ORC USE ONLY	
BUP #:	
Date Received:	

Part I: Overview

Biohazardous Use Protocol for Research, Testing, or Teaching

TEXAS A&M UNIVERSITY CORPUS CHRISTI
RESEARCH COMMERCIALIZATION OUTREACH

Instructions and Certifications (Failure to follow may result in a delay in processing)

Complete this form (**Parts I-IV**) if the research, testing, or teaching involves the use of **biohazardous materials**, including the following:

Biological agents that may cause disease in humans, animals, or plants (e.g., bacteria, rickettsia, fungi, viruses, protozoa, parasites, prions);

Recombinant or Synthetic Nucleic Acid Molecules as defined in the National Institutes of Health (NIH) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ("NIH Guidelines");

Human and non-human primate blood, tissue, cells, and cell lines;

Toxins of biological origin as defined in the *Biosafety in Microbiological and Biomedical Laboratories* ("BMBL"); or

Any material requiring a Centers for Disease Control and Prevention ("CDC") or U.S. Department of Agriculture ("USDA") permit.

To (1) request a determination whether **recombinant or synthetic nucleic acid molecules** may be exempt from the NIH Guidelines, (2) register experiments with molecules that require approval before initiation, or (3) register experiments with molecules that require notice with initiation, complete the form entitled "Exempt Experiment Determination and Registration (*NIH Guidelines*)," instead.

By signing this Biohazardous Use Protocol (BUP), all Principal Investigators (PIs), co-PIs, and personnel (collectively, "Researchers") or Instructor(s), as applicable, certify the following:

1. CITI Training "Initial Biosafety Training - Basic Course" has been completed and is current (expires after three years);

2. Have enrolled in or opted-out of the Occupational Health and Safety Program (OHSP) (annual requirement);

3. Have completed the Risk Assessment form for this BUP and included it as an attachment; have read and understood the information provided in the Risk Assessment and the sections entitled "Medical Assessment" and "Medical Treatment" herein about the risks to personnel; as appropriate, have consulted and reviewed information about risks and biosafety practices and procedures as set forth in the CDC *Appendix A: CDC Guidance and Information on Microorganisms*, NIH Guidelines, American Biological Safety Association (ABSA) Risk Group Database, *BMBL*, CDC Index Search, or other relevant sources;

4. Have read and understood the "Responsibilities of the Principal Investigator" as set forth in TAMUCC Rule 15.99.06.C1;

5. Have read and understood the laboratory's standard operating procedures and/or biosafety manual and have included it as an attachment; will implement and maintain required records of activities;

6. Have read and reviewed this BUP (**Parts I-IV**); any applicable supporting documentation or third-party approval has been obtained from the appropriate authority and has been included as an attachment to the BUP (e.g., biosafety manual, permit, grant, institutional approval, third party permission, etc); have signed the BUP electronically;

7. Have submitted the BUP a **minimum of thirty (30) days in advance** of the anticipated start date; and

8. Will submit a Completion Report at the conclusion of research, testing, or teaching under this BUP.

After completing the foregoing, submit the BUP with supporting documentation via email to:

IBC@tamucc.edu

Biohazardous Use Protocol (BUP) Checklist

- ☐ Part I: Overview *(required)*
- ☐ Part II: Agent, Vector, Insert, or Host Information *(required)*
- ☐ Part III: Viral Vectors *(if applicable)*
- ☐ Part IV: Personnel List *(required for BSL 2+ laboratories, use of animal subject(s), or use of human materials)*
- ☐ APHIS/CDC Form 1 and FBI FD-961 Form, third party approval, or other institutional approval *(if applicable)*
- ☐ Proposal or Award *(if applicable)*
- ☐ Biosafety Manual *(required for BSL 2+ laboratories)*

Researcher or Instructor Information

Principal Investigator or Instructor

Name:

Address:

Phone:

Emergency Phone:

Email:

Co-Principal Investigator or Instructor

Name:

Address:

Phone:

Email:

Co-Principal Investigator or Instructor

Name:

Address:

Phone:

Email:

Co-Principal Investigator or Instructor

Name:

Address:

Phone:

Email:

Researcher or Instructor Signatures

By signing this BUP, the Researcher(s) or Instructor(s), as applicable, certifies that he/she has read and understood the requirements and responsibilities set forth in the section entitled "Instructions and Certifications" in relation to the

research, testing, or teaching. In addition, the Researcher(s) or Instructor(s) certifies that he/she will abide by any and all applicable federal, state, and/or institutional regulations, including any requirements from the Institutional Biosafety Committee (IBC), Environmental, Health and Safety (EHS), and/or the Office of Research Compliance (ORC).

Principal Investigator or Instructor

Name:

Signature:

Date:

Co-Principal Investigator or Instructor

Name:

Signature:

Date:

Co-Principal Investigator or Instructor

Name:

Signature:

Date:

Co-Principal Investigator or Instructor

Name:

Signature:

Date:

BUP Overview and Design

External Funding

Indicate source(s) of funding, if applicable.

☐ Funded. Maestro #, source of funding, title, and PI. *(Include award as an attachment).*

☐ Unfunded.

Abstract

Provide an abstract **below**, in **layman's terms**, of the purpose(s) and objective(s) of the research, testing, or teaching.

In addition, include a technical abstract as an **attachment** to this BUP (i.e., procedure(s), manipulation(s), risk assessment and containment practices, experience/training, and decontamination and waste disposal).

Abstract:

Use and Storage of Biohazardous Materials

Location ID	Building	Room Number	Room Use (Storage/Use)	Current Biosafety Level	Shared Lab (Y/N)	PI (If Shared Lab)
1						
2						
3						
4						
5						
6						

Use of Subject(s)

Indicate all that apply.

☐ Human Subjects

Human Subjects Protocol # and approval date:

☐ Animal Subjects

Animal Use Protocol # and approval date:

☐ Other (specify):

Use of Biohazardous Materials

Indicate all that apply. Enter information into "Use and Storage of Biohazardous Materials" above.

☐ Biological agents which may cause disease in humans

☐ Biological agents which may cause disease in animals

☐ Biological agents which may cause disease in plants

☐ Recombinant or synthetic nucleic acid molecules (complete the section below entitled "Recombinant or Synthetic Nucleic Acid Molecules")

☐ Human and non-human primate blood, tissue, cells and cell lines

☐ Toxins of biological origin

☐ Any material requiring a CDC or USDA permit

Recombinant or Synthetic Nucleic Acid Molecules

Indicate all that apply. Complete the tables in **Part II** of this BUP.

☐ 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 (complete the section below entitled "Viral Vectors")

☐ The creation of transgenic animals

☐ The creation of transgenic plants

☐ The use of transgenic animals or plants *(exclude the use of commercially-obtained transgenic rodents at BSL 1 containment)*

Viral Vectors Characteristics

Complete a copy of **Part III** of this BUP for **each** viral vector used.

Insert Characteristics

Indicate all inserts that apply from **Part II** of this BUP.

☐ From a Risk Group 2 Agent

☐ From a Risk Group 3 or 4 Agent

☐ 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 marked, describe the LD50 of the toxin and whether the insert will code for an active toxin.

☐ Antibiotic resistance will be transferred to microorganisms

If marked, describe what antibiotic resistance genes will be transferred to which agents (microorganism).

If marked, explain why this action does not fall under Section III-A-1-a of the NIH Guidelines. Include relevant references.

Applicability of *NIH Guidelines*

Provide the applicable section(s) of the *NIH Guidelines* for each biohazardous material used.

Table A ID	Agent Genus, Species	Strain	BL/ABSL/BL-P (select)	Applicable section(s) of the *NIH Guidelines*
A-1				
A-2				
A-3				
A-4				
A-5				
A-6				

Risk Assessment

Complete the form entitled "Risk Assessment" and include it as an attachment to this BUP.

Medical Risk Assessment

Describe any health risks associated with the use of any biohazardous material(s) described in the Risk Assessment or otherwise, and list associated symptoms/disease(s).

Agent ID	Health Risks/Symptoms/Disease/Target organ(s)
A-1	
A-2	
A-3	
A-4	
A-5	
A-6	

Medical Treatment

Include any treatment options/plans available in case of a potential exposure to biohazardous material(s).

Exposure Control

Indicate the personal protective equipment to be used.

- ☐ Face Mask
- ☐ Boots/Crocs
- ☐ Lab Coats
- ☐ PAPR (HEPA)
- ☐ Gloves
- ☐ N 95 (HEPA)
- ☐ Face Shield
- ☐ Shoe Covers
- ☐ Eye Protection
- ☐ Disposable Outers
- ☐ Head Covers
- ☐ Double Gloves
- ☐ P100 (HEPA)
- ☐ Other

Other (specify):

Biological Safety Cabinet

Indicate which type(s) of Biological Safety Cabinet (BSC) will be used.

☐ Class II A (recirculating)

Building and Room Number:

☐ Class II B1 (70% exhausted - ducted outside)

Building and Room Number:

☐ Class II B2 (100% exhausted - ducted outside)

Building and Room Number:

☐ None

☐ Other

Specify type; Building and Room Number:

Decontamination; Disposal Procedures; Autoclaves

Notes on Decontamination and Disposal of Contaminated Waste

Contact Environmental, Health and Safety for more information: EHS@tamucc.edu or (361) 825-5555.

Contaminated Waste

Decontamination or inactivation procedures must be used for working surfaces (e.g., benchtops), equipment, biohazardous materials, and/or contaminated waste. The following materials ("contaminated waste") must be sterilized, decontaminated or inactivated before disposal:

All materials containing infectious agents, including materials potentially exposed to the same (e.g., gloves);

All materials containing recombinant DNA or items potentially exposed to recombinant DNA (e.g., pipette tips, tubes, gloves), including any recombinant DNA containing cell cultures, microorganisms, plants, animals (e.g., vertebrate, invertebrate, protists);

All biological toxins or agents, including materials potentially exposed to the same; and/or

Human blood or other potentially infected body fluids.

Notes on Specific Types of Decontamination or Disposal

For incineration, provide facility to be used.

For chemical disinfection, include final concentration and contact time (see *BMBL (5th edition)*, Appendix B).

For autoclaves, see the *NIH Guidelines*:

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)

Decontamination and Disposal Procedures of Contaminated Waste

Provide the procedure(s) that will be used for the decontamination and disposal of contaminated waste.

Type of Waste	Potential Hazard	Decontamination/Sterilization/Disposal Procedures
Liquids		
Solids		
Glassware		
Animals		

Decontamination of Work Surface or Equipment

Indicate the procedure(s) in place for decontamination of work surfaces and/or equipment.

Procedure(s):

Autoclaves: Procedures, Operation, Testing, Recordkeeping

Procedure(s)

Indicate whether the BUP will follow the *NIH Guidelines* (above) for its procedure(s).

☐ Yes, the PI assures that the *NIH Guidelines* will be followed in the BUP's autoclave procedure(s).

☐ No, an alternative procedure(s) will be used. *(Provide scientific rationale below or in an attachment).*

Rationale:

Operation: Departmental or Individual

Indicate how the autoclave is operated.

☐ The autoclave is **departmentally** operated.

Name:

Phone:

Location *(Building and Room Number)*:

Indicate testing frequency:

☐ Minimum - 1 time per week (BSL 3)

☐ Minimum - 1 time every other week (BSL 2)

☐ Minimum - 1 time per month (BSL 1)

☐ The autoclave is **individually** operated (supervised by the Principal Investigator).

Location *(Building & Room Number)*:

☐ Minimum - 1 time per week (BSL 3)

☐ Minimum - 1 time every other week (BSL 2)

☐ Minimum - 1 time per month (BSL 1)

Testing

Autoclaves are **required** to be tested by a commercially-available test indicator kit that uses bacterial spores (i.e., *Bacillus (Geobacillus) stearothermophilus*).

☐ Yes, the PI assures that the autoclave is and will be tested per the requirement above.

Recordkeeping

The IBC requires each load of contaminated waste treatment to be documented on an autoclave waste treatment record ("record").

The record **must** contain the date of treatment, the amount of waste treated, the method/conditions of treatment, the printed name and initials of the person performing the treatment, and the results of all verification tests using biological indicators with the date ("mandatory recordkeeping requirements").

The record **may** contain charts or printout strips.

☐ Yes, the PI assures that the mandatory recordkeeping requirements (above) will be used in the BUP.