West Texas A&M University
Institutional Biosafety Committee
Registration Document

Research or teaching of any type involving any of the agents listed below must be approved by the West Texas A&M University Institutional Biosafety Committee (IBC) prior to initiation:

- Pathogens and potential pathogens of humans, animals, or plants that are classified by the American Tissue Culture Collection (ATCC) as Biosafety Level 2 (BSL-2) or higher and/or listed by the American Biological Safety Association (ABSA) as Risk Group 2 or higher (based on the *NIH Guidelines* and/or *BMBL*).

- Human-derived materials that contain or potentially contain human pathogens (including human blood and blood components and unfixed tissue).

- Non-human primate-derived materials that contain or potentially contain human pathogens (including non-human primate blood and blood components and unfixed tissues).

- Use of all cell lines, whether human or non-human primate, that are classified as BSL-2 or higher by the ATCC and/or as Risk Group 2 or higher by the ABSA (based on the *NIH Guidelines* and *BMBL*).

- Recombinant DNA and recombinant RNA including creation or use of transgenic plants and animals.

- Select agents and toxins (see https://www.selectagents.gov/SelectAgentsandToxinsList.html) including strains and amounts exempted from the select agent regulations.

- Any material(s) (pathogenic or nonpathogenic) requiring a CDC import license or a USDA permit.

The Principal Investigator (PI), Course Instructor (CI), or Course Coordinator (CC) is responsible for completing all applicable parts of this document that pertains to the respective research and teaching areas. Each PI, CI, or CC is also responsible for notifying the IBC when **any** information submitted in this document changes, such as personnel, laboratory location, classroom location, procedures, funding, etc. If such changes occur the PI, CI, or CC will be required to fill out an Amendment Form preferably prior to the changes taking place, or immediately upon the change being made.

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

Only typed forms will be accepted. For your convenience, each required form is downloadable online and can be filled out and saved using Microsoft Word or Adobe. Only the most current forms will be accepted and reviewed, therefore you must access our website prior to all submissions of any forms to ensure that the proper forms are used. The application must be completed, signed by all appropriate personnel, and submitted to AR-EHS via email (ar-ehs@wtamu.edu) **prior** to initiation of research or teaching. Signature pages can be submitted separately as scanned files or hard copies. 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 required signatures, will lead to a delay in processing your request. If further instructions are necessary, please contact the IBC chair, Dr. John Richeson, at x2522.

Application for New IBC Proposal

Checklist and Table of Contents for Institutional Biosafety Protocols

Following is the table of contents of the items included in the application for IBC proposal. In order for your proposal to be approved, you must provide **all applicable** sections to the IBC, including a Laboratory Biosafety Manual, Laboratory-Specific Standard Operating Procedure (fillable templates for both of these items can be found on the IBC website), and a copy of the grant proposal if the research or teaching performed is funded (includes both internal and external funding). **Please check and attach all applicable items.**

Only typed applications will be processed for review. You do not need to submit blank or non-applicable pages to the IBC.

Please send the completed Application for New IBC Proposal to AR-EHS via email **(ar-ehs@wtamu.edu).**

Review of your proposal 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 final IBC approval.**

Part I. Application for IBC Proposal **(required for all applications)**

Part II. Agent Information **(required for all applications)**

Part III. Viral Vectors

Part IV. Personnel Information **(required of BLS2 laboratories)**

Laboratory Biosafety Manual **(required for all applications whose work is considered to be at the BSL-2 level)**

Laboratory-Specific Standard Operating Procedure **(required for all applications whose work is considered to be at the BSL-2 level)**

Grant Proposal or Contract **(required for all applications whose work is internally or externally funded, excluding departmental funds)**

Part I.

Application for New IBC Proposal

A. Principal Investigator / Course Instructor / Course Coordinator Information

Last Name: First Name:

Department: College:

Campus Mail Stop:

Office Location - Building Room Number:

Office Phone:

Laboratory Phone (if applicable):

After-Hours / Emergency Phone:

Email:

B. Investigator Assurance

- I attest that the information contained in this registration is complete and accurate.
- I agree to comply with all West Texas A&M University IBC requirements and Texas A&M University System requirements regarding research and teaching involving biohazardous and/or recombinant material(s).
- I agree not to initiate any research or teaching subject to IBC approval unless I have received such approval.
- I agree to notify the IBC immediately of incidents involving biohazardous and/or recombinant agents.
- I have read and agree to comply with the *NIH Guidelines* and *BMBL*. I acknowledge my responsibility for the conduct of this research and/or teaching in accordance with Section IV-B-7 of the *NIH Guidelines*.
- I have the knowledge and training required to safely handle the material(s) described.
- I agree to train all of my laboratory personnel according to the BSL of the laboratory or all students according to the BSL of the classroom, and maintain accurate training records for five years.
- Entry doors to all BSL-2 laboratories or classrooms will be closed and locked at all times when the laboratory is unattended.
- I agree to provide all personnel or students having access to the laboratory or classroom notification, information, and training on the hazards, security, and emergency policies and procedures associated with working or residing in my laboratory or classroom. **I agree to inform all personnel working or residing in my laboratory or classroom 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 pipettes, and the proper disposal of biohazardous materials. All personnel are advised that if they are in an immunocompromised or 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 immunocompetent individuals. All personnel are further advised that working in a laboratory or classroom that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health.**

Signature of PI / CI / CC	**Date**	**Printed Name**
Signature of Department Chair	**Date**	**Printed Name**

C. Protocol Information

1. Protocol Title (limit to 20 characters):

2. Type of Protocol: **Teaching** **Research**

3. Funding Source (Please check all that apply)

External: NIH NSF DOD USDA Other

Internal: KFR GSR USR Other
(Exclude Departmental Funds)

4. Grant Proposal

Please include a copy of all grants or contracts associated with this IBC proposal. The submission must include all sections of the grant proposal except for the budget information.

Grant PI if different from protocol PI:

Grant Title(s):

5. Lay Description of the Project

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

6. Technical Description of the Project

Provide a technical summary of your project in terms of the items listed below. Provide information detailed only enough so that IBC members can perform a risk assessment of your protocol. Include the following information:

6a. 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).

6b. 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).

6c. 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 bacteria before, however, Dr. Smith, who developed this method 7 years ago, has agreed to assist me for the first 3 runs).

6d. Decontamination and waste disposal methods

7. Agent Use and Storage Locations

Enter building name and room number. Pick room use, current biosafety level, and shared lab/classroom status from the drop down menu.

Location ID	Building Name	Room Number	Room Use	Current Biosafety Level	Shared room?
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

If selected “yes” for Shared Room, please indicate the shared PI/CI/CC with respective Location ID in the space below. If there is any other pertinent information you feel should be included regarding the information above, please indicate it in the space below.

8. Protocol Subjects. Does this protocol involve any of the following?

Yes	No	
		Human subjects. If yes, enter IRB approval date and ID below:
		Live vertebrate animals. If yes, enter IACUC approval date and ID below:
		Live invertebrate animals
		Plants

9. Agent Characteristics. Doe this protocol involve the use or storage of any of the following?

Yes	No	
		Agents potentially affecting humans
		Agents potentially affecting animals
		Agents potentially affecting plants
		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.

10. Recombinant DNA. Does this protocol involve any of the following?

Yes	No	
		The use, but not creation of, recombinant agents
		Cloning in bacteria or yeast non-pathogenic to humans, plants, or animals

Yes **No**

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 BSL1)

- **If you answered "no" to all of the above questions, skip to question 14 below.**
- **If you answered "yes" to any of the above questions, you must enter the information into Table A and B of Part II, then continue with question 11.**

- **Enter host (target) name (e.g. *Mus musculus*) and information into Table A of Part II;**
- **Enter vector name, if used (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 or Part II.**

11. Viral Vector Characteristics If viral vectors are used, complete a **separate Part III for each**.

12. 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 an animal or plat pathogen not affecting humans?

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.

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

13. Which sections of the NIH Guidelines does the research or teaching described in this protocol fall? (Choose all that apply for each agent):

Agent ID (from Table A)	Agent Genus, Species	Strain	BSL/ABSL/ BL-P	Sections of the NIH Guidelines that covers research/teaching (See note below table; Include all that apply.)
A-1				
A-2				
A-3				
A-4				
A-5				
A-6				
A-7				
A-8				
A-9				
A-10				

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:

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

14. Risk Assessment

Yes	No	
		Will any 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/classroom listed in Section C-7 above?
		Will more than one (1) liter of agent be generated at any one time?

Yes	No	
		Will any of the agents be administered to animals? If yes, please describe the experiment in detail below (e.g. animal species, how the agent is given, how long the animal will be followed).
		Does the research or teaching involve the environmental release of genetically engineered material?
		Does the research or teaching involve the environmental release of pathogenic or potentially pathogenic material (other than recombinant agents)?
		Will human tissues or cells be transplanted into animals of the same or difference species?
		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 provide a detailed explanation in the space provided below:

Risk Assessment Explanation:

13. Medical Risks

Describe health risks associated with the use of all pathogens used in your laboratory or classroom, and list the symptoms/disease that may occur. Note that Agent ID's are those listed in Table A, Section C-13 above.

Agent ID (from Table A)	Health risks/symptoms/disease/target organ(s)
A-1	
A-2	
A-3	
A-4	
A-5	
A-6	
A-7	
A-8	
A-9	
A-10	

14. Medical Treatment

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

15. Exposure Control

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

Face mask	Double gloves
Gloves	Lab coats
Shoe covers	Face Shields
Head covers	Disposable outerwear
Closed-toe footwear	P100 (HEPA)
N 95 (HEPA)	PAPR (HEPA)
Eye protection	Other (Please specify.)

16. 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 of the BSC (building name and room number).

Class II A (recirculating) None
Location:
Class II B1 (70% exhausted - ducted outside) Other (Please specify.)
Location:
Class II B2 (100% exhausted - ducted outside
Location:

Is the biosafety cabinet inspected annually

No. Please explain.

Yes. Date(s) of most recent certification(s)

D. Disposal/Decontamination of Laboratory and Classroom 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 RNA (or items potentially exposed to recombinant DNA or RNA, such as pipette tips, tubes, gloves). This includes any recombinant DNA or RNA containing cell cultures, microorganisms, plants, animals (vertebrate, invertebrate).

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

Human and non-human primate blood and blood products or other potentially infected body fluids.

Decontamination or inactivation procedures must also be in place for working surfaces (bench tops) and equipment that may become contaminated with infectious agents, recombinant DNA or RNA, or biological toxins.

1. Materials Sterilization/Decontamination/Disposal Methods.

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

- See Section D-3 below for suggested autoclave temperature and exposure times.
- If using chemical disinfection: (i) indicate final concentration of disinfectant **and** contact time required to achieve decontamination. Please refer to BMBL (5^{th} edition), Appendix B. (Available at the CDC website: https://www.cdc.gov/biosafety/publications/bmbl5/).
- If using incineration, please also indicate the facility to be used in the table below.

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

2. Surface/Equipment Decontamination

Indicate the methods/procedures that are in place for decontamination of work surfaces and equipment. Please refer to BMBL (5th edition), Appendix B. (Available at the CDC website: https://www.cdc.gov/biosafety/publications/bmbl5/).

3. 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)

A. Please provide assurance that you will use the guidelines above or provide scientific rationale for using an alternative method.

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

Other (Please include explanation and scientific rationale for the use of alternate conditions, i.e. time, temperature, etc.):

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

1. The autoclave is **departmentally** operated.

Contact name and phone: Location of autoclave:

A. Indicate testing frequency (these are **required** frequencies):

Minimum - 1 time every other week (if being used by **any** BSL2 labs)

Minimum - 1 time per month (if used **only** by BSL1 labs)

2. The autoclave is **individually** operated (supervised by the PI/CI/CC).

Location of autoclave:

A. Indicate testing frequency (these are required frequencies):

Minimum - 1 time every other week (if being used by any BSL2 labs)

Minimum - 1 time per month (if used only by BSL1 labs)

C. 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 testing method indicated above will be used.

D. 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. 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.

Part II
Agent Information

A. Table A: Agent/Vector/Host Characteristics.

In the table below, list each agent that will be used. Ensure that the Agent ID and Location ID correspond to those listed in Part I, Table A, Section C-13, and Part I, Section C-7, respectively. Note the ID of the agent for later use in your application. If the agent is recombinant, pick "yes" in the appropriate cell, and enter insert information into Table B below. Please note that if a vector is used to generate a recombinant host, **both** the vector and host need to be entered into Table A (in the Genus, species column). If the agent is to be used with animals or plants, give the species, otherwise enter "no".

Agent ID	Genus, species	Strain	RG	BSL	ABSL	Recombinant	List all location IDs (Section C-7 above) where agent will be used/stored	Use in Animals / Plants? (If yes, give species)
A-1								
A-2								
A-3								
A-4								
A-5								
A-6								
A-7								
A-8								
A-9								
A-10								

B. Table B: Insert Characteristics.

In Table B below, enter information about each vector or host DNA insert. Enter the appropriate Host ID from Table A above (Section II – A) to indicate which host will contain the insert.

Insert ID	Host ID (From Table-A)	Source of Insert (e.g. human)	Insert Source Risk Group	Insert Name (e.g. insulin)	Insert Characteristic/Function (e.g. hormone)
I-1	A-				
I-2	A-				
I-3	A-				
I-4	A-				
I-5	A-				
I-6	A-				
I-7	A-				
I-8	A-				
I-9	A-				
I-10	A-				

Part III
Viral Vector Information

Complete a <u>separate</u> Part III for <u>each</u> viral vector used.

- Agent ID from Table A:

- Is the virus replication competent?

- Are assay systems used to measure the titer of replication of competent viruses that may be present? ☐ No ☐ Yes, please describe:

- What percent of the original viral genome remains in the vector?

- Describe the genome organization of the viral vector. Include information about what genes or genome regions have been removed.

- 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 of competent viruses is excluded.

Part IV
Personnel Information

A. Personnel List

To be completed by the PI/CI/CC when working in settings that are **BSL-2**.
Please include all employed personnel that are under your immediate supervision.

Action	Last Name	First Name	Building Name	Room #	Position Title	Email Address

B. Employee-Agent Access

It is assumed that each employee listed above will have access to every agent (organism, pathogen, toxin, rDNA/RNA, etc.) described in this document. Please note that "having access" means that the employee has the capability of accessing and handling the agent, but does not refer to the employee's work involving direct contact with the agent.

If an employee listed above will not have access at any time during their employment to any or all of the agents described in this document, please indicate this in the space provided.

C. Employee Signature Page

Each employee working in a BSL2 setting must complete this page. Documents containing original signatures must be submitted with this document.

By my signature below, I certify that in addition to the required training listed below, I have been trained by my supervisor (Principal Investigator, Course Instructor, or Course Coordinator), and understand the laboratory / classroom security and emergency procedures while working in the building and room(s) under the direction of .

I further certify that I understand the hazards of working with the agents included in the WTAMU New IBC Proposal Application; the indications of infection or intoxication by this biological material; the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory / classroom; the specific biosafety practices required for BSL-2 work, in accordance with the *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*) *Guidebook* and the standard operating procedures for this laboratory / classroom.

Finally, I certify that any transfer of this biological material will be done in accordance with WTAMU policies and regulations and under the supervision of the WTAMU Academic and Research Environmental Health and Safety Department. In addition, I ensure that the detailed records of information necessary to account for all activities related to these agents will be maintained.

(Employee Signature) (Date) (Supervisor Signature) (Date)

(Employee Printed Name) (Position Title) (Supervisor Printed Name) (Position Title)

Proposals will not be reviewed until all training listed below has been completed and verified by all personnel listed.

General Biosafety Training via the online CITI Program (required for all proposals).

Responsible Conduct in Research Training via the online CITI Program (not required for teaching proposals).

(IBC Chair Signature Verifying all Above Training) (Date)