The University of Texas Rio Grande Valley

HBA

PROTOCOL REGISTRATION

Institutional Biosafety Committee (IBC) Protocol Registration for Research with infectious and/or potentially Hazardous Biological Agents

Application must be typed.

Principal Investigator: _____ Department: _____

Campus and Office Location: _____ Office Phone: _____

Email Address: _____ Emergency Phone Number: _____

Co-Investigator: _____ Department: _____

Campus and Office Location: _____ Office Phone: _____

Email: _____ Emergency Phone Number: _____

1mary Lab Location (Campus, Bldg., Room): _____ Laboratory Phone: _____

2ndary Lab Location (Campus, Bldg., Room): _____ Laboratory Phone: _____

Additional Location(s): _____ Laboratory Phone: _____

Protocol Title: _____

Application Status: ☐ New ☐ 4-Year Renewal ☐ Protocol Change

List previously approved title and HBA #: _____

If funded, please provide the following: Start Date: _____ End Date: _____

Title: _____ Agency: _____ Grant #: _____

Answer the following questions and complete the applicable section for each affirmative answer:

TABLE 1			
Section 1	Fill BOXES 1-4 describing project, risk assessment, containment and waste disposal		
Section 2	Fill TABLE 2: list at-risk personnel associated with protocol, training, and surveillance (if applicable)		
Section 3	Fill TABLES 3-7: EH&S Laboratory Containment Evaluation/Risk Assessment		
		Yes	**No**
Section 4	Does this study involve the use of biological agent(s) ***POTENTIALLY HAZARDOUS*** to humans, animals or plants ***OR*** tissue(s), cell(s), soil or water samples *from any source* (including human) ***contaminated with any infectious protein, virus, bacteria, fungi or parasites***?	☐	☐
Section 5	Does this study involve ***PROPAGATION or CULTURE*** of human or other vertebrate or plant cells, tissues (primary or immortal), or what may be found in their fluids - not suspected to be contaminated with infectious agents?	☐	☐
Section 6	Does this study involve an Investigational New Drug (IND)?	☐	☐
Section 7	Does this study involve the use of a Select Agent?	☐	☐
Section 8	Does this study involve the use of live vertebrates? Animal Use (IACUC protocol number(s):_____)	☐	☐
Section 9	Does this study involve the use of recombinant or synthetic nucleic acids? (IBC protocol number _____)	☐	☐
Section 10	Does this study involve human volunteers? Institutional Review Board (IRB protocol number(s):_____)	☐	☐
Section 11	Does this study involve the use of human reagents (tissues, cells, blood, saliva, body fluids, etc.) without culture or propagation harvested from individuals not suspected to be infected with any pathogens? Institutional Review Board (IRB protocol number(s) – if applicable: _____)	☐	☐

INSTITUTIONAL BIOSAFETY COMMITTEE USE ONLY

HBA APPLICATION/REGISTRATION #: _____ DATE RECEIVED: _____

BY (IBC CONTACT): _____

Section 1

BOX 1: Project Summary and Experimental Procedures

Provide a detailed summary of the project(s) [summarize multiple projects in separate paragraphs]: Summary should describe all the biohazardous materials and procedures in sufficient detail for committee members to review the protocol. Use technical terminology only when necessary to enable all IBC members to understand the research project. Attach additional documents such as procedures, descriptions, and other pertinent information.

BOX 2: Risk Assessment

To assist the IBC in evaluating the risks, provide a risk assessment for IBC members to evaluate the containment level and/or clinical safety of your proposed research. Discuss the risks associated of work with potentially hazardous biological agents such as human blood, cell lines and/or infectious agents (if applicable). If working with viral vectors or pathogenic microorganisms, the risk assessment should include a description of the, source replication competency, biosafety features, method of packaging, potential for replication competent virus (as applicable), culture volumes and titers, and aerosol generating procedures, and animal experiments (if applicable).

BOX 3: Proposed Biosafety Precautions and Containment Levels

Describe the proposed biosafety precautions and containment level. Describe procedures and precautions in place to reduce the risk to the employees and students working in the laboratory. (e.g. administrative controls, engineering controls; safety equipment, personal protective equipment, etc.)

BOX 4: Proposed Biological Waste Disposal Methods

Describe methods for disposal of liquid and solid biological waste streams. Identify if disposal is in house or from external contractor. Identify disinfectants used in the disposal of liquid waste streams. etc.)

Section 2: At-risk personnel

TABLE 2: Personnel working with potentially Hazardous Biological Agents (include the Principal Investigator).

Name	UTRGV ID#	Title	See "IBC Committee Training Guide" for required training.				Applicable Medical Surveillance / Vaccinations	
			UTRGV EHSRM Live Training utrgv.edu/ehsrm/programs/training		CITI Training https://about.citiprogram.org/en/homepage/			
			Module	Date	Module	Date	Occurrence	Date
Johnny Doe	6000012563	Research Assistant	BSL-3a	4/1/2017	ACU	6/20/2017	HBV TIB	3/1/2017 7/1/2017

Section 3

EH&S Laboratory Containment Evaluation and Risk Assessment
The purpose of this containment evaluation is to help the EH&S office determine whether or not your project requires special containment in a designated biohazard area and to confirm the Biosafety level and safety equipment to be used. Please refer to the Institutional Biosafety Manual and the CDC / NIH "Biosafety in Microbiological and Biomedical Laboratories" for information concerning biohazard levels and recommended containment procedures.

Environmental Health and Safety Review: This proposal and the classification/containment are reviewed by the Biological Safety Manager to confirm that the identified facilities and practices meet the biosafety level specifications for the agents indicated above.

TABLE 3: Generation of Aerosols

Are aerosols likely to be formed during manipulation or testing? ☐ Yes ☐ No ☐ N/A

Aerosols can be produced by common laboratory equipment such as sonicators, centrifuges, blenders, shakers, homogenizers, vortex mixers, heated inoculating loops.

If yes, what measures will be taken to minimize the risk posed by these manipulations?

What is the biological agent(s) stability or ability to remain viable over time in the environment? Consider such factors as humidity, desiccation, pH, osmolarity, exposure to sunlight, UV light, or to chemicals & disinfectants.

What is the highest concentration/titer/volume/density (whichever best describes quantity) of biological agent(s) you will work with?

TABLE 4: Safety Equipment

Identify the Biosafety Level you plan to work with? ☐ BSL-1 ☐ BSL-2 ☐ BSL-3
If YES to **BSL-3**, describe campus location and facilities:

Identify type of Biological Safety Cabinet #1: ☐ Class I ☐ Class II ☐ Class III
Identify type of Biological Safety Cabinet #2: ☐ Class I ☐ Class II ☐ Class III
Describe PPE: _____
Chemical fume hood: _____

TABLE 5: Facility Design	Yes	No	N/A
Is your laboratory separated from public access and have self-closing door?	☐	☐	☐
Are you using a separate tissue culture room?	☐	☐	☐
Do you have access to an emergency eyewash and safety shower?	☐	☐	☐
Do you have access to an autoclave?	☐	☐	☐
Are spill procedures and other placards posted in the laboratory?	☐	☐	☐
Will biological agents be transported between laboratories/buildings?	☐	☐	☐
If YES, describe containment, method of transport, safe practices:			

TABLE 6: Use of Shared Facilities:

Will your research require the use of UTRGV Core Facilities/ Common Rooms? ☐ Yes ☐ No ☐ N/A

If YES, describe which biological agents will be brought into shared facilities (describe campus location, building and room number) and what measures will be taken to prevent exposure or contamination of personnel and facilities:

Section 4: List all POTENTIALLY HAZARDOUS biological agent(s) involved in proposed work.

(Add rows as required and/or attach pages)

TABLE 7:

	Source: (tissue, cells fluids, soil, water, lab collection, ATCC, etc.)	**Organism Type:** (bacterium, virus, fungus, protozoan, nematode, etc.)	**Name/Strain of organism:**	**Risk Group (WHO/NIH) and Biosafety Level (BSL 1-4):**	**Building/Room(s) agent will be used in during the study:**	**Building/Room(s) where agent will be stored:**	**Will culture amount be >10 liters? Check box if yes.**
1							☐
2							☐
3							☐
4							☐
5							☐
6							☐
7							☐
8							☐

TABLE 8: Identify and describe sources of potentially hazardous biological agent(s)		
Animal / Plant / Environmental: _____		
Human Clinical Sample (IRB protocol number(s): _____)		
Commercial Company: _____		
Academic Institution: _____		
Other: _____		
Identify shipping/receiving of biohazardous agents		
Will you receive potentially biohazardous agents from external sources?	☐ Yes	☐ No
Will you ship potentially biohazardous agents from UTRGV?	☐ Yes	☐ No
Anticipated future recipients: _____		
Anticipated future sources: _____		

TABLE 9: Risk Containment Analysis			
List Host range (animals,/humans/plants), route of infection (respiratory, oral, contact, transdermal…) and infectious dose:			
Will visitors be routinely allowed into areas in which agents will be handled? ☐ Yes ☐ No ☐ N/A If yes, describe how visitors will be apprised of the agents used or other special hazards, recommended vaccinations and offered Personal Protective Equipment:			
In case of multiple agents please respond in consideration of the highest risk group:	**Yes**	**No**	**N/A**
Does this infectious agent pose an aerosol risk or potential for respiratory transmission?	☐	☐	☐
Are biophysical or biochemical techniques to be used which will require handling biological agents in uncovered containers on the open benchtop?	☐	☐	☐
Will agents be openly manipulated in areas occasionally shared by non-laboratory personnel?	☐	☐	☐
Are any populations (e.g., pregnant women, elderly, immunocompromised individuals) at increased risk to become infected and/or manifest symptoms upon exposure to this agent?	☐	☐	☐
Is a vaccine recommended or necessary to handle any of these agents?	☐	☐	☐
Is a vaccine available for any of these agents?	☐	☐	☐
Do technical personnel require special medical surveillance as a result of exposure to any of these agents?	☐	☐	☐
If YES, describe any special medical surveillance and/or recommended vaccine:			

Section 5

Propagation/culture of human or other vertebrate or plant cells, tissues (primary or immortal), or what may be in their fluids not suspected to be contaminated with any infectious agent.

IF AT ANY TIME EVIDENCE OR SUSPICION EMERGES OF INFECTIOUS AGENTS PRESENCE IN SAMPLES, CONTACT IBC COMMITTEE IMMEDIATELY.

TABLE 10: Cells/tissues or fluids from human and/or other vertebrates or plants to be propagated (from)

List source species: _____

Cell/tissue type/name (if applicable/known): _____

Fluids (blood, saliva, lymph, ascites, urine, stool, CSF, etc.): _____

Source of biological reagents:

Commercial source: _____ Please check if certified pathogen free: ☐

Direct human patient/volunteer source: _____ IRB #_____

Direct animal harvest: _____ IACUC # _____

Academic/clinical collaborative source: _____ Name of agency/institution: _____

Name of point of contact _____ Address: _____

Describe alternate source if none of the above are applicable: _____

Are any fluids, cells and/or tissues from known at-risk populations/sources? Describe the reagents and the applicable risk using one line for each:	**Unknown**	**Yes**	**No**
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Total number of individual cell/tissue lines/body fluid samples to be propagated: _____

Starting amounts (volume, weight or cell numbers) to be propagated/cultured for each sample: _____

Does this project involve propagation of immortal cell lines? ☐ Yes ☐ No

If the project involves primary cell lines, will any be transformed/immortalized? ☐ Yes ☐ No

If YES to the latter, explain how:

Identify and describe sources of human/animal/plant reagents described above.

TABLE 11: Identify FUTURE shipments and/or acceptance of biological agents described in this application

Will you receive biological reagents from external sources? ☐ Yes ☐ No

Will you ship biological agents from UTRGV? ☐ Yes ☐ No

Anticipated future recipients: _____

Anticipated future sources: _____

Animal/Plant/Environmental: _____

Clinical facility (hospital, clinic, etc.): _____

Commercial Company: _____

Academic Institution: _____

Other: _____

Section 6: Investigational New Drugs (INDs):

TABLE 12: The IND Involves potentially infectious/hazardous biological agents
Report FDA approval #:
If IND is manufactured on-site list specific lab location (reported on page 1) must match in vitro laboratory containment and BSL reported in TABLE 3 on page 2:
If IND is manufactured elsewhere report facility and contact information here:
Describe IND Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and report quality assurance testing site and contact information here:
Describe how IND are tested for sterility:

Section 7: Select Agents

Attach copies of:
1. SOP for handling Select Agent(s)
2. Select Agent specific training modules developed for laboratory personnel
3. Describe and attach Select Agent specific precautions (sign-up sheets, records of use, storage, infrastructural modifications, warning placards, designated areas, etc.)

TABLE 13: Use of Select Agents
Is the select agent on the CDC/USDA Select Agents and Toxin list? ☐ Yes ☐ No www.selectagents.gov/SelectAgentsandToxinsList.html If YES, Responsible Official approval? ☐ Yes ☐ No ☐ Pending If YES*, list CDC Select Agent Registration #:
Is the agent on the USDA High consequence Livestock Pathogen and Toxins or Overlap Select Agent & toxin List? ☐ Yes ☐ No www.cdc.gov/phlp/docs/forensic_epidemiology/additional%20materials/salist.pdf If YES, List Permit #:
Name/list the select agent(s):
List the amount (quantity, titer, culture volume as applicable) for each Select Agent named above you intend to use in the course of 1 year:

* *Note: Requires prior approval of UTRGV Responsible Official or Alternate and facility registration for each agent and lab. For agents not listed, contact the Centers for Disease Control and Prevention, Biosafety Branch, Atlanta Georgia 30333*

Section 8: Animal subjects

Attach copies of IACUC approval letter(s)

BOX 5:
Provide a detailed description of the provisions, safety and containment measures to insure safety of personnel, community and environment taken in the use of this/these biological agent/s with vertebrate animals.

Section 9: rDNA work

Attach copies of IBC approval letter(s)

BOX 6:
Provide a detailed description of the provisions, safety and containment measures to insure safety of personnel, community and environment taken in the use of rDNA with this/these biological agent/s.

Section 10: Human subjects

Attach copies of IRB approval letter(s)

BOX 7:
Provide a detailed description of the provisions, safety and containment measures to insure safety of human subjects, personnel, community and environment taken in the use of this/these biological agent/s with human volunteers.

Section 11:

Work with human reagents (tissues, cells, blood, saliva, body fluids, etc.) without culture or propagation from individuals not suspected to be infected with any pathogens.

IF AT ANY TIME EVIDENCE OR SUSPICION EMERGES OF INFECTIOUS AGENTS PRESENCE IN SAMPLES, CONTACT IBC COMMITTEE IMMEDIATELY.

Attach copies of IRB approval letter(s) – if applicable

TABLE 14: Human reagents

Describe human reagent(s) collected (blood, saliva, CSF, lymph, feces, urine, etc): _____
_____

Describe population to be sampled from (geographical location, age groups, ethnicity, etc.): _____
_____

Describe volume/weight/cell number (whichever best describes quantity) of human reagent collected: _____

Are source volunteers healthy? ☐ Yes ☐ No ☐ Unknown
If not, describe any pathological condition shared among the population to be sampled: _____

Number of samples: _____

Describe downstream experimental application (antibody titers, DNA extraction and/or sequencing/PCR, blood glucose determination, etc): _____

Will human reagents be shipped externally? ☐ Yes ☐ No
If YES, state number of samples to be shipped, name(s) of recipient(s), agency/institution(s) and shipping method:

Sample collection:
IBC oversees use of human reagents for research purposes only, not for clinical or diagnostic applications

Is collection of the sample included in this protocol? ☐ Yes ☐ No

If sample collection is not included in this protocol, state source of samples (clinic/university/agency) collected by third parties and shipping/transport method to UTRGV facilities:_____
_____

If sample collection is included in this protocol state location(s) of sample collection and transport method to UTRGV campus if applicable: _____
_____

Is a certified phlebotomist listed on this protocol? ☐ Yes ☐ No
If YES, name: _____

Name of authorizing licensed physician and license number: _____

Principal Investigator (PI) Responsibilities

The principle investigator, the individual who submits the application, has the responsibility to:

1. Be fully aware of the potential hazards associated with the agents used in your work area.
2. Be familiar with and agree to abide by the provisions of the current edition of "Biosafety in Microbiological and Biomedical Laboratories," as published by the CDC and NIH.

   http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf
3. Agree to comply with all Federal and State requirements pertaining to shipment, storage and disposal of infectious agents, and biological specimens.
4. Be aware of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) and Texas Department of Health regulations (25 TAC Part I TDH, Chap. 96 Bloodborne Pathogen Control) and comply with the UT Health Science Center's Bloodborne Pathogen Exposure Control Plan when working with HIV, HBV, and human blood or other potentially infectious materials as defined in these regulations and plan.

   https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

   http://www.dshs.state.tx.us/idcu/health/infection_control/bloodborne_pathogens/plan/
5. Accept responsibility for informing and training (or arranging for training by the Environmental Health and Safety dept. or other qualified personnel) of all laboratory workers about the hazards, risks, precautions, and appropriate emergency procedures for working with the agent to be used, before commencing any work. Staff must not be allowed to handle the agent until training is completed and then Principal Investigator will insure that the proper safety practices and techniques required will be followed.
6. Prior to commencement of research, the Principle Investigator agrees to an initial and periodic inspection of the research laboratory to determine whether bio-containment procedures, equipment, and facilities are adequate. Standard Operating Procedures (SOPs) should be readily available to all laboratory personnel.
7. Written reports will be submitted to the Institutional Biosafety Committee through the Biosafety Officer and/or the Environmental Health and Safety dept. when:
   - Any injury involving sharps or other accident that results in inoculation, ingestion, and inhalation of infectious agents or recombinant or synthetic nucleic acid molecules or any incident causing serious exposure of personnel or danger of environmental contamination.
   - Any problems pertaining to the operation and implementation of containment safety procedures or equipment or facility failure.
   - Any serious adverse event from a gene transfer clinical trial, regardless of whether or not they are thought to be related to gene transfer intervention.
   - Any major changes or modification to this protocol that may affect safety of laboratory personnel, community or the environment.
8. Submit either an IBC annual protocol renewal thirty days prior to the date of expiration of this approved research protocol or a project completion/termination memorandum.

Principal Investigator Certification:

I certify that the information I have provided is complete and correct, to the best of my knowledge. I am familiar with and agree to abide by the provisions of the current NIH/CDC Provisions, UTRGV Handbooks on biological safety, and other specific granting agency instructions pertaining to the proposed project, the Principal Investigator's responsibilities and administrative procedures.

_____ _____

Principal Investigator (Signature) **Date**

INSTITUTIONAL BIOSAFETY COMMITTEE USE ONLY

APPROVAL PERIOD: FROM_____TO:_____ APPROVED BIOSAFETY LEVEL: _____

MODIFICATIONS NOTED: _____

IBC CHAIRPERSON: _____ DATE: _____