Institutional Biosafety Committee
Application Document

Research involving any of the agents listed below must be approved by the Texas A&M University-Commerce Institutional Biosafety Committee (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);
- Recombinant DNA (and RNA) including creation or use of transgenic plants and animals.
- Select agents and toxins (see http://www.cdc.gov/od/sap/docs/salist.pdf) 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) is responsible for completing all appropriate parts of this application 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 will be required to fill out an Amendment Form (located online).

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

Only typed forms will be accepted. For your convenience, each required form is fillable online. Only the most current forms will be accepted and reviewed; therefore we ask that you access our website for all submissions. The application must be completed, signed by all appropriate personnel, and submitted to the **IBC**, c/o Glenda Denton through the Office of Sponsored Programs, **prior** to initiation of research. At the time of submission, you are asked to also submit all grant proposals pertaining to your research. Failure to provide all information requested, including requested signatures, will lead to a delay in processing your request. If further instructions are necessary, please contact the IBC at glenda.denton@tamuc.edu or call (903) 886-5766.

Routing # _____
AUP # _____
IRB # _____

FOR INTERNAL USE ONLY
IBC # _____

Application for IBC Permit

Checklist and Table of Contents for Biohazard Use Protocols (BUP)

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. **Please check and attach all items that apply to your research.**

Part I, II, and IV are required and must be completed then submitted. Parts III and IV should be completed and submitted as applicable. **Only typed applications will be processed for review.** You need not submit blank or not-applicable pages to the IBC.

Please send completed Applications for IBC Permits to **Office of Sponsored Programs**. The office may be contacted at (903) 886-5766 or by email at glenda.denton@tamuc.edu.

Your protocol will be delayed if it is missing any required information. **Please allow sufficient time for processing of your application. It may take 30-60 days to obtain IBC approval.**

- ☐ Part I: Application for IBC Permit **(required for all permits)**
- ☐ Part II: Agent Information **(required for all permits)**
- ☐ Part III: Viral Vectors
- ☐ Part IV: Personnel Information **(required of Biosafety Level 2 [BSL 2] and above laboratories)**
- ☐ Part V: Select Agent Plan Review Form
- ☐ Grant Proposal **(required for all permits)**
- ☐ Biosafety Manual **(required for all Biosafety Level 2 [BSL2] research)**

Part I
Application for IBC Permit

1. Principal Investigator Information

Last Name: _____ First Name: _____

Department: _____ College: _____

Email: _____ Office Phone: _____

Fax: _____

Campus Mailing Address: _____

Office location: Building _____ Room number _____

Address _____
City State Zip

Other Phone Numbers: _____ _____
Laboratory Emergency/after hours

2. Investigator Assurance

- I attest that the information contained in this registration is accurate and complete.
- I agree to comply with all Texas A&M University-Commerce IBC requirements regarding research involving biohazardous and / or recombinant materials.
- I agree not to initiate any research subject to IBC approval unless I have received such approval.
- I agree to notify the IBC via the Research Compliance Coordinator (RCC) immediately of incidents involving biohazardous and / or recombinant agents
- I have read and agree to comply with the *NIH Guidelines for Research Involving Recombinant DNA* (*NIH Guidelines*). I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the *NIH Guidelines*.
- I have the knowledge and training required to safely handle the materials described.
- I agree to train all of my laboratory personnel according to the Bio-safety Level of the laboratory.
- Entry doors to the laboratory will be closed and locked when the laboratory is unattended.
- I agree to provide all personnel working in the laboratory notification, information and training on the hazards, laboratory security and emergency policies 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 technique, the use of automatic pipetters 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.**

_____	_____	_____
Signature of Principal Investigator	Date	Typed/Printed Name
_____	_____	_____
Signature of Principal Investigator Supervisor	Date	Typed/Printed Name

3. Protocol Information

A. Funding Source (Please check all that apply)

☐ NIH ☐ NSF ☐ DOD ☐ USDA ☐ Other: _____

B. Routing Agency

☐ A&M-Commerce ☐ Research Foundation ☐ TEES ☐ TAES (Agrilife)
☐ Other: _____

C. Grant Proposal

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. (Budget information is not required.)

