NJIT New Jersey Institute of Technology

Protocol #:

Registration Document For Biohazards

All applicants are required to complete the following sections:

- Principal Investigator Information
- Location of Study
- Section A: General Administrative Information
- Section B: Material Use Checklist and Risk Assessment
- Section H: Transport
- Section I: Dual Use Research of Concern
- Section J: Protocol Specific Laboratory Safety

In addition to the sections above, please complete the appropriate protocol-specific sections:

- Section C: Exempt Recombinant DNA Experiments
- Section D: Non-Exempt Recombinant DNA Experiments
- Section E: Research with Potentially Infectious Biological Agents
- Section F: Human and Non-human Primate Blood, Body Fluids, Cell Lines, and Tissue Explants
- Section G: Toxins of Biological Origin

P.I Information

Name:	Title:
Department:	Email:
Phone Number:	

Location of Study

Building:	Room #'s:
Are the facilities shared: ☐ Yes ☐ No	If yes, with what group:
Date of study:	

Section A: General/Administrative Information

Protocol Title:	
PI's Anticipated Biosafety Level:	

Brief Description of Protocol (please describe experimental protocol including how the biological material will be utilized in the laboratory, attach additional sheet if necessary):

Section B. Material Use Checklist and Risk Assessment

Please check the materials that are used in your lab then complete the specified section for each material.

1) Recombinant DNA: Genetic manipulation of microorganisms including inserting or deleting genes, use of viral vectors, development of human gene therapy, experiments involving siRNA, development of synthetic DNA constructs, etc.	
☐	Recombinant DNA, gene transfer and/or host vector systems
☐	Use of transgenic animals (including knockouts, knock ins, crossbreeding of two different transgenic strains)
☐	Use of transgenic plants
☐	Complete Section C for Exempt rDNA Experiments
☐	Complete Section D for Non-Exempt rDNA Experiments
2) Microorganisms/Potentially Infectious Agents:	
☐	Bacteria
☐	Virus
☐	Yeast and other Fungi
☐	Prions and/or Parasitic Agents
☐	Complete Section E for Potentially Infectious Biological Agents
☐	Complete Section E for Host Organisms Listed in Section B and C (Above)
3) Human/Non-Human Primate Derived Materials, Blood, Body Fluids, and Cell Lines:	
☐	Human cell lines including established human cell lines from commercial sources
☐	Primary human tissue explants
☐	Non-Human primate cell lines
☐	Primary non-human primate tissue explants
☐	Human and/or non-human primate blood, body fluids
☐	Complete Section F for human and non-human primate cell lines, tissue explants, and body fluids
4) Other:	
☐	Biological Toxins - NOT Select Agents (please complete section G)
☐	CDC/APHIS Select Agents
☐	Human Subjects - Embryonic Stem Cells
☐	Human Subject Research - Other
☐	Vertebrate Animal
☐	Non-Viral Delivery Systems (nanoparticles, liposomes, etc.)

Section B. Material Use Checklist and Risk Assessment (Continued)

Please check the materials that are used in your lab then complete the specified section for each material

5) Risk Assessment: Please describe the risk assessment process and how the appropriate biosafety precautions were determined for this protocol.

Describe the potential risk posed by the organism, vector, product, genetic insert, toxin, cell line, product, or material:

Describe the potential risk posed by the laboratory manipulations and procedures that are to be performed (will aerosols or droplets be generated, will sharps be utilized, are large volumes of culture involved, etc.):

Describe the laboratory equipment and facilities utilized to mitigate the risk described above:

Describe the training, proficiency, and experience of the laboratory director, staff, and students in performing experimental procedures with a similar risk potential:

Describe the supervision and oversight provided by the laboratory director to assure adherence to safety guidelines:

Describe the safety literature consulted, search terms used, and risk assessment process:

☐	rDNA Guidelines	☐	CDC-NIH Guidelines
☐	OSHA BBP Standard	☐	NJIT Safety Literature
☐	PubMed Search, Search Terms:	☐	CDC-NIH Guidelines
☐	rDNA Guidelines	☐	NJIT Safety Literature
☐	Other (*describe*):		

Section B. Material Use Checklist and Risk Assessment (Continued)

Please check the materials that are used in your lab then complete the specified section for each material

6) Protocol Specific Laboratory Safety: Please complete Section J for all protocols submitted to the Biosafety Committee for consideration.

Principal Investigator Acknowledgement:

By signing below, the Principal Investigator acknowledges that the laboratory workers (including students, faculty, staff or visitors) under his or her direction have received appropriate training required to manipulate, store, and disinfect the microorganisms, human-derived materials, recombinant or other materials proposed for use in the following protocol. Further, laboratory workers have been instructed on emergency procedures involving potentially infectious materials as outlined in the NJIT Biological Safety Guide.

Principal Investigator: _____ Date: _____

Biosafety Committee Action:

This protocol was reviewed by the NJIT Institutional Biosafety Committee on:_____
The following IBC action was taken:

☐	Protocol Approved
☐	Protocol Withdrawn
☐	Protocol Conditionally Approved
☐	Protocol Tabled Until Next Meeting
☐	Protocol Not Approved

Protocol Approved By:	
Assigned Biosafety Level:	
Signature:	

Section C: Exempt Recombinant DNA Experiments

(please check those sections of the NIH Guidelines under which your experiments are exempt)

☐	**Section III-F-1**. Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), 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. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.
☐	**Section 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.
☐	**Section 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.
☐	**Section III-F-4**. Those that consist entirely of nucleic acids from a 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
☐	**Section 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).
☐	**Section 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. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.
☐	**Section 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.
☐	**Section III-F-8**. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment.
☐	**Appendix C-VII**. The Purchase or Transfer of Transgenic Rodents
☐	**Appendix C-VIII**. Generation of BL1 Transgenic Rodents via Breeding The breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment will be exempt from the NIH Guidelines if: (1) both parental rodents can be housed under BL1 containment; and (2) neither parental transgenic rodent contains the following genetic modifications: (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gamma retroviral long terminal repeat (LTR); and (3) The transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

Section C: Exempt Recombinant DNA Experiments (continued)

(please check those sections of the NIH Guidelines under which your experiments are exempt

Most experiments involving E. coli K-12 host vector systems and *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host vector systems are exempt from the NIH Guidelines. If the answer to all 3 of the following questions are no, then the experiments are exempt according to Appendix C-II (for *E. coli* K-12) or Appendix C-III (for *Saccharomyces cerevisiae and Saccharomyces uvarum*).

Yes	No	*Please check yes or no for the following questions*
☐	☐	Do any experiments involve Risk Groups 3, 4 or restricted organisms or nucleic acids from Risk Groups 3, 4 or restricted organisms?
☐	☐	Do any experiments involve introduction of genes coding for molecules toxic for vertebrates?
☐	☐	Will there be any large-scale experiments (more than 10 liters of culture)?

Please include only information regarding **Exempt** rDNA experiments in the tables below.

#	**Host (s)** Indicate the host(s) into which the recombinant material (rDNA, RNA, virus) will be introduced. Examples include: *E. coli*, *S. cerevisiae*, human/animal cells, whole animals, plants.	**Species** Subspecies, variety, serotype, strain.	**Vectors** Which host-vector system will be used for this research? Examples include: bacterial plasmids, yeast plasmids, cultured cell plasmid vectors, baculovirus, AAV, other viral vectors	**DNA Sequence** List names of genes or DNA segments that will be evaluated	**Proteins** List proteins produced if applicable
#1					
#2					
#3					
#4					
#5					
#6					

Yes	No	*Please check yes or no for the following questions*
☐	☐	Will an attempt be made to purify any of the foreign gene products encoded by the gene?
☐	☐	Will a virus-derived vector system that is engineered to be replication-incompetent be used?

Section D: Non-Exempt Recombinant DNA Experiments

This section describes experiments covered by the NIH Guidelines. Check the appropriate registration category(s) for your experiment.

Experiments that require IBC approval BEFORE initiation:	
☐	**Section III-D-1-a**. Introduction of recombinant or synthetic nucleic acid molecules into risk group 2 agents
☐	**Section III-D-2-a**. Introduction of DNA from risk group 2 (or 3) agents into non-pathogenic bacteria or lower eukaryotes
☐	**Section III-D-3-a**. Use of infectious risk group 2 virus (or defective virus plus helper virus) in tissue culture systems
☐	**Section III-D-3-e**. Use of infectious risk group 1 virus (or defective virus plus helper virus) in tissue culture systems
☐	**Section III-D-4-a**. Transfer of recombinant or synthetic nucleic acid molecules EXCEPT for >2/3 of eukaryotic viral genomes into any non-human vertebrate or invertebrate organism
☐	**Section III-D-4-b**. Transfer of recombinant or synthetic nucleic acid molecules from risk group 2 (or higher risk group) human or animal pathogens into whole animals
Experiments that require IBC notification CONCURRENT WITH initiation:	
☐	**Section III-E-1**. Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any eukaryotic virus
☐	**Section III-E-2**. All components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes
☐	**Section III-E-3**. Experiments involving transgenic rodents
Some experiments require additional review/approval by NIH OBA before initiation:	
☐	**Section III-A-1-a**. Transfer of a drug resistant gene into microorganisms that do not acquire the gene naturally that could compromise use of the drug to control disease in humans, veterinary medicine or agriculture
☐	**Section III-B-1**. Cloning of genes for toxins with LD50 of > 10 ng/kg body weight

If your non-exempt research does not fall into any of the categories listed above, review Section III of the NIH Guidelines and use the space below to provide a brief description of the research and the appropriate NIH Guidelines referenced.

Section of the NIH Guidelines:	
Description:	

Section D: Non-Exempt Recombinant DNA Experiments (Continued)

Generation and Use of rDNA

Complete this section if you are generating and/or using non-exempt rDNA in your laboratory.

Answer questions 1-8 for EACH host-vector system.

Transgene

1. Describe the gene sequence(s) inserted into the recombinant vector:	
a. Source of gene(s) (genus/species):	
b. Do any of the gene sequences increase oncogenic potential, originate from an HHS or USDA select agent or toxin, transfer a drug resistance trait that has the potential to compromise the use of the drug to control disease or have the potential to increase the pathogenicity or virulence of a vector system?	
☐	No
☐	Yes, explain below:
c. Describe the function and activity of the transgene(s):	
If you are planning on using an extensive number of transgenes, list classes.	
If you are using a genome-wide approach, indicate the components of the constructs in the library or libraries.	
2. If any of the above genes are from a viral source, do they compromise more than 2/3 of the viral genome?	
☐	No
☐	Yes, specify:
3. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA or RNA?	
☐	No
☐	Yes
4. Identify vector system – Please check appropriate boxes below and describe host-vector systems:	
☐	Bacterial Plasmid
☐	Adeno-Associated Virus
☐	Adenovirus
☐	Simple Retrovirus
☐	Lentivirus
☐	Viruses other than lentivirus, simple retrovirus, adenovirus or adeno-associated virus Describe:
☐	Non-Viral Delivery Systems (nanoparticles, liposomes, other):

Section D: Non-Exempt Recombinant DNA Experiments (Continued)

5. List host cell line or packaging cells for recombinant vector propagation:	
6. Viral vector system(s)	
a. What % of the viral genome remains?	
b. Is a helper virus required for replication?	
☐	No
☐	Yes
7. Target Recipient(s) - Indicate the recipient(s) of the DNA (check all that apply):	
☐	Bacterial Cells
☐	Animal Cells in Culture
☐	Animals
☐	Modified Tissue Culture Cell Lines into Animals
☐	Plant Cells
☐	Plants
☐	DNA Vaccine, specify target recipient(s)
8. Investigators assessment of risk – This work will be conducted at (check appropriate biosafety level):	
☐	Biosafety Level 1
☐	Biosafety Level 2

Please fill out a separate section D for each additional non-exempt host-vector system used in the lab

Section E: Research with Potentially Infectious Biological Agents

Complete this section if you are working with an agent that could cause an infection in humans, including opportunistic infections. Provide the information requested below for each agent.

Please check yes or no for each question		Yes	No	Please Provide Details Below
1.	Name of agent (include genus, species, sub-species, strain, etc.):	☐	☐	
2.	Will antibiotic resistance be expressed?	☐	☐	
3.	Will toxin be produced?	☐	☐	
4.	Largest volume of agent to be cultured?	☐	☐	
5.	Will agent be concentrated?	☐	☐	
6.	If agent is to be concentrated, how will it be concentrated?	☐	☐	
7.	How frequently will agent be manipulated?	☐	☐	
8.	How will agent be inactivated?	☐	☐	
	a. heat	☐	☐	
	b. chemical	☐	☐	
	c. other (list):	☐	☐	
9.	Will agent be introduced into animals?	☐	☐	
10.	Have all personnel that will be handling this agent received appropriate biosafety training?	☐	☐	

Please fill out a separate section E for each additional potentially infectious agent used in the lab.

Section F: Human and Non-human Primate Blood, Body Fluids, Cell Lines, and Tissue Explants

Identify the type and source of the materials to be used:

1. Samples to be manipulated (for human or non-human primate cells lines, indicate if cells are established or primary):
2. Source of samples:
3. If commercially obtained, please list vendor and specific cell lines:
4. Have all personnel who work with human material completed the appropriate Biological Safety/Bloodborne Pathogens training program (please answer below and complete section J)?
5. Is laboratory equipped with biological safety cabinet or other containment equipment to safely manipulate these materials (please answer below and complete section J)?

Section G: Toxins of Biological Origin

Complete this section if you are working with a toxin of biological origin. Provide the information requested below for each toxin.

1. Name of toxin(s):
2. Largest quantity in use and stored:
3. Describe how the toxin is stored:
4. Describe the toxin deactivation and disposal procedures:
5. At what Biosafety Level is this material to be handled:

Please fill out a separate section G for each additional toxin used in the lab.

Section H: Transportation/Shipping (includes 'hand-carrying' specimens)

If you are involved in shipping hazardous materials and/or dangerous goods please contact the EHS department at 973-596-3059 or at healthandsafety@njit.edu

Will materials be transported outside of the laboratory in which they are being used? (*please check one*)	☐	Yes	☐	No

Please describe the nature of the materials to be transported

Describe:

Please describe the proposed method of transport

Describe:

Section I: Dual Use Research of Concern

Complete this section to determine if your research is considered dual use research of concern—research that may be used for beneficent goals as well as malevolent purposes

1. Please check any categories below that apply to your research	
☐	Increase in virulence of the pathogen
☐	Production of a novel toxin
☐	Enhance transmissibility of the pathogen
☐	Alteration of the pathogen's host range
☐	Interfere, by-pass or diminish the effectiveness of diagnostic tools and therapeutic or prophylactic antimicrobial or antiviral treatments
☐	Enhance capacity for spreading or for easy release of making them weapons-grade
☐	Not Applicable

2. Please describe how your research fits any of the above category

3. Please identify and address additional risks to employees, the environment and/or public health that this research could present

Section J: Protocol Specific Laboratory Safety

1. Personnel and Training

Please list all laboratory personnel involved in this protocol and indicate the dates of the required training. If training has not yet been scheduled, please indicate pending or TBD.

Name	Title	Date of Biosafety Training	Date of BBP Training	Other Protocol Specific Training

2. Laboratory Inspection

Please list date of last laboratory Inspection conducted by the EHS Department. If your lab has not been inspected, please contact EHS at 973-596-3059 or at healthandsafety@njit.edu

Building	Department	Room Numbers	Date of Inspection	Approved Biosafety Level

Section J: Protocol Specific Laboratory Safety (Continued)

3. Containment and Safety Equipment

Please list type and location of containment equipment (e.g., biological safety cabinet) and date of last certification. Please note if Biological Safety Cabinet is shared with other groups.

Containment Equipment	Location	Type/Class	Certification Date
Biological Safety Cabinet			
Biological Safety Cabinet			
Other Laminar Flow Device			
Centrifuge with Safety Caps and Sealed Rotors			
Splash Guard			
Other:			

4. Equipment and Surface Decontamination

Please list the decontamination solution used, concentration, and frequency for various laboratory equipment and work surfaces.

Equipment and/or Work Surfaces	Decontamination Solution	Concentration	Frequency
Biological Safety Cabinet			
Laboratory Bench			
Mechanical Pipetter			
Reusable Safety Equipment			
Other:			

Section J: Protocol Specific Laboratory Safety (Continued)

5. Spill Control

Please describe available laboratory spill control equipment and procedures used for biological spills

6. Waste Decontamination

Please describe how potentially contaminated laboratory waste, both liquid and solid, is decontaminated and subsequently disposed. Please note location of autoclave if one is available for waste decontamination.

7. Control of Sharps:

Please describe how sharps are handled in the lab. Is an attempt made to limit the use of sharps when working with potentially infectious materials?