- |
| Please explain No or Other |

1. If transporting samples to or from A&M-SA 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, please explain:

|  |
| --- |
| Please explain No or Other |

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

|  |
| --- |
| Please explain |

1. *I understand that prior to shipment and transfer of samples from non-commercial entities, a Research Sample Transport Form (*[*click here*](https://www.tamusa.edu/graduate-studies-research/research/institutional-biosafety-committee/forms.html)*) must be submitted to and approved by the Office of Research Compliance.*

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |

1. I give assurance that any possible biohazardous samples received that are not covered by an existing IBC-approved protocol will be held under the IBC University-level holding protocol (number) until IBC approval has been obtained. Please contact the Biological Safety Officer (vpantusa@tamusa.edu) for holding protocol details.

|  |  |
| --- | --- |
| [ ]  Yes | [ ]  No |