UNT DALLAS IBC Project Registration

University of North Texas

Initial Review:

Use this form to apply for any new research using potentially biohazardous materials for *teaching* or *research*. After review by the Institutional Biosafety Committee (IBC), subsequent research will be restricted to that outlined in the application. This application must be submitted prior to initiation of the project. Detailed IBC policies and procedures apply and are available from Risk Management Services. Detailed instructions are available on the Biosafety/IBC website.

Expiration:

The maximum period of approval for an application is *three* years, subject to *Annual Review* (after year 1 and year 2 of research/instructional activity). Within 60 days prior to the *first* and *second* anniversaries of the initial IBC approval (the date referenced on your approval letter), an **Annual Research Registration Review** application must be submitted to the IBC. If activity is to be continued beyond the *third* anniversary, a new **IBC Project Registration** (this form) must be submitted 60 days prior to the end date for full IBC review.

Amendment:

Following initial approval of a protocol, proposed changes in personnel, space, or equipment should be submitted to the IBC using an **IBC Project Amendment** form. Changes to methodology or agents require new registration.

Instructions:

1. Answer all questions. For all yes/no check boxes, you must click either yes or no.

2. Forward one (1) copy of this application (minus this page), signed by the Principal Investigator or Lab Manager to:

   Institutional Biosafety Committee (IBC)
   Biosafety@untdallas.edu

3. Copies of your protocol will be forwarded (as approved by the Biosafety Officer) to the IBC committee. The IBC will meet to review all new applications.

4. Reference the assigned registration number in all internal activities involving the project.

UNT Dallas IBC PROJECT REGISTRATION

Biosafety Disclosure Form	
IBC# IBC Only	BSL: IBC Only

Complete and email to Biosafety@untdallas.edu

☐ New Submission		☐ Renewal: Previous IBC#: Click to enter text.	
Project Title:	Click to enter text.		
PRINCIPAL INVESTIGATOR OR LAB MANAGER:	Click to enter text.	Phone #:	Click to enter text.
Department	Click to enter text.	Cell/emerg.#:	Click to enter text.
Building, Office Room #	Click to enter text.	Email:	Click to enter text.
Co- INVESTIGATOR:	Click to enter text.	Phone #:	Click to enter text.
Department	Click to enter text.	Cell/emerg.#:	Click to enter text.
Building, Office Room #	Click to enter text.	Email:	Click to enter text.
Co- INVESTIGATOR:	Click to enter text.	Phone #:	Click to enter text.
Department	Click to enter text.	Cell/emerg.#:	Click to enter text.
Building, Office Room #	Click to enter text.	Email:	Click to enter text.
Is this project for a teaching or a research activity?	Click to enter text.		
Project Start Date	Click to choose date.	**Project End Date***	Click to choose date.

*IBC registration will expire on this date or 3 years after IBC approval, whichever comes first, and will need to be resubmitted at that time.

The University's Institutional Biosafety Committee (IBC) is comprised of both active researchers and lay persons. Each member has one vote, and it is therefore particularly important that the language used in each section of the application be understood by all. Present the goals and justifications of the proposed research in the clearest possible terms. Upon approval, this disclosure may become a public record, so do not disclose proprietary information. You must complete all questions on the form or the submission will not be approved.

I. SYNOPSIS

In the space below, provide a brief synopsis of the proposed project(s)/course(s) in lay terms including, if appropriate, a graphical abstract, as well as information regarding the experiments to be performed:

Click here to enter text.

II. CONTAINMENT

Select the highest required biosafety containment level for the proposed work (BSL-1 or -2 only; BSL-3 and -4 level containment facilities are not available at UNT Dallas) from the drop down list: Select biosafety level

III. RESEARCH MATERIALS

Select <u>and</u> list <u>all</u> materials used in experiments:

A. ☐ Human/NHP Products—blood and blood products, tissues, bodily fluids, archaeological samples:
List all materials here (include risk groups)

B. ☐ Primary Cells, Cell lines, or tissues (include species of origin and risk groups)
List here

C. ☐ Microorganisms—bacteria, viruses, yeasts, parasites, algae, protozoa, etc.:
List all organisms here (include risk groups)

a. Are any microorganisms transgenic?
☐ No ☐ Yes: If yes, describe here.

b. Is there a possibility of new strains being created?
☐ No ☐ Yes: If yes, describe here.

c. Is the organism inactivated prior to other manipulation?
☐ No ☐ Yes:
   i. Method of inactivation Click here to enter text.
   ii. Method to verify inactivation Click here to enter text.

d. Do you culture the organism? Click here to enter text.
☐ No ☐ Yes: If yes, specify the amount.

e. Do you concentrate the organism?
☐ No ☐ Yes: If yes, specify method.

D. ☐ Recombinant and/or Synthetic Nucleic Acids **(fill out APPENDIX A – RECOMBINANT/SYNTHETIC NUCLEIC ACIDS)**

E. ☐ Arthropods:
List all organisms here

a. Are any arthropods transgenic?
☐ No ☐ Yes: If yes, describe here.

F. ☐ Whole plants or fungi?
List all organisms here (include risk groups)
Are any plants transgenic?
☐ No ☐ Yes: If yes, describe here.
Are any plants exotic?
☐ No ☐ Yes: If yes, describe here.

G. ☐ Environmental Samples
List all materials here (include risk groups)

H. ☐ Toxins of Biological Origin
List all toxins here (include LD_{50})

a. Method of aliquot Click here to enter text.
b. Usual volume to be used (L) Click here to enter text.
c. Largest volume to be used Click here to enter text.
d. Will dilutions be used? ☐ No ☐ Yes: If yes, describe here.

I. ☐ Human Subjects
IRB Protocol #: Enter text here

J. ☐ Carcinogens
List all carcinogens here.

K. ☐ Animals ☐ Animal Tissues

IACUC Protocol # Enter text here

IACUC approval date: Enter date here

List all animals here

a. Are any animals transgenic?

☐ No ☐ Yes: If yes, describe here.

b. Are any materials listed above (A. through K.) used with animals?

☐ No ☐ Yes: If yes, describe here.

c. Does work involve anesthetics, analgesics, or tranquilizers?

☐ No ☐ Yes: If yes, describe here.

IV. METHODS

A. Select all methods used and include additional information as needed:

☐ Pipetting ☐ Vortex/mixing ☐ Blending ☐ Sonication ☐ Grinding

☐ Glassware ☐ Scalpels, Scissors, Razors ☐ Injecting Animals ☐ Excretion by Animals

☐ Needles, Type: Type of Needles. Intended procedures for needles Procedures for needles.

☐ Centrifuging using: ☐ Sealed Rotors ☐ Safety Cup

☐ Other: Describe other methodologies here.

B. List all procedures that are performed in a biosafety cabinet (if applicable):

List procedures here

C. Will there be any transfer or transport of potentially biohazardous material? **Click yes or no.**

☐ No ☐ Yes: If yes, explain transfer/transport procedures here

V. SPECIAL CONSIDERATIONS (DURC and Select Agents) For each you must click yes or no.

Does the proposed research (include explanations for those marked "Yes"):

A. Involve any material volumes of 10 liters or larger?

☐ No ☐ Yes: If yes, describe here.

B. Involve an intentional release into the environment?

☐ No ☐ Yes: If yes, describe here.

C. Enhance the harmful consequences of a biological agent/toxin (e.g. increase pathogenicity/symptom severity)?

☐ No ☐ Yes: If yes, describe here.

D. Disrupt immunity or the effectiveness of immunization without clinical and/or agricultural justification?

☐ No ☐ Yes: If yes, describe here.

E. Confer to a biological agent/toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent/toxin or facilitate their ability to evade detection methodologies?

☐ No ☐ Yes: If yes, describe here.

F. Increase the stability, transmissibility, or the ability to disseminate a biological agent/toxin?

☐ No ☐ Yes: If yes, describe here.

G. Alter the host range or tropism of a biological agent or toxin?

☐ No ☐ Yes: If yes, describe here.

H. Enhance the susceptibility of a host population?

☐ No ☐ Yes: If yes, describe here.

I. Generate a novel pathogenic agent/toxin, or reconstitute an eradicated or extinct biological agent?

☐ No ☐ Yes: If yes, describe here.

J. Are you using any biological select agents (click here for a list)?

☐ No ☐ Yes: If yes, describe here.

K. Select any of the following agents, including nucleic acids from the agents, or toxins that you use:

☐ Avian influenza virus (highly pathogenic)	☐ *Bacillus anthracis*	☐ *Botulinum* neurotoxin
☐ *Burkholderia mallei*	☐ *Burkholderia pseudomallei*	☐ Ebola virus
☐ Foot-and-mouth disease virus	☐ *Francisella tularensis*	☐ Marburg virus
☐ Reconstructed 1918 Influenza virus	☐ Rinderpest virus	☐ Toxin-producing strains of *Clostridium botulinum*
☐ Variola major virus	☐ Variola minor virus	☐ *Yersinia pestis*

VI. SAFETY

A. **Attach and submit** a copy of the following documents as separate files (use this check-list to verify):

1. ☐ Lab-Specific Biosafety Manual **BSL2 Labs Only** (including Accidental Spill and Exposure Procedures and Biohazardous Disposal Procedures, Template provided here)

2. ☐ Standard Operating Procedures (SOPs) related to this project

B. Select all personal protective equipment (PPE) or safety equipment used:

☐ Lab Coat	☐ Gloves	☐ Cover Gown/Booties
☐ Safety Glasses	☐ Goggles	☐ Surgical Mask
☐ Face shield	☐ Respirator, Type: type of respirator.	
☐ Biological Safety Cabinet (BSC) ☐ Non-ducted or ☐ Hard-ducted		
☐ Other describe here.		

C. If working with animals, will the animals, caging, bedding material, or other animal equipment be contaminated with potentially hazardous materials that will pose a risk to personnel handling these animals or animal materials?

☐ No ☐ Yes: If yes, describe decontamination procedures here.

D. Do any of the proposed materials pose a health risk to humans?

☐ No ☐ Yes (If yes, attach and submit a copy of the material's hazard information sheet (SDS))

E. Medical surveillance requirements; exposure and medical intervention:

E1. Are personnel at risk of infection or disease from the use of the biohazard(s) or hazardous drug(s) (e.g. pregnant, immune-compromised, allergic, etc.)?

☐ No ☐ Yes: If yes, explain.

E2. Are any special immunizations or vaccinations needed or provided for personnel involved in the research (e.g. Hepatitis B, Tetanus/Tdap, etc.)?

☐ No ☐ Yes: If yes, explain.

E3. Is there a need to monitor the health of personnel involved (e.g. serum banking, continued testing)?

☐ No ☐ Yes: If yes, explain.

E4. Are any agents being used resistant to any therapeutics used for treatment? This information will be forwarded to health services in the case of an emergency.

☐ No ☐ Yes: If yes, explain.

F. Have you completed a risk assessment for the proposed agents/materials?
☐ No ☐ Yes: (If yes, attach and submit a copy of the risk assessment if no, complete risk assessment and submit)

G. Have you submitted your laboratory's annual Bioinventory?
☐ No ☐ Yes: If yes, indicate date

VII. LOCATIONS

List all locations associated with this project:

Campus	Building	Room	Room Function	Biosafety Level	Cold Storage Type	IBC Use Only Inspection
Example: Dallas	Founders Hall	255-A	☒ Lab ☒ Storage ☐ Live Animals ☐ Greenhouse	BSL 1	☒ 4 °C ☒ -20 °C ☐ -80 °C ☐ LN_2	1/10/19
Campus.	Building	Room #.	☐ Lab ☐ Storage ☐ Live Animals ☐ Greenhouse	Biosafety Level	☐ 4 °C ☐ -20 °C ☐ -80 °C ☐ LN_2	IBC use only.
Campus.	Building	Room #.	☐ Lab ☐ Storage ☐ Live Animals ☐ Greenhouse	Biosafety Level	☐ 4 °C ☐ -20 °C ☐ -80 °C ☐ LN_2	IBC use only.
Campus.	Building	Room #.	☐ Lab ☐ Storage ☐ Live Animals ☐ Greenhouse	Biosafety Level	☐ 4 °C ☐ -20 °C ☐ -80 °C ☐ LN_2	IBC use only.
Campus.	Building	Room #.	☐ Lab ☐ Storage ☐ Live Animals ☐ Greenhouse	Biosafety Level	☐ 4 °C ☐ -20 °C ☐ -80 °C ☐ LN_2	IBC use only.
Campus.	Building	Room #.	☐ Lab ☐ Storage ☐ Live Animals ☐ Greenhouse	Biosafety Level	☐ 4 °C ☐ -20 °C ☐ -80 °C ☐ LN_2	IBC use only.

VIII. PERSONNEL

All personnel must have biosafety training prior to working in the laboratory. See the UNT Dallas Lab Specific Biosafety Training Form for required training for laboratory personnel.

A. Indicate the Principal Investigator's degree or Lab Manager, training, experience and proficiency working with the materials on this disclosure.

Click here to enter text.	**Biosafety Training Verification**	
	IBC use only.	

B. Identify all personnel conducting the experiment(s). Specify degree, project responsibilities, and applicable training and experience (including experience duration). *Approval of the proposed experiments is given only for the identified personnel listed below. Once approved, submit an amendment to add personnel to this project. All required training must be completed prior to participation.* **Attach a completed lab-specific training form for each participant**.

Participant Name	UNT email	Degree	Project Responsibilities	Prior Experience or Training Related to Responsibilities	Biosafety Training Verification
Example: John Smith	**Jsmith1@untdallas.edu**	**B.Sc.**	**miRNA extraction from whole blood, urine, and saliva qPCR**	**1 yr. BSL2 bench experience during undergraduate studies performing PCR; 3 week training by lab manager**	**12/21/18**
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.
Name	Email	Degree	Responsibilities	Experience and Training.	Date Completed.

IX. FUNDING

List all funding associated with the project(s) covered by this disclosure.

Note: Lack of outside funding does not exempt a research project from IBC registration/approval.

Sponsor	UNT Proposal or Award Number	Title	Status
Example: NIH	**FP00001111**	***Acanthamoeba* keratitis and Legionnaires disease correlation**	**Pending**
Sponsor	Award #	Title	Status
Sponsor	Award #	Title	Status
Sponsor	Award #	Title	Status
Sponsor	Award #	Title	Status

X. PERMITS

List all permits associated with the project(s) covered by this disclosure:

Agency	Permit #	Type	Status	Expiration
Example: USDA	**FP00001111**	**Import Permit VS 16-7**	**Pending**	**Expiration Date**
Agency	Permit #	Permit type	Status	Expiration Date
Agency	Permit #	Permit type	Status	Expiration Date
Agency	Permit #	Permit type	Status	Expiration Date
Agency	Permit #	Permit type	Status	Expiration Date

By signing below, you are agreeing that all work on this project will be conducted using biosafety practices described in the CDC/NIH Publication entitled *Biosafety in Medical and Biomedical Laboratories (BMBL)* and *NIH Guidelines.* Additional stipulations required by the Institutional Biosafety Committee on behalf of the University of North Texas will also be followed.

Principal Investigator's Signature or Lab Manager: _____Date: _____

Send the completed form to IBC:

Email: Biosafety@untdallas.edu

IBC USE ONLY		
Approved by IBC	**IBC Chair or Designee**	**Date**
☐	IBC Only	**IBC Only**

APPENDIX A – RECOMBINANT/SYNTHETIC NUCLEIC ACIDS

A. Briefly describe, in lay terms, the work to be performed with recombinant or synthetic nucleic acid molecules.

Description of Work

B. List the vectors included in this project:

Vector Type (plasmid, viral, phage, etc.)	**Technical Name** (include vendor if applicable)	**Gene Transfer Method** (transformation, transfection, electroporation, etc.)
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method
Vector Type	Technical Name	Gene Transfer Method

C. List the genes/nucleic acids included in this project:

Gene/Nucleic Acid (specific name of gene, promoter, regulatory sequence, etc.)	**Source Organism** (genus and species or common name)	**Nature of Insert or Protein Expressed** (reporter gene, virulence factor, DNA repair, etc.)	**Use/Purpose** (cloning for sequencing, PCR, expression, etc.)
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose
Gene/Nucleic Acid	Source Organism	Nature of Insert or Protein Expressed	Use/Purpose

D. **Attach and submit** a detailed map of a representative sample of the vectors and inserts to be used. Indicate any regions that increase the safety of this construct. Provide copies of key references that describe the construction of the vector(s) used.

E. List any proteins that are produced:

List proteins produced

F. Will the nucleic acids contain genes for the biosynthesis of toxic molecules lethal to vertebrates?

☐ No ☐ Yes (If yes, list the toxin's LD50):

G. Will the nucleic acids contain genetic material from select agents or toxins?

☐ No ☐ Yes (If yes, list and explain)

H. What is the maximum volume of culture per container used at any one time?

Maximum volume

I. Is secondary containment used?

☐ No ☐ Yes (If yes, describe the containment)

J. If using a virus vector:

J1. Describe how nucleic acids will be used to create the virus:

Click here to enter text.

J2. What will host the virus vector?

Click here to enter text.

J3. Are nucleic acid molecules containing ≥ 2/3 of the genome of any eukaryotic virus created?

☐ No ☐ Yes (If yes, explain)

J4. Do experiments involve the use of infectious human, animal, or plant viruses?

☐ No ☐ Yes (If yes, explain)

J5. Do experiments involve the use of defective animal or plant viruses in the presence of a helper virus?

☐ No ☐ Yes (if yes, **attach** your procedures to determine the relative proportions of helper virus and defective virus)

J6. Are the nucleic acids likely to make the virus more pathogenic?

☐ No ☐ Yes (If yes, explain)

K. Are oncogenic genes being used?

☐ No ☐ Yes (If yes, list and explain)

L. Does your research involve a gene editing technology?

☐ No ☐ Yes (If yes, select the technology/technologies being proposed):

☐ CRISPR/Cas9	☐ ZFN	☐ TALENS	☐ Meganucleases
☐ Other: Click to enter text.			

L1. Will the genome editing technology be used in prokaryotes, eukaryotes, or mammalian cells?

☐ No ☐ Yes (If yes, specify which)

L2. How is the gene editing technology being delivered (e.g., nanoparticles, plasmid, lentivirus, adeno-associated virus, etc.)? Click to enter text.

L3. Will the gene editing technology target embryos or germ line cells?

☐ No ☐ Yes (If yes, explain)

L4. Will the gene editing technology be used for human gene transfer research?

☐ No ☐ Yes (If yes, explain)

L5. For CRISPR/Cas9 systems, are the guide RNA (gRNA) and nuclease on the same plasmid, vector, or delivery vehicle?

☐ No ☐ Yes (If yes, explain if this plasmid, vector, or delivery vehicle can transfect or infect a human cell and explain if the gRNA or CRISPR nuclease can be expressed in human cells): click here and explain.

L6. For CRISPR/Cas9 systems, are you inserting the gene for Cas9 (or a similar nuclease) and a guide RNA into the chromosome of a sexually reproducing organism?

☐ No ☐ Yes (If yes, explain)

L7. For CRISPR/Cas9 research involving viral vectors, a Genome Target Scan (GT-Scan) for off target effects by your gRNA must be completed. This is necessary to determine if there is homology to human DNA and for assessing the risk of potential exposure in the event of an unanticipated incident (Bae et al., 2014; O'Brien and Bailey, 2014). An off-target database is available here.

L8. Will the inserted nucleic acid sequences contain a guide RNA that can target the insertional locus of the unmodified chromosome?

☐ No ☐ Yes ☐ I don't know

L9. Can the inserted nucleic acids act as a gene drive (i.e., can the inserted sequences in any way alter Mendelian inheritance at this locus)?

☐ No ☐ Yes ☐ I don't know

NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES

The *NIH Guidelines* can be found at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety

On the following pages, select all *NIH Guidelines* categories that apply to your research:

SECTION III-F includes recombinant or synthetic nucleic acid molecules that are exempt from the *NIH Guidelines*, but still require registration with the Institutional Biosafety Committee:		
☐	**III-F-1:**	Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell, and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.
☐	**III-F-2:**	Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
☐	**III-F-3:**	Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
☐	**III-F-4:**	Those that consist entirely of nucleic acids from a non-pathogenic prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another non-pathogenic host by well-established physiological means.
☐	**III-F-5:**	Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
☐	**III-F-6:**	Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.
☐	**III-F-7:**	Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA.
☐	**III-F-8:**	Those that do not present a significant risk to health or the environment as determined by the NIH Director. Check the appropriate appendices below.
SECTION III-F-8 Appendices		
☐	**C-I:**	Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in cells in tissue culture.
☐	**C-II:**	Experiments that use *Escherichia coli* K-12 host-vector systems.
☐	**C-III:**	Experiments involving *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems.
☐	**C-IV:**	Experiments involving *Kluyveromyces lactis* host-vector systems.
☐	**C-V:**	Experiments involving *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems.
☐	**C-VI:**	Extrachromosomal Elements of Gram Positive Organisms.
☐	**C-VII:**	The purchase or transfer of transgenic rodents, BSL1 only.
☐	**C-VIII:**	Generation of BSL1 transgenic rodents via breeding.
SECTION III-E covers experiments not found in sections A, B, C, D, and F, and are not exempt from the *NIH Guidelines*, but still require Institutional Biosafety Committee notice simultaneous with initiation of work:		
☐	**III-E:**	Experiments not included in Sections III-A, III-B, III-C, III-D, III-F; and experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes and may be conducted at BSL1.
☐	**III-E-1:**	Recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus may be propagated and maintained in cells in tissue culture (BSL1). For such

		experiments, it must be demonstrated that the cells lack helper virus for the specific families of defective viruses being used.
☐	**III-E-2:**	Experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants.
☐	**III-E-3:**	Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). BSL1 containment only. Experiments BSL2 or higher are covered under Section III-D-4.
SECTION III-D covers experiments that require Institutional Biosafety Committee notice <u>prior</u> to initiation of work:		
☐	**III-D-1:**	Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as host-vector systems.
	Select Risk Group: ☐ RG2 ☐ RG3 ☐ RG4	
☐	**III-D-2:**	Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
	Select Risk Group: ☐ RG2 ☐ RG3 ☐ RG4	
☐	**III-D-3:**	Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.
	Select Risk Group ☐ RG2 ☐ RG3 ☐ RG4	
☐	**III-D-4:**	Recombinant or synthetic nucleic acid experiments involving whole animals (e.g., non-human vertebrate or invertebrate organism, including arthropods).
	Select Risk Group: ☐ RG1 ☐ RG2 or RG3	
☐	**III-D-5:**	Experiments involving whole plants or insects. Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules (BSL2 or higher).
☐	**III-D-6:**	Experiments involving more than 10 liters of culture in a single culture vessel.
☐	**III-D-7:**	Experiments involving influenza viruses.
Risk Group Definitions		
Risk Group 1 (RG1): Agents that are not associated with disease in healthy adult humans. **Risk Group 2 (RG2):** Agents are associated with human disease which is rarely serous and for which preventative or therapeutic interventions are often available. **Risk Group 3 (RG3):** Agents that are associated with serious or lethal human disease for which preventative or therapeutic interventions may not be available. **Risk Group 4 (RG4):** Agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available.		
Experiments that fall under sections A, B, and C require NIH pre-approval. Contact the IBC Office for assistance.		
☐	**III-A-1:**	The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the ability to control disease agents in humans, animals, or plants.
☐	**III-B-1:**	Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight.
☐	**III-C-1:**	Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants.