Routing # _____
AUP # _____
IRB # _____

For Internal Use Only
IBC # _____

Biohazardous Use Protocol (BUP) for IBC Permit

Checklist and Table of Contents for Institutional Biosafety Protocols

The following is a table of contents of the items included in the BUP for the 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. Parts III and V should be completed and submitted as applicable. Only typed applications will be processed for review. You need not submit blank pages or pages that are not applicable to the IBC.

Please send completed BUP for IBC Permits to Environmental Health, Safety, and Risk Management.

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.

List of Included Parts (check included parts)

☐ Part I: BUP for IBC Permit (required for all applications)

☐ Part II: Agent Information (required for all applications)

☐ Part III: Viral Vectors

☐ Part IV: Personnel Information (required of BSL-1 and above laboratories, personnel working with animals and human materials)

☐ Part V: Select Agent Plan Review Form

☐ Grant Proposal or Draft Grant Proposal (required for all applications supported by grants)

☐ Biosafety Manual (required for all BSL-2 or higher research)

Part I: ASU Biohazardous Use Protocol for IBC Permit

1. Title & Principal Investigator/PI Supervisor Information

A. Project Title: _____

B. Principal Investigator:

Last Name: _____ First Name: _____

Department: _____ College: _____

Office Building: _____ Office Room Number: _____

Mailing Address: _____

Phone: _____ _____ _____ _____
Office Laboratory Emergency/After Hours Fax

ASU Email: _____

C. Principal Investigator Supervisor:

Last Name: _____ First Name: _____

Department: _____ College: _____

Office Building: _____ Office Room Number: _____

Mailing Address: _____

Phone: _____ _____ _____ _____
Office Laboratory Emergency/After Hours Fax

ASU Email: _____

2. Investigator Assurance

- I attest that the information contained in this registration is accurate and complete.
- I agree to comply with all Angelo State University 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 BSO immediately of incidents involving biohazardous and / or recombinant agents.
- I am thoroughly familiar with the *NIH Guidelines* and BMBL as they relate to this research project. 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 BSL 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 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 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.*

		Click here to enter text.
Principal Investigator Signature	Date	Typed/Printed Name
		Click here to enter text.
Principal Student Investigator Signature	Date	Typed/Printed Name
		Click here to enter text.
Department Chair Signature	Date	Typed/Printed Name

3. Protocol Information

A. Funding Source (Please check all that apply)

☐ NIH ☐ NSF ☐ USDA ☐ N/A ☐ Other: _____

B. Routing Agency

☐ ASU ☐ TEES ☐ Texas AgriLife ☐ Other: _____

C. Grant Proposal (☐ Not 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. (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

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. 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. Smith, 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, room number, room use, current biosafety level and shared lab status. If laboratory is shared, please indicate all of the Principal Investigators.

Location ID	Building	Room Number	Room Use (Storage, Laboratory, Animal Housing)	Current Biosafety Level (Identify Level 1-4)	Shared Lab?
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

G. Protocol Subjects

Does this protocol involve:

Yes No

☐ ☐ Humans 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:

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)? *F. tularensis* and *C. burnetii* are exempt strains

☐ ☐ 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 of recombinant agents created elsewhere?

☐ ☐ Creation of recombinant bacteria or yeast non-pathogenic to humans, plants, or animals?

☐ ☐ Creation of recombinant 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 the following 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 of 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 an 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 cover experiments (pick 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 may be found in the *NIH Guidelines*.

For assistance, contact Environmental Health, Safety, and Risk Management.

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 below (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?

☐ ☐ Will an attempt be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced?

☐ ☐ Will specialty signage and specialized access control be necessary to prohibit unauthorized access to the area without approval, escort, or PPE?

If you answered "Yes" to any of the above questions, please provide an 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	
A-6	
A-7	
A-8	
A-9	
A-10	

O. Medical Treatment

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

P. Exposure Control

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

☐ Face Mask	☐ Gloves	☐ Shoe Covers	☐ Head Covers
☐ Boots/Crocs	☐ N95 (HEPA)*	☐ Eye Protection	☐ Double Gloves
☐ Lab Coats	☐ Face Shield	☐ Disposable Outers	☐ P100 (HEPA)*

☐ PAPR (HEPA)*

☐ Other (Specify): _____

_____

*Please contact Environmental Health, Safety, and Risk Management to schedule respirator medical clearance, training, and fit testing.

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 locations:

☐ Class II A (recirculating) Location: _____

☐ Class II B1 (70% exhausted – ducted outside) Location: _____

☐ Class II B2 (100% exhausted – ducted outside Location: _____

☐ None

☐ Other (Specify:) _____

Is the biological safety cabinet(s) certified annually?

☐ No

☐ Yes Provide date(s) of most recent certification. _____

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 C below for suggested autoclave temperature and exposure times.
- If using chemical disinfection, indicate final concentration of disinfectant and contact time required to achieve decontamination. Please refer to BMBL (5th edition), Appendix B.

- If using incineration please indicate the facility to be used.

Type of Waste	Potential Hazard	Decontamination, Sterilization, Disposal Procedure
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 departmentally operated

      Contact Name: _____ Phone No: _____

      Building and Room Number: _____

      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 and Room Number: _____

      Indicate testing frequency:

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

3. A test indicator kit will be used to test autoclave efficiency for BL2 or above.

   For the research project, ….

   ☐ 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, 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 Environmental Health, Safety, and Risk Management for more information on disposal of hazardous materials or instructions regarding Select Agent disposal.

Angelo State University **APPENDIX B**

Institutional Biosafety Committee

Part II: Agent Information

A. Table A: Agent/Vector/Host Characteristics

In the table below, list each agent that will be used. Note the ID of the agent for later use in your application. If the agent is recombinant, indicate "Yes" in the appropriate cell and enter insert information into Table B. 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."

ID	Genus, Species	Strain	RG-Risk Group (pick)	BSL (pick)	ABSL Animal Biosafety Level (pick)	Recombinant? (pick)	List all location IDs where agent will be used or stored	Use in Animals/Plants? (give specifics)
	Example – E. coli	K-12	RG-1	BSL-1	N/A	Yes	1, 2, 3	No
A-1								
A-2								
A-3								
A-4								
A-5								
A-6								
A-7								
A-8								
A-9								
A-10								

Table B: Insert characteristics

In the table below, enter information about each vector or host DNA inserts. Enter the appropriate Host ID from Table A to indicate which host will contain the insert.

ID	Host ID (Table A)	Strain	Insert Source Risk Group (pick)	Insert Name (e.g. insulin)	Insert Characteristic or Function (e.g. hormone)
	Example	Human	RG-2	Insulin	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

(One Agent per Page – Reproduce as Needed)

A. Agent ID from Table A: _____

B. Is the virus replication competent?

_____

C. Are assay systems used to measure the titer of replication competent viruses that may be present? If yes, please describe: _____

D. What is the host range of the viral vector?

_____

E. What percent of the original viral genome remains in the vector?

_____

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

_____

G. 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.

_____

Angelo State University **APPENDIX B**

Institutional Biosafety Committee

Part IV: Personnel Information

Personnel List

To be completed by the lab director (or PI) when working in laboratories that are BSL2 and above containment.

Action A=Add D=Del M=Mod	First Name	Last Name	CID	Associated with an Animal Use Protocol (AUP)? Y/N	List all organisms (Pathogens, Toxins, rDNA) employees will have access	Laboratory Building/Room	Position Title	Employee Email Address

Part IV: Personnel Acknowledgement

Signature Page

(Reproduce this page as needed)

Each employee working in BSL2 and above laboratories must complete this page.

Employees working in laboratories containing Select Agents may
submit copies of training certificates instead of signature pages.

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with (list of agents) in laboratory building (building name) and room(s) (room numbers) under the direction of (principle investigator).

I further certify that I understand the hazards of working with (list of agents); 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; the special Biosafety practices required for Biosafety Level work, in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guidebook and the standard operating procedures for this laboratory.

Finally, I certify that any transfer of this biological material will be done in accordance with Angelo State University policies and regulations and under the supervision of the Angelo State University Office of Environmental Health, Safety, and Risk Management. In addition, I ensure that the detailed records of information necessary to account for all activities related to this agent will be maintained.

Signature	Date	Laboratory Director/Supervisor Signature
Typed Name	Position/Title	Laboratory Director/Supervisor Typed Name

Have you completed lab-specific training for this research?

☐ Yes ☐ No Date of lab-specific training: _____