The University of Texas Rio Grande Valley

IBC

Protocol Registration

Institutional Biosafety Committee (IBC) Protocol Registration for Research with Recombinant/Synthetic Nucleic Acids

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 IBC #: _____

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 Tables 2-7		
Section 2	Fill Boxes 1-4 describing project, risk assessment, in vitro containment and waste disposal.		
Section 3	Fill Table 8: list at-risk personnel associated with protocol, training, and surveillance (if applicable).		
		Yes	**No**
Section 4	Does this study involve the use of infectious/potentially Hazardous Biological Agents (HBAs) including human/primate blood, tissues and/or cells? (HBA protocol number(s): _____)	☐	☐
Section 5	Does this study involve Human subjects (including their tissues, blood, etc.) or Human Gene Transfer (HGT)? Institutional Review Board (IRB protocol number(s): _____)	☐	☐
Section 6	Does this study involve an Investigational New Drug (IND)?	☐	☐
Section 7	Does this study involve the use of "Dual Use" or potential biological weapons or drug resistance enhancements? https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/	☐	☐
Section 8	Does this study involve the introduction of rDNA/synthetic DNA into animals or the use of transgenic/knockout animals? (IACUC protocol number(s): _____)	☐	☐

INSTITUTIONAL BIOSAFETY COMMITTEE USE ONLY

IBC APPLICATION/REGISTRATION #: _____ DATE RECEIVED: _____

BY (IBC CONTACT): _____

Section 1

NIH Guidelines:
The primary reference for completion of this section is the most current amendment of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*: https://osp.od.nih.gov/biotechnology/nih-guidelines/

TABLE 2			
Check <u>all</u> that apply in the boxes below:			**NIH Guidelines reference:**
☐	a.	Use of animal cells/cell lines or tissues (e.g. tissue culture research).	II-A-3, Appendix C-1
☐	b.	Use of human cells/cell lines or tissues (e.g. human blood, 293 cell lines, CSF).	II-A-3
☐	c.	Transfer of Drug Resistance trait to microorganisms (engineering resistance against a drug used to treat disease caused by the biological agent requires NIH approval).	III-A-1-a
☐	d.	Use/cloning of genes for biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 ng/kg body weight (requires NIH approval).	III-B-1
☐	e.	Use of or the cloning of genes from, or into a Risk Group 2, 3, 4 or restricted agent.	III-D-1, 2
☐	f.	Use of virus or viruses (experiments involving Influenza viruses fall under III-D-7).	III-D-3, III-E-1
☐	g.	Propagating culture volumes ***exceeding*** 10 liters.	III-D-6
☐	h.	Generation or use of cDNA/genomic libraries.	III-E, III-F
☐	i.	Cloning and vector construction in bacteria and yeasts.	III-E, III-F
☐	j.	Use of recombinant or synthetic nucleic acid molecules for detection (e.g. probes).	III-F
☐	k.	Expression of recombinant or synthetic nucleic acid molecules in cultured cells.	III-E, III-F
☐	l.	Administration of recombinant or synthetic nucleic acid molecules into humans (e.g. Gene Transfer Protocol).	III-C-1, Appendix M
☐	m.	Administration of recombinant or synthetic nucleic acid molecules into animals (e.g. transformed cells, vectors) - complete section 9.	III-D-4
☐	n.	Experiments involving transgenic/knockout animals requiring ABSL-1 containment.	III-E-3
☐		Experiments involving transgenic/knockout animals requiring ABSL-2 and above containment.	III-D-4
☐	o.	Experiments involving whole plants.	III-D-5

Description of host cell(s), vectors, inserts, and material transfers:

TABLE 3: Host Cell(s)
Describe rDNA/synthetic nucleic acid expression and/or propagation ***host species*** and/or cell line lineage (e.g. *E. coli*, Human Immortal Cervical Cancer, *Pan troglodytes* primary kidney cell lines):
List strain(s) and/or cell line name(s) (e.g. DH5-α, HELA):
Proposed containment for host/rDNA synthetic nucleic acids experiments: ☐ BSL-1 ☐ BSL-2 ☐ BSL-3
Are any host cells pathogenic or potentially hazardous to humans, animals or plants? ☐ Yes ☐ No

TABLE 4: Host Sources

External academic institution: _____

Commercial company: _____

If environmental specimen(s), describe: _____

If clinical specimen(s), describe: _____

If laboratory collection specimen(s), describe: _____

Other: _____

Will you receive host cells from external sources? ☐ Yes ☐ No

Will you ship host cells from UTRGV? ☐ Yes ☐ No

Anticipated future recipients: _____

Anticipated future sources: _____

TABLE 5: Vector Description

Name and describe the vector(s) used (e.g. pBAD, arabinose-inducible bacterial expression vector):

If the vector has viral sequences	Yes	No	N/A
Is vector replication competent (wild-type)?	☐	☐	☐
Is vector replication defective?	☐	☐	☐
Has vector product been tested for RCV (replication Competent Virus)?	☐	☐	☐
Is a helper virus or packaging system involved?	☐	☐	☐

TABLE 6: Vector Sources

Generated in UTRGV laboratory: _____

Commercial company: _____

External academic institution: _____

Other: _____

Will you receive vectors and/or rDNA constructs/synthetic nucleic acids from external sources? ☐ Yes ☐ No

Will you ship vectors and/or rDNA constructs/synthetic nucleic acids from UTRGV? ☐ Yes ☐ No

Anticipated future recipients: _____

Anticipated future sources: _____

TABLE 7: Insert(s) or synthetic nucleic acids description

List the DNA inserts (Gene names, explain acronyms): Gene/biological source (genus, species, strain), nature of insert, protein expressed, any toxic or oncogenic potential, gene function (attach a map of the construct or sequence of synthetic nucleic acids):

Will the rDNA molecule contain more than 2/3 of the genome of any eukaryotic virus? ☐ Yes ☐ No

If applicable, will transcription of insert(s) be controlled from ☐ native, ☐ alternate or ☐ inducible promoter?

Describe the promoter(s) that will control transcription of the insert(s) and how this may affect risk assessment:

Section 2:

BOX 1: Project Summary and Experimental Procedures

Provide a detailed summary of the project(s): (More than one project should be summarized in separate paragraphs.) Summary should describe all the recombinant/biohazardous materials and procedures in sufficient detail for committee members to review your protocol. Use non-technical terminology to enable IBC members to understand the research project. Attach additional documents such as procedures, vector maps, and other pertinent information.

BOX 2: Risk Assessment

To assist the IBC in evaluating the risks, provide a risk assessment for the IBC reviewers to evaluate the containment level and/or clinical safety of your proposed research. Discuss the risks associated of work with rDNA associated with potentially hazardous biological agents such as human blood, cell lines and infectious agents (if applicable). If working with viral vectors or pathogenic microorganisms, the risk assessment should include: 1) the nature of the vector system (vector name, source replication competency, biosafety features, method of packaging, potential for replication competent virus (as applicable), 2) the nature of the transgene inserts, 3) the vector titer and amount used, 4) aerosol generating procedures, and 5) 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 the methods for disposal of liquid and solid biological and rDNA waste streams. Identify if disposal is in house or from external contractor. Identify disinfectants used in the disposal of liquid waste streams, etc.

Section 3: At-risk personnel

TABLE 8: Personnel working with rDNA/synthetic nucleic acids (include the Principal Investigator)

Name	UTRGV Employee 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	04/01/2017	ACU	06/20/2017	HBV TIB	03/01/2017 07/01/2017

Section 4: Potentially Hazardous Biological Agents involved with rDNA/synthetic nucleic acids work.

Attach copies of HBA approval letter(s).

TABLE 9	Yes	No
Is the agent on the CDC/USDA Select Agent and Toxins list? www.selectagents.gov/SelectAgentsandToxinsList.html	☐	☐
Is the agent on the USDA High consequence Livestock Pathogen and Toxins or Overlap Select Agent and toxin List? USDA/Overlap agents list: www.cdc.gov/phlp/docs/forensic_epidemiology/additional%20materials/salist.pdf	☐	☐
Does the rDNA project involve handling Human Blood, tissue, body fluids?	☐	☐
Are source patients of high risk with known infection?	☐	☐
Does the rDNA project involve primate blood, tissue, body fluids? If YES, name primate species and source facility: _____	☐	☐
Does the rDNA project include Human Primary Cell Lines?	☐	☐
Does the rDNA project include Human Immortal cell lines?	☐	☐
Does the rDNA project include pathogenic microorganisms?	☐	☐

TABLE 10

List infectious agents associated with proposed rDNA work (add rows as required and/or attach pages.)

	Organism Type: (Bacterium, virus, fungus, parasite, etc.)	**Organism species and strain name:**	**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						☐

Section 5: Human Subjects and/or Human Gene Therapy (HGT)

Attach copies of: 1. NIH/RAC approval letter(s)
2. IRB approval letter(s)

TABLE 11: Human Subjects
Does the study involve the transfer of rDNA, viral or synthetic nucleic acids or biological agents containing rDNA into human subjects? If so, consult Appendix M of NIH Guidelines. ☐ Yes ☐ No
Name and describe the HGT product:
Describe the location where the HGT product was manufactured, provide address and contact information:
Describe HGT products Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and report quality assurance testing site and contact information here:
Is vertical transmission of from an individual to the offspring possible? ☐ Yes ☐ No Is horizontal transmission of HGT products to other persons or the environment possible? ☐ Yes ☐ No
Name the patient care facility, location (address and contact information) and room number(s) where the HGT agent(s) will be handled prior to administration:
Name the patient care facility, location (address and contact information) and room number(s) where the HGT agent(s) will be administered (if all else is the same as above, mention only the room numbers):

Section 6: Investigational New Drugs (INDs)

TABLE 12: The IND Involves rDNA and/or synthetic nucleic acids technology
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: Potential Dual Use of rDNA/synthetic nucleic acids.

The National Research Council and the National Science Advisory Board for Biosecurity (NSABB) list seven classes of experiments (Experiments of concern) involving microbial agents that "raise concerns about their potential for misuse." If you answer "YES" to any of the following questions, then your experiment may be considered "Dual Use."

TABLE 13: Your project may have "Dual Use" applications if it:	Yes	No
Demonstrates how to render a vaccine ineffective? (Applies to human and animal vaccines. Example: vaccine resistant smallpox)	☐	☐
Confers resistance to therapeutically useful antibiotics or antiviral agents? (This would apply to therapeutic agents used to control disease agents in humans and animals or crops. Example: introducing ciprofloxacin resistance in *Bacillus anthracis)*	☐	☐
Enhances the virulence of a pathogen or render a non-pathogen virulent? (Applies to human, animal and plant pathogens. Example: introducing cereolysin toxin gene into *Bacillus anthracis*)	☐	☐
Increases the transmissibility of a pathogen? (includes enhancing transmission within or between species, altering vector competence to enhance disease transmission.)	☐	☐
Alters the host range of a pathogen? (includes converting non-zoonotic into zoonotic agents, altering the tropism of viruses)	☐	☐
Enables the evasion of diagnostic/detection modalities? (includes microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.)	☐	☐
Enables the weaponization of a biological agent or toxin? (includes environmental stabilization of pathogens)	☐	☐

Section 8: rDNA or synthetic nucleic acids introduced in animals and transgenic animals

Attach copies of IACUC approval letter(s).

TABLE 14: Animal Subjects
Does the study involve the transfer of rDNA, viral or synthetic nucleic acids or biological agents containing rDNA into animals? ☐ Yes ☐ No
Proposed containment for rDNA/synthetic nucleic acids experiments with animals: ☐ ABSL-1 ☐ ABSL-2 ☐ ABSL-3
Name the animal species and describe the purpose of this aspect of the study:
Describe the location where the rDNA/synthetic nucleic acids experiments with animals will take place:
Will rDNA be propagated in live animals? Will live animals be infected with microorganisms harboring rDNA?
Is vertical transmission of rDNA/synthetic nucleic acids from animals to offspring possible? Allowed? ☐ Yes ☐ No Is transmission of rDNA/synthetic nucleic acids from animals to persons or the environment possible? ☐ Yes ☐ No Does the study involve transgenic animals? ☐ Yes ☐ No Will rDNA/synthetic nucleic acids be transferred into transgenic animals? ☐ Yes ☐ No
Name the genotype and phenotype of transgenic animals:
Describe the source of transgenic animals (contact information and address) or the location where they were generated:

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 NIH "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" and the current edition of "Biosafety in Microbiological and Biomedical Laboratories," as published by the CDC and NIH.
   https://osp.od.nih.gov/biotechnology/nih-guidelines/
   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 recombinant or synthetic nucleic acid molecules, Infectious agents, and Biological Specimens.
4. Be aware of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) and Texas Department of Health regulations (Health and Safety Code, § 81.304, Chap. 81 Infectious Disease Control, Bloodborne Pathogens) and comply with the UTRGV'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. Agree to an initial and periodic inspection of the research laboratory to determine whether bio-containment procedures, equipment, and facilities are adequate prior to commencement of research. Standard Operating Procedures (SOPs) should be readily available to all laboratory personnel.
7. Submit written reports to the Institutional Biosafety Committee through the Biosafety Officer and/or the Environmental Health and Safety Department 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. (The NIH Guidelines apply to all NIH-funded projects involving recombinant or synthetic nucleic acid molecules techniques as well as to all non-NIH funded research.)
   - 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 Guidelines, 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: _____