

MONTCLAIR STATE UNIVERSITY

Institutional Biosafety Committee

For IBC Use

Submission Date:

Project Title:

Key Personnel

Principal/Responsible Investigator	
Name:	<input type="text"/>
Phone:	<input type="text"/>
Email:	<input type="text"/>
School:	<input type="text"/>
Department:	<input type="text"/>
Office/Laboratory Locations: <small>(Please specify room number)</small>	<input type="text"/>
Experimental Locations: <small>(Please specify room number)</small>	<input type="text"/>
Animal Housing Locations: <small>(Please specify room number)</small>	<input type="text"/>

Co-Investigator (if applicable)	
Name:	<input type="text"/>
Phone:	<input type="text"/>
Email:	<input type="text"/>
School:	<input type="text"/>
Department:	<input type="text"/>
Office/Laboratory Locations: <small>(Please specify room number)</small>	<input type="text"/>
Experimental Locations: <small>(Please specify room number)</small>	<input type="text"/>
Animal Housing Locations: <small>(Please specify room number)</small>	<input type="text"/>

Alternate Contact (if applicable)	
Name:	
Phone:	
Email:	
School:	
Department:	
Office/Laboratory Locations: (Please specify room number)	
Experimental Locations: (Please specify room number)	
Animal Housing Locations: (Please specify room number)	

Flow Sheet of Experiment(s) and Project Narrative

1. Please submit a step-by-step flow sheet, including containment equipment used (e.g., fume hood, biosafety cabinet) and location(s) where each step is taking place. **(Submit Flow Sheet as a separate attachment)**
2. Please provide a project narrative describing your research project. The information should be:
 - succinct (no more than 2-3 sentences long)
 - in plain language understandable by a general, lay audience
 - include project goals

Overview

The Montclair State University Institutional Biosafety Committee (IBC) reviews research protocols to ensure compliance with the CDC/NIH guidelines for biosafety and OSHA guidelines for blood borne pathogens in research laboratories. In completing this form you must convey to the IBC that you: understand the potential hazards of the proposed research, have designed the experiments to minimize potential hazards, and have communicated potential hazards to others who may come in contact with the products you propose to use or generate. Please be sure to complete all applicable sections of the form and contact the Biosafety Officer at the address listed below.

Note: text boxes will expand to fit

Instructions

In some cases it is acceptable to combine multiple experiments or organisms in the same registration form. Please contact the Biosafety Officer listed below if you have questions about use of this form. Once the IBC Chair and Biosafety Officer have performed a preliminary review, the protocol will be distributed to the IBC members. All IBC members will have two weeks to review the protocol and submit concerns. The Biosafety Officer will compile the comments and forward them to the PI. The PI will be responsible for making the appropriate revisions and re-submitting the application to the IBC for further review. The IBC will prepare an approval letter that is sent to the PI. Protocol applications should be submitted as soon as possible.

How do I submit this form?

Save the file as the PI's last name and date. Email it as an attachment to ibc@montclair.edu.

Questions?

Contact ibc@montclair.edu

Study Details

Please indicate which of the following your study involves.

Recombinant or Synthetic Nucleic Acid Molecule Experiments

Pathogenic Microorganisms

Agents capable of causing disease in humans must be noted. These agents include organisms classified as biosafety level 2 (BSL-2) or higher in the latest edition of the CDC Biosafety in Microbiological and [Biomedical Laboratories \(BMBL\) publication](#). **You must disclose use of organisms at BSL-2 or higher.**

Human and Non-Human Primate Blood, Cell Lines, and Tissues or Other Potentially Infections Materials (OPIM).

OPIM is material with the potential for transmission of HIV, HBV, HCV, and other blood borne diseases, including tissue from animals known to be infected with any of these agents, microbial stocks and cultures, certain body fluids, unfixed human tissue, primary tissue/cell cultures. This includes human and non-human primate cell lines obtained from commercial sources. Also included are blood and tissues from live non-human primates as they may harbor unknown zoonotic conditions. These must be handled under BSL-2 conditions. For more information see the [CDC BMBL publication](#).

Possession, Use, and Transfer of Select Agents, Toxins, High Consequence Livestock or Plant Pathogens

The use of these agents, toxins, or pathogens is regulated by the CDC Select Agent Regulation, 42 CFR 73, and the USDA Select Agent Rule 7 CFR 331/9 CFR 121. Facility registration is required and is administered by the Centers for Disease Control, and/or the USDA. If you anticipate using these materials you must disclose this information to the IBC. Additional requirements of the "USA Patriot Act" and the "Public Health Security, Bioterrorism, and Response Act of 2002" must also be satisfied. [Click for more information about Federal Select Agent Program](#).

Animal Use

Administration to animals of any of the above categories of biologicals including in the creation of a stable germline alternative of an animal's genome (transgenic animal), creation of a novel transgenic animal, or *in vivo* (whole animal) testing of a restricted agent or viable micro-organism containing recombinant or synthetic nucleic acid molecules. Note: the purchase or transfer of transgenic rodents is exempt. Administration of any of the above agents to animals also requires approval of the IACUC.

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Recombinant or Synthetic Nucleic Acid Molecules:

My study will NOT be using recombinant or synthetic nucleic molecules

Select the category that best reflects the type of experiment that you are conducting.

Please identify the type of experiment described in this registration form by checking the appropriate category in column D. Information listed in parentheses in column A cites the reference located in the NIH document "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)." For more information, the NIH Guidelines can be accessed [here](#).

A If your experiment involves:	B Registration w/ NIH required?	C IBC Approval Required?	D Does the experiment described involve this factor?
Deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD ₅₀ of less than 100 ng/kg body weight (ref. III-B-1)	Yes	Yes	
Transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived therefrom, into one or more human research participants (ref.II-C-1)	Yes	Yes	
Transfer of a drug resistant trait to organisms not known to naturally acquire the trait, if such acquisition could compromise use of the drug to control the disease in humans, veterinary medicine, or agriculture (ref. III-A-1-a)	Yes	Yes	
Using Risk Group 2, 3, or 4 agents or restricted agents as host-vector systems (ref. III-D-1)	No	Yes	
Cloning of DNA from Risk Group 2, 3, or 4 microorganisms into non-pathogenic prokaryotic or lower eukaryotic host-vector systems (ref. III-D-2)	No	Yes	
More than 10 liters of culture (ref. III-D-6)	No	Yes	
Recombinant or synthetic nucleic acid molecules 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) (ref. III-F-4)	No	No	
Recombinant or synthetic nucleic acid molecules that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host, when transferred to another host by well-established physiological means (ref. III-F-4)	No	No	

A	B	C	D
Recombinant or synthetic nucleic acid molecules that consist entirely of nucleic acids from a eukaryotic host when propagated only in that host or a closely related strain of the same species (ref. III-F-5)	No	No	
Recombinant or synthetic nucleic acid molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes (ref.III-F-6)	No	No	
Recombinant or synthetic nucleic acid molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature (ref. III-F-3)	No	No	
Recombinant or synthetic nucleic acid molecules that are in organisms, cells, or viruses and that have been modified or manipulated (e.g. encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes (ref. III-f-2)	No	Yes	
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 DNA 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. <i>Note: synthetic nucleic acid deliberately transferred into one or more human research participants is not exempt</i> (ref. III-F-1)	No	No	
VIRUSES Use of infectious or defective/non-replicating DNA or RNA viruses in the presence of helper virus in tissue culture systems (ref. III-D-3)	No	Yes	
Propagation and maintenance in tissue culture of recombinant or synthetic nucleic acid molecules containing <2/3 of the genome of any eukaryotic virus in the demonstrable absence of helper virus, or of a virus that has been established to be non-replicating (ref. III-E-1)	No	Yes	
Formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 the genome of any eukaryotic virus (ref. III-E-1)	No	Yes	
Experiments involving Influenza viruses (ref. III-D-7)	No	Yes	

A	B	C	D
ANIMALS			
Creating of transgenic animals (ref. III-D-4 and III-E-3)	No	Yes	
Breeding of transgenic rodents strains requiring BSL-2 and higher containment (ref. III-D-4-b)	No	Yes	
<i>In vivo</i> use of viable microorganisms containing recombinant or synthetic nucleic acid molecules (ref. III-D-2 and III-D-4)	No	Yes	
Administration of recombinant or synthetic nucleic acid molecules to any non-human vertebrate or any invertebrate organism (ref. III-D-4)	No	Yes	
Use of transgenic animals at BSL-2, BSL-3, or BSL-4 (ref. III-E-3 and III-D-4)	No	Yes	
Use/breeding/creation of BSL-1 transgenic rodents with incorporation of more than 50% of the genome of an exogenous eukaryotic virus from single family of viruses (Appendix C-VIII)	No	Yes	
Use/breeding/creation of BSL-1 transgenic rodents in which the transgene is under the control of a functional gammaretroviral long terminal repeat (LTR) (Appendix C-VIII)	No	Yes	
Use/breeding of transgenic rodents at BSL-1 (ref. III-E-3 and Appendix C-VIII)	No	No	
Existing transgenic animal purchased or transferred from another institution requiring BSL-2 and higher containment (Material Transfer Agreement required) (ref. III-D-4)	No	Yes	
Existing transgenic rodent purchased or transferred from another institution requiring BSL-1 containment (Material Transfer Agreement required)	No	No	

Please complete the following sections to describe your experiment.

Indicate the possible adverse events of the nucleic acid molecule, quantity of culture, and a description of the experiment. Also, provide detailed information regarding the nucleic acid molecule, vectors, and host cells being used in your recombinant or synthetic nucleic acid molecule system. Vector maps are also helpful.

Does your research involve the use of a viral expression vector?

- Yes
- No

If your study involves the use of viral expression vector, please fill out the chart below.

Mark if Using	Viral Vector or Component
	Adenovirus (add links?)
	Adeno-associated virus
	Herpes-1 Virus
	Vaccinia virus
	Retrovirus

1. Specify source and nature of the nucleic acid sequence(s) to be inserted/mutated (genus, species, gene name):

a. Will the inserted gene(s) be expressed?

- Yes
 No

i. If yes, what are the gene product effects? Specifically identify its toxicity, physiological activity, allergenicity, oncogenic potential or ability to alter the cell cycle.

2. Location in which the recombinant or synthetic nucleic acid molecule research is to be conducted (building and room #):

3. Does the recombinant or synthetic nucleic acid molecule donor/source or its vector have any recognized or anticipated pathogenic, toxigenic, or virulence potential for animals, plants, or humans?

- Yes
 No

a. If yes, please explain:

4. Quantity of Material to be used:

- <1 liter
 1-10 liters
 >10 liters

5. Describe the virus, phage, and/or plasmid used for constructing your recombinants (prokaryotic, eukaryotic):

6. If possible, provide a diagram or map illustrating the construct with your application. If appropriate, include the [Entrez Gene nomenclature](#).

7. Identify host cell(s) or packaging cell line in which recombinant vector will be amplified:

8. Is the vector replication competent?

Yes

No

9. Are any viral component(s)/sequence(s) present in the vector?

Yes

No

a. Specify the nature of the viral component(s):

10. Does the insert contain 2/3 of a eukaryotic viral genome?

Yes

No

11. Is a helper virus used?

Yes

No

a. If yes, specify type:

12. What cells, cell lines, tissues, animals, humans, insects, or plants will be exposed to recombinant? Indicate type and species:

13. Will recombinant or synthetic nucleic acid molecule(s) be used to create a novel transgenic animal?

Yes

No

14. Will breeding between 2 strains of transgenic animals (housed at BSL-2) be performed?

- Yes
- No

a. If yes, please describe the strains that will be bred:

15. Will this experiment include the transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived therefrom, into one or more human research participants?

- Yes
- No

16. Provide a flow sheet to describe your experiment. Provide enough information to describe the project's specific aims, the packaging vector, the cell lines used, and the function of the recombinant or synthetic nucleic acid molecules in the context of the overall project.

Pathogenic Microorganisms

My study will NOT be using pathogenic microorganisms

To be completed by the Principal Investigator for all laboratories handling or storing pathogenic microorganisms (agents capable of causing disease in immune-normal, healthy adults and included organisms classified as requiring work at BSL-2 or higher in the latest edition of either the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* or the NIH's *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

1. Name of organism (genus, species, strain description):

2. Is the organism attenuated?

 Yes No

3. Is there a toxin produced?

 Yes No

a. If yes, will you work with the toxin?

 Yes No

4. Is drug resistance expressed?

 Yes No

a. If yes, please indicate to which drugs:

5. Where is the organism stored?

Building:

Room:

a. Are biohazard labels in use?

 Yes No

6. Is a stock culture prepared?

 Yes No

a. Maximum volume of stock culture that will be prepared:

b. Volume aliquotted per individual vial:

c. Concentration/mL per individual vial:

d. Maximum volume used in an experiment:

7. Is the organism inactivated prior to use?

Yes

No

a. If yes, what is the method of inactivation?

8. Do you concentrate the organism in your protocol?

Yes

No

a. Indicate which method is used:

Centrifugation

Precipitation

Filtration

Other

9. Are cultures, stocks, and contaminated items decontaminated prior to disposal?

Yes

No

a. Indicate which method(s) is/are used:

Autoclave

Chemical disinfectant

Other

10. Is this a BSL-3 Project? Yes No

a. Previously approved SOP number

If not using a pre-approved SOP, be sure to include a copy of your SOP.

11. Does this protocol involve work with human blood or blood products, unfixed human tissue, hum/non-human primate cell lines? Yes No**12. Provide a flow sheet to describe your experiment. Include enough information to describe the project's specific aims and the role of the pathogen in the context of the overall project.****Human and Non-Human Primate Cells and Tissues**

-
- My study will NOT use human and non-human primate blood, cell lines, tissues, or Other Potentially Infections Materials (OPIM).**

1. Please list the cell lines, body fluids, and tissues that you will be using from humans and/or non-human primates. Attach additional sheets if needed. Include established human or primate ATCC cell lines. *Note: Use of human cell lines or human source materials may require approval from the [Institutional Review Board](#).*

2. Provide a flow sheet to describe your experiment. Include enough information to describe the project's specific aims and the role of the human/non-human primate cell line, human body fluid or tissue in the context of the overall project.

Possession, Use, or Transfer of Select Agents, Toxins, High Consequence Livestock Pathogens, and Plant Pathogens

My study does NOT involve possession, use, or transfer of select agents, toxins, high consequence livestock or plant pathogens

The University is required to register with the CDC or USDA for possession, use, or transfer of any of these agents, toxins, or pathogens. These agents are regulated by Select Agent Regulation, 42 CFR 73.0 and the Agricultural Bioterrorism Protection Act of 2002. If you anticipate obtaining these materials complete this section of this form. Additional requirements of the USA Patriot Act and the Public Health Safety, Bioterrorism and Response Act of 2002 must also be satisfied.

Please indicate which of the following will be used in your laboratory.

Viruses (HHS and USDA)	
African swine fever virus	
African horse sickness virus	
Highly pathogenic avian influenza virus	
Classical swine fever virus	
Crimean-Congo hemorrhagic fever virus	
Eastern Equine Encephalitis virus	
Ebola virus	
Foot-and-mouth disease virus	
Goat pox virus	
Hendra virus	
Influenza virus, reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	
Lassa fever virus	
Lujo virus	
Lumpy skin disease virus	
Marburg virus	
Monkeypox virus	
Newcastle disease virus (VVND)	
Nipah virus	
Peste Des Petits Ruminants virus	

Viruses (HHS and USDA)	
Rift Valley fever virus	
Rinderpest virus	
Sheep pox virus	
SARS-associated coronavirus (SARS-Co V)	
Swine vesicular disease virus	
Variola major virus (Smallpox virus)	
Variola minor virus (Alastrim)	
Venezuelan Equine Encephalitis virus	
<i>South American Hemorrhagic fever viruses</i>	
Junin	
Machupo	
Sabia	
Chapare	
Guanarito	
<i>Tick-borne encephalitis complex (flavi) viruses</i>	
Far Eastern subtype	
Siberian subtype	
Kyasanur Forest disease virus	
Omsk hemorrhagic fever virus	
Toxins (Toxins (HHS and USDA)HS and USDA)	
Abrin	
Botulinum neurotoxins	
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence: X1CCX2PACGX3X4X5X6CX7)	
Diacetoxyscirpenol	
Ricin	
Saxitoxin	
Staphylococcal enterotoxins A,B, C, D, E subtypes	
T-2 toxin	
Terodotoxin	

Bacteria (HHS and USDA)HS and USDA)	
<i>Bacillus anthracis</i>	
<i>Bacillus anthracis</i> Pasteur strain	
<i>Brucella abortus</i>	
<i>Brucella melitensis</i>	
<i>Brucella suis</i>	
<i>Burkholderia mallei</i> (formerly <i>Pseudomonas mallei</i>)	
<i>Burkholderia pseudomallei</i> (formerly <i>Pseudomonas pseudomallei</i>)	
<i>Clostridium</i> , Botulinum neurotoxin producing species only	
<i>Coxiella burnetti</i>	
<i>Francisella tularensis</i>	
<i>Mycoplasma capricolum</i>	
<i>Mycoplasma mycoides</i>	
<i>Rickettsia prowazekii</i>	
<i>Yersinia pestis</i>	
USDA Plant Pathogens	
<i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)	
<i>Phoma glycinicola</i> (formerly <i>Pyrenochaeta glycines</i>)	
<i>Ralstonia solanacearum</i>	
<i>Rathayibacter toxicus</i>	
<i>Sclerophthora rayssiae</i>	
<i>Synchytrium endobioticum</i>	
<i>Xanthomonas oryzae</i>	

- Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses
- Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed above if the nucleic acids: 1) are in a vector or host chromosome, 2) can be expressed *in vivo* or *in vitro*, or 3) are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*
- Viruses, bacteria, fungi, and toxins listed that have been genetically modified

Note: if your research involves recombinant or synthetic nucleic acid models, you must complete the relevant selection of this application

Animal Use

My study does NOT involve animal use

Complete this section if biohazardous materials or nucleic acid molecules will be administered to animals.

1. What species of animal will be exposed?

2. State the Institutional Animal Care and Use Committee (IACUC) protocol #:

a. Is IACUC approval active or pending?

3. State the maximum dose volume to be administered per animal:

4. State the maximum dose concentration to be administered per animal:

5. State the total amount of animals that will be dosed per experiment:

6. State the total amount of animals that will be dosed in the duration of study (Note: please make sure the number you provide corresponds to details provided in your IACUC submission):

7. State the Animal Biosafety Level Requested:

Attach detailed procedure if biohazards do not fit conventional Animal BSL2 or 3 work practices.

8. Indicate the proposed route of administration (check all that apply):

- Aerosol
 Indwelling catheter or cannula
 Intranasal
 Parenteral (e.g. IV, IM, IP)

Please specify:

Other

9. Will the animal be anesthetized or tranquilized during administration?

- Yes
 No

Indicate the route of anesthesia:

Indicate the chemical and dosage used:

10. Is the agent(s) an animal pathogen?

- Yes
 No

11. Is the agent(s) a human pathogen?

- Yes
 No

12. Is the agent transmitted from animal to animals?

- Yes
 No

13. Is the agent transmitted from animal to humans?

- Yes
 No

14. Will the agent be inactivated prior to use in animals?

- Yes
 No

15. Will the animals be housed in microisolator (shoebox cage with a filter-top bonnet) cages?

- Yes
 No

a. Will the cages be ventilated?

- Yes
 No

16. Will there be any special procedures or containment needed?

- Yes
 No

a. If yes, please describe:

17. Will work with animals be performed in the biological safety cabinet?

- Yes
 No

18. Will work with transgenic animals requiring BSL2 or higher containment be conducted in these experiments?

- Yes
 No

a. Please explain. Be sure to list the information for the transgenic animal, a reference for its construction, and address the requirement for increased containment:

19. Please describe the method of carcass disposal and any vendors used.

Safety Measures

Research will be conducted at Biosafety Level:

Contact IBC if you need assistance in determining the appropriate classification, or refer to the [CDC/NIH BMBL 5th edition](#).

1. Engineering controls

The following devices are available to minimize exposure to aerosol generating steps for work requiring BSL-2 containment or higher (e.g. centrifugation, vortexing, sonication, egg harvesting). Check that which will be utilized in your research.

	Yes	No
Class II biological safety cabinet		
Type A (A1 or A2)		
Type B (B1 or B2)		
Most recent certification date:		

2. Sharps

(e.g., syringes, scalpels, glass) used with BSL-2 and higher organisms must be minimized.

a. Will syringes, scalpels, glass, or other sharps be used?

Yes

No

i. If yes, has the research been reviewed to eliminate or minimize the use of sharps where possible?

Yes

No

ii. Are sharps with integrated safety devices/mechanisms available and used?

Yes

No

(1). If yes, please describe the safety device (type, model, brand):

(2). Has training been given to the staff on this safety device?

Yes

No

(a) Who provided this training?

3. Personal protective equipment

Indicate the personal protective equipment required for your work:

	Lab Use	Animal Facility Use
Tyvek suit or coverall		
lab coat		
apron or rear fastening gown with sleeves		
apron or rear fastening gown without sleeves		
bonnet or hair cover		
powered air purifying respirator (PAPR)		
N-95 respirator		
N-100 respirator		
surgical mask		
shoe covers		
safety glasses/goggles		
gloves		
latex, non-powdered		
nitrile		
vinyl		

4. Decontamination/Disinfection

Indicate the disinfection method. Check all that apply.

	Specific Disinfectant and Concentration Used (e.g. 10% Bleach or 70% ethanol)	Routine Cleanup	Spill Cleanup	Solid Waste	Liquid Waste	Animal Carcasses	Animal Bedding
Autoclave							
Chlorine compounds							
Iodophors							
Alcohols (ethyl or isopropyl)							
Phenolic Produce (e.g. Vesvine)							
Quaternary ammonium product (e.g. Quatricide)							
Other							

a. Please indicate the location for all appropriate spill cleanup materials:**b. Will radioactive infectious waste be generated?** Yes No

i. How will contaminated radioactive solid waste be disposed?

ii. PI radiation license number:

iii. Expiration date:

5. Principal Investigator's Assessment of Risk**a. What is the most serious adverse event you can foresee as a result of this experiment? For example: recombination, employee exposure, environmental release, activation of latent virus, etc.****b. How did you determine the appropriate biosafety level for this protocol?****c. Please list the following information about your most recent literature search on the safety of the organisms and experimental procedures used in this protocol. Note: Literature search must have been conducted within one month of the submission to the IBC.**

i. What is the date of your most recent search?

ii. What databases did you search?

iii. What keywords did you use?

iv. Please describe any pertinent safety or hazard analysis findings:

d. Is there a significant potential for this material to be contaminated with an organism requiring a higher biosafety level?

E.g. a live virus/bacterium contaminating a preparation of dead virus/bacteria

i. How would you determine if the material was contaminated with an organism requiring a higher biosafety level?

ii. Is your lab equipped to perform such an evaluation

Yes

No

(a). What steps will be taken to ensure the safety of staff and students working with the material?

e. What was the source of this material? Please indicate if the material from the ATCC, colleague (include name an institution), or another source.

i. Can the sender provide background information or quality control data on the material? Please include information on the types of infections microorganisms screened for in these samples.

f. What infection or disease can be recombinant or synthetic nucleic acid molecules, pathogens, cell lines, or human materials used in this application cause?

g. List the routes(s) of exposure for the recombinant or synthetic nucleic acid molecules, pathogens, cell lines, or human materials used in this protocol application.

h. List the signs and symptoms of exposure to the recombinant or synthetic nucleic acid molecules, pathogens, cell lines, or human materials listed in this protocol application.

6. Export Control and Dual Use Research

According to the [2007 Fink Report](#) and the [National Science Advisory Board for Biosecurity](#), research with a legitimate scientific purpose that could be misused to pose a biological threat to public health and/or national security is considered "dual use research." All research performed at Montclair State University will be assessed for dual use potential.

a. Do you plan to ship any materials? **If yes**, please answer the following questions.

Yes

No

i. What are you planning to ship?

ii. Do you plan to ship internationally?

Yes

No

iii. Where are you planning to ship? List all shipping destinations.

iv. Do you plan to ship dry ice?

Yes

No

v. Where are you planning to ship dry ice? List all shipping destinations.

Please read the following and acknowledge that you understand the definition of dual use experiments by checking each box. If you have any questions you can contact the Biosafety Officer.

a. Disrupting immunity or effectiveness of an immunization (This applies to both human and animal vaccines)	
b. Enhancing the harmful consequences of a biological agent or toxin (i.e. increase virulence, pathogenicity)	
c. Conferring to a biological agent or toxin resistance to clinically and/or agriculturally prophylactic or therapeutic interventions.	
d. Conferring the ability of a biological agent to evade detection methodologies	
e. Increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin. This includes the environmental stabilization of pathogens	
f. Altering the host range and/or tropism for a biological agent	
g. Enhancing the susceptibility of a host population to illness by a biological agent or toxin	
h. Generating a novel pathogenic agent or toxin, or reconstitute an eradicated biological agent	

Please acknowledge by typing your name that you comprehend dual use concerns in research with legitimate scientific purposes similar to experiments described within this protocol and that you will report any change in your awareness of dual use concepts to the Biosafety Officer immediately.

PI Name:

7. Security Methods

Indicate the types of security used in your laboratory. Check all that apply.

Security Method	
Lab doors are closed and locked when no one is present (e.g. staff are away at a lab meeting)	
Pathogen stock vials are stored in locked refrigerators/freezers/incubators, etc.	
Unknown persons who enter the lab are questioned/challenged (e.g. "May I help you? Why are you here?")	
Card swipe and/or pin access for authorized laboratory staff only	
Other	

8. Medical Surveillance and Training Requirements

	Yes	No	N/A
All personnel who are potentially exposed to human blood, human body fluids, or human cell lines have received Hepatitis B vaccine or proven immunity (required for work with human and non-human primate cell lines, blood, and tissues)			
All personnel who are potentially exposed to <i>Mycobacterium tuberculosis</i> have completed baseline TB surveillance (either TB skin test or gamma interferon release assay)			
Additional vaccination/surveillance is required for work on this project			
There is a known vaccine and/or therapy			
Individuals at increased risk of susceptibility to the agents in this protocol (e.g. preexisting diseases, medications, compromised immunity, pregnancy, or breast feeding) have been referred to PLACE.			

Personnel

List all personnel (including any students) in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in this protocol. *Include the PI.*

Will the PI be performing experiments included in this protocol?

Yes

No

PI Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

Will initiate shipping of biohazardous material or dry ice

Will handle animals

Will handle human or non-human primate cell lines, blood, or tissues?

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Affirmation

I accept responsibility for the safe conduct of work with this material. I accept responsibility for ensuring that all personnel associated with this work have received the appropriate training on the hazards and the level of containment required to perform this research safely. I will report to the Biosafety Officer any accident, incident, or adverse event that results in a potentially toxic exposure to personnel or any incident releasing recombinant or synthetic nucleic acid molecules or other potentially hazardous materials into the environment.

Principal/Responsible
Investigator Signature:

Date:

Grant Agency:

Award #:

For Committee Use

- Approve
 Approve pending modifications (see notes below)
 Not approved

Committee's Determination of Required Biological Containment-Biosafety Level:

Signatures:

IBC Chairman/
Representative

Date:

Biosafety Officer:

Date:

Modifications:

Personnel Member 1

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 2

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 3

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 4

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 5

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 6

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 7

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 8

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 9

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.

Personnel Member 10

List all personnel (including any students in your laboratory who handle or may otherwise be exposed to any of the recombinant or synthetic nucleic acid molecules, human cell lines, or microorganisms listed in the protocol.

Name:

Title:

Date of last blood-borne pathogen training:

Date of last lab safety training:

For viral vector protocols only:

Date of viral vector training:

- Will initiate shipping of biohazardous material or dry ice
- Will handle animals
- Will handle human or non-human primate cell lines, blood, or tissues

Note: If no, then the person is not required to receive the Hepatitis B vaccination. If this changes, then they need to receive the vaccination [students may visit UHC and faculty/ staff their personal providers] and the PI must notify the IBC prior to starting work.

For BSL-3 protocols only:

Is personnel member a BSL-3 approved user?

- Yes
- No
- In training

Electronic Signature:

I certify that I have been informed of potential hazards and safe work practices.