FLORIDA A&M UNIVERSITY

FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY

2024

All research using any kind of biological materials need to complete this form. The completed form can be uploaded in to the IRBNet.org system for IBC review, and, if required per NIH Guidelines, approval. Read the instructions carefully. PIs are required to complete the entire form and any applicable appendices- a lab manager may help complete the form but the PI is responsible for submission of the form and its contents.

Make sure all appropriate appendices are also completed as part of the protocol. Do not include in your submission appendices that do not apply to your project. All protocol submissions must have completed sections 1-7. Only complete the appendices if necessary. Attach additional files as requested with protocol registration.

Resources for completing the protocol:

- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- CDC Diseases and Conditions Page.
- ATCC Website
- Pathogen Safety Data Sheets

Office Use Only IBC Protocol Number: Date Approved: Approval By: Renewal Date:
Biological Safety Officer Signature:
PI Signature:

Principal Investigator Contact Information

Principal Investigator (PI):	
Position/ Title:	
E-mail:	
Department and Program:	
Phone:	
Campus/ Office Address:	

Alternate Contact (must be part of this protocol as a researcher)	
E-mail:	
Phone:	

Emergency Contact Information- Cannot be personnel in study.

Name:	
E-mail:	
Phone:	

Checklist for IBC Protocol Submission

☐ Completed protocol form (this form)
☐ Risk Assessment
☐ Completed biosafety inspection (within last year for BSL-2 and higher labs, every other year for BSL-1 labs).
☐ Completed biosafety training within last three years
☐ Completed NIH Guidelines training within the last three years

Supplemental Documents (Check all included with this protocol submission)

☐ IACUC Protocol
☐ IRB Protocol
☐ Plasmid Map
☐ Appendix A: Experiments Covered by the NIH Guidelines
☐ Appendix B: Biological Toxins
☐ Appendix C: Viruses or Viral Vectors
☐ Appendix D: Human or Non-Human Primate Cells, Tissues, and Fluids
☐ Appendix E: Animal Biosafety
☐ Appendix F: Plant Biosafety
☐ Section III-A, III-B, or III-C approvals (as required)
☐

Section 1. General Information

Protocol Title: _____

This submission is a (select one): ☐ New
☐ Renewal- provide IBC Protocol #:

Type of Grant: ☐ Internal ☐ None
☐ External

Specify Source: _____

Grant Number: _____

Linked Protocol: ☐ IACUC ☐ None
☐ IRB

Protocol Number(s): _____

Most Recent Approval Date (If already approved): _____

Personnel Training

List all personnel involved in the study, their title/ job description, and all applicable current training on file.

Name (include all personnel involved in protocol)	Title/ Job Description	Training: lab safety, chemical hygiene plan, biological safety, animal care, etc.

Research Location(s)

List the building and room number for each laboratory used in the experiments. Identify the research activities conducted in each space, their approved BSL, and the most recent lab safety and biosafety inspection dates.

Building and Room Number	Research Activity/ies	Highest BSL	Most Recent Lab Safety and Biosafety Inspections and Dates

Section 2. Research Description

New Research Study

1. Explain the rationale for this research study and the overall goal of this study. Provide the research question (hypothesis/ hypotheses) to be tested. Please use layman's terms when possible. **Limit 300 words**

2. Provide a description of the procedures employed in this protocol. Be specific on chemicals and biological agents that may present biohazards. List all test agents to be used. Must be in uniform font.

Renewals Only

1. Summarize the rationale for this research study and the overall goal of this study. Do not exceed 200 words.

2. Summarize the progress and accomplishments of this study since its start date.

3. Summarize procedures and describe any proposed modifications that are included in this proposal that were not in the previous submission(s)- attach supplemental information as needed (and indicate attachments below and on checklist).

4. Identify any changes to the protocol since the previous submission to IBC.

Section 3. Biological and Chemical Materials

1. Will your experiments involve recombinant or synthetic DNA (including whole animals, plants, microorganisms, viruses, cell culture, viral vectors, etc.)?
   - ☐ Yes: Complete Appendix A and any other applicable Appendices as Required.
   - ☐ No: Move on to Question 2.

2. Are you working with any of the following biological materials (Check all that apply and attach appendices or supplemental materials)? Include all biological materials in the biological materials table below.
   - ☐ Recombinant and Synthetic Nucleic Acid Molecule Experiments- Attach Appendix A
   - ☐ Biological Toxin (any toxin derived from an organism)- Attach Appendix B
   - ☐ Viruses or viral vectors- Attach Appendix C
   - ☐ Human or Non-Human Primate Blood, Cells, or Tissues- Attach Appendix D (note: if you are only doing blood draws on patients not known to be infected with any bloodborne diseases, you need to use the IBC Blood Draw Registration Form instead of this form)
   - ☐ Animals- Complete Appendix E, animal biosafety
   - ☐ Plants- Complete Appendix F, plant biosafety
   - ☐ Plasmids- Attach a plasmid map.

Biohazard Table

In the chart below, identify the biohazardous material(s) being handled, their host range, if they are zoonotic, their risk group, your proposed containment level, if there are vaccinations available, and routes of transmission (check box). For all Risk Group 2 and higher agents, please attach a risk assessment and/ or biosafety/ exposure control plan.

Biological Material (Species, strain, type of biomaterial, cell lines)	**Source (Company, donated, etc.)**	**Infectious Host Range**	**Zoonotic (List Y/N)**	**Risk Group (RG1, RG2, or RG3)**	**Containment Level (BSL)**	**Vaccination available (List Y/ N)?**	**Routes of Transmission (Put an x in all that apply)**				
							Ingestion	Inhalation	Direct Contact, Open wound	Direct contact, mucous membranes	Other: specify

Section 4. Biocontainment

For the following sections, provide information regarding laboratory equipment, PPE, biosafety levels you will be working in, and any additional procedures that will be taken to prevent accidental release or exposure. All PIs should complete a risk assessment (attach as supplement) to determine the appropriate biosafety level of containment for work.

1. What is the proposed BSL for your experiments? *Note: The IBC will make the final determination regarding the biosafety level for the protocol.*

☐ BSL 1
☐ BSL 2
☐ BSL 3
☐ BSL 4

2. Identify the PPE used in experiments, the type, when it's used, and how it will be decontaminated and/ or disposed of in the table below.

Type of PPE	**Type of PPE (i.e. brand, material)**	**When PPE will be worn/ used**	**Decontamination/ Disposal Method**
Gloves			
Eye Protection			
Lab Coat			
Face Shield			
Respirator			
Other (specify)			

3. Describe the biosecurity measures in place to minimize access to this lab facility (i.e. locked doors at all times, agents in locked freezers, restricted access, key card access, etc.)

4. Summarize what measures will be taken to minimize accidental release or risk of an exposure event occurring. If this is in your exposure control plan or biosafety manual, just refer to that supplement.

Section 5. Decontamination and Disposal of Biohazardous Waste

1. How will biohazardous waste generated from the experiments outlined in this protocol be decontaminated prior to disposal, and how will they be disposed of after decontamination? (Can attach SOP)

2. How will equipment be decontaminated before/ after use? Identify the type of disinfectants used, contact time, and procedure for disinfectant use provided to all lab personnel.

3. Will you be using a biosafety cabinet for your work? ☐ Yes ☐ No

3. If Yes : attach lab SOP for use and decontamination.

4. Are you using needles or other needle-type sharps in your laboratory facility?
   ☐ No
   ☐ Yes: Please describe below how the needles are collected for safe disposal below. Include record of annual bloodborne pathogens training in the training record for all personnel handling needles.

Section 6. Occupational Health

1. Is there a vaccine recommendation for working in your research facility?
   ☐ No
   ☐ Yes- Use space below to describe vaccine recommendations.

2. In addition to the required biosafety training, what additional training requirements do all personnel have to complete to work in your laboratory?

3. Where are the training records housed for the personnel in your laