MONTCLAIR STATE UNIVERSITY

For IBC Use

Institutional Biosafety Committee

Submission Date:

Project Title:

Key Personnel

Principal/Responsible Investigator	
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)	

Co-Investigator *(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)	

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)	

Project Narrative and Flow Sheet of Experiment(s) **(Submit Flow Sheet as a separate attachment)**

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 MSU 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 transgemic 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.

Recombinant or Synthetic Nucleic Acid Molecules:

☐ **My study will NOT be using recombinant or synthetic nucleic molecules**

Click here to proceed to the next section

Select the category that best reflects the type of experiment that you are conducting.
Please identity 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	B	C	D
If your experiment involves:	**Registration w/ NIH required?**	**IBC Approval Required?**	**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 LD50 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. *Note: synthetic nucleic acid deliberately transferred into one or more human research participants is not exempt* (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	☐
In vivo 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 transge 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**

Click here to proceed to the next section

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).**

Click here to proceed to the next section

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**

Click here to proceed to the next section

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	☐
South American Hemorrhagic fever viruses	☐
Junin	☐
Machupo	☐
Sabia	☐
Chapare	☐
Guanarito	☐
Tick-borne encephalitis complex (flavi) viruses	☐
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 entertoxins A,B, C, D, E subtypes	☐
T-2 toxin	☐
Terodotoxin	☐

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

☐ 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**

Click here to proceed to the next section

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)		☐		☐	☐	☐	☐
Phenholic 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. 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 MSU will be assessed for dual use potential. 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 *Mycobacterium tuberculosis* 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 initate 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.

Add Personnel Member 1

Add Personnel Member 2

Add Personnel Member 3

Add Personnel Member 4

Add Personnel Member 5

Add Personnel Member 6

Add Personnel Member 7

Add Personnel Member 8

Add Personnel Member 9

Add Personnel Member 10

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 avid 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.