Grant PI if different from this protocol PI:_____
Grant Title(s):_____

D. Lay description of the project.

In terms understandable to a non-scientist please provide, in the space below, a brief summary of this project describing its goal(s), methodology, and use of biohazardous or recombinant material.

E. Technical description of the project.

Attach a technical summary of your project. Provide information detailed enough so that IBC members can perform a risk assessment of your protocol. Include the following information:

- Procedures, practices, and manipulations involving biohazardous or recombinant agents (e.g. cloning of genes in *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 risk to personnel or the environment; 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)
- Briefly describe your experience with the manipulations described in this section (e.g. I have use 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. XXXX, who developed this method 7 years ago, has agreed to assist me for the first 3 runs.)
- Decontamination and waste disposal methods

F. Agent use and storage locations.

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

Location ID	A&M-Commerce Campus	Building	Room Number	Room Use (Storage/Use)	Current Biosafety Level	Shared Lab, Y or N?
1				-	-	
2				-	-	
3				-	-	
4				-	-	
5				-	-	
6				-	-	
7				-	-	
8				-	-	
9				-	-	
10				-	-	

G. Protocol Subjects. Does this protocol involve:

Yes	No	
☐	☐	Human Subjects? If **Yes**, enter the Institutional Review Board (IRB) approval date _____ and ID: _____
☐	☐	Live vertebrate animals? If **Yes**, enter the Institutional Animal Care and Use Committee (IACUC) approval date _____ and ID: _____
☐	☐	Live invertebrate animals? (i.e. Drosophila)
☐	☐	Plants?

H. Agent Characteristics. Does this protocol involve the use or storage of:

Yes	No	
☐	☐	Agents potentially affecting humans?
☐	☐	Agents potentially affecting animals?
☐	☐	Agents potentially affecting plants?
☐	☐	Materials potentially containing human pathogens (including human cell lines, human blood, unfixed human tissue)?
☐	☐	Biological Toxins?
☐	☐	Select Agents and Toxins (including exempt strains and exempt quantities of toxins)?
☐	☐	Any material requiring a CDC or USDA permit?

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

I. Recombinant DNA. Does this protocol involve:

Yes	No	
☐	☐	The use, but not creation, of recombinant agents?
☐	☐	Cloning in bacteria or yeast non-pathogenic to humans, plants, or animals?
☐	☐	Cloning in bacteria or yeast potentially pathogenic to humans, plants, or animals?
☐	☐	Use of viral vectors?
☐	☐	The creation of transgenic animals?
☐	☐	The creation of transgenic plants?
☐	☐	The use of transgenic animals or plants (excluding the use of commercially obtained transgenic rodents kept at BL-1)?

If you answered "No" to all of the above questions, skip to question M below.

If you answered "Yes" to any of the above questions you must enter information into Tables A and B of Part II, then continue with question J:

- **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).**

J. Viral Vectors Characteristics.

If viral vectors are use, complete a separate Part III for each.

K. Insert Characteristics

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

Yes	No	
☐	☐	From a Risk Group 2 Agent?
☐	☐	From a Risk Group 3 or 4 Agent?
☐	☐	From a animal or plant pathogen not effecting humans?

☐ ☐ From a Select Agent or coding for a Select Toxin?

☐ ☐ Encodes for a known or suspected oncogene gene?

☐ ☐ 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. _____

☐ ☐ Will antibiotic resistance be transferred to microorganisms? If yes:

- Describe what antibiotic resistance genes will be transferred to which agents (microorganism?). _____
- Explain why this action would not fall under Section III-A-1-a of the NIH Guidelines. Include relevant references._____

L. Which Sections of the *NIH Guidelines* does research described in this protocol fall (pick all that apply for each agent):

Table A ID	Agent Genus, species	Strain	BL/ABSL/BL-P (pick)	Sections of the *NIH Guidelines* that covers experiments (pick all that apply)
A-1			-	- , - , -
A-2			-	- , - , -
A-3			-	- , - , -
A-4			-	- , - , -
A-5			-	- , - , -
A-6			-	- , - , -
A-7			-	- , - , -
A-8			-	- , - , -
A-9			-	- , - , -

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:

http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261559

For assistance, contact Texas A&M University-Commerce at: glenda.denton@tamuc.edu

M. Risk Assessment

Yes	No	
☐	☐	Will any experimental procedures result in acquisition of new characteristics such as enhanced virulence, infectivity, or 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 agent be generated at any one time?
☐	☐	Will any of the agents be administrated to animals? If yes please describe the experiment in detail (e.g. animal species, how is the agent given, how long will the animal be followed.)
☐	☐	Does this project involve the environmental release of 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 provided on the following page.

Risk Assessment Explanation

N. Medical Risks

Describe health risks associated with the use of all pathogens used in your laboratory and list the symptoms/disease that may occur.

Agent ID	Health risks/symptoms/disease/target organ(s)
A-1	
A-2	
A-3	
A-4	
A-5	

O. Medical Treatment

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

P. Exposure Control

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

- ☐ Face Mask
- ☐ Boots/Crocs
- ☐ Lab coats
- ☐ PAPR (HEPA)*
- ☐ Other (Specify:)
- ☐ Gloves
- ☐ N-95 *
- ☐ Face shield
- ☐ Shoe Covers
- ☐ Eye protection
- ☐ Disposable outers
- ☐ Head covers
- ☐ Double gloves
- ☐ P-100 (HEPA)*

***Please contact Risk Management** at (903) 468-8781 to obtain required Fit Testing, Pulmonary Function Testing, and/or Respiratory Protection Training.

Q. 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_____

☐ Class II B1 (70% exhausted – ducted outside)
Location ID_____
☐ Class II B2 (100% exhausted – ducted outside
Location ID_____
☐ None
☐ Other (Specify:)

Is the biological safety cabinet(s) certified annually?

☐ No.
☐ Yes. Provide date(s) of most recent certification and certifying person/agency.

4. Disposal/Decontamination of Laboratory Facilities

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

All materials containing infectious agents (including materials potentially exposed to infectious agents, for example gloves)

As *per NIH Guidelines*: All materials containing recombinant DNA (or items potentially exposed to recombinant DNA, such as pipette tips, tubes, gloves). This includes any recombinant DNA containing cell cultures, microorganisms, plants, animals (vertebrate, invertebrate, protists)

All biological toxins (or materials potentially exposed to biological toxins)

Human blood or other potentially infected body 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 or biological toxins.

A. Materials Sterilization/Decontamination/Disposal Methods.

Indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste.

- See section 3.1 below for suggested autoclave temperature and exposure times.
- If using chemical disinfection: (i) indicate final concentration of disinfectant & contact time required to achieve decontamination. Please refer to BMBL (5^{th} edition), Appendix B.
- If using incineration please indicate the facility to be used.

Type of waste	Potential hazard	Decontamination/sterilization/ disposal procedures
Liquids		
Solids		
Glassware		
Animals		

B. Surface/equipment decontamination:

Indicate the methods/laboratory procedures that are in place for decontamination of work surfaces and equipment. Please refer to BMBL (5th edition), Appendix B.

C. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping:

- Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guidelines are:

Liquids	*121°C (250°F) 1 hour, (each gallon)*
Laundry	*121°C (250°F) 30 minutes*
Trash	*121°C (250°F) 1 hour*
Glassware	*121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

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 indicated above will be used.
   ☐ Other (*Please attach explanation and include scientific rationale for the use of alternate conditions, i.e.: time, temperature, etc*.)

2. Autoclaves should be tested before being placed into service and then periodically for effectiveness.

   a. ☐ The autoclave is <u>departmentally</u> operated
   Contact name:_____ Phone No: _____
   Building Location: Building No.: _____/Room No.: _____
   i. Indicate testing frequency:
   ☐ Minimum - 1 time per week (BL3)
   ☐ Minimum - 1 time every other week (BL2)
   ☐ Minimum - 1 time per month (BL1)

b. ☐ The autoclave is individually operated (supervised by Principal Investigator)
Building Location: Building No.: _____ Room No.: _____

i. Indicate testing frequency:

☐ Minimum - 1 time per week (BL3)
☐ Minimum - 1 time every other week (BL2)
☐ Minimum - 1 time per month (BL1)

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

☐ I give assurance that the method indicated above will be used.

4. 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 the printed name and initials of the person performing the treatment. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.

☐ I give assurance that the method indicated above will be used.

- Contact the Department of Risk Management and Safety at 903-468-8781 for more information on disposal of hazardous materials or instructions regarding Select Agent disposal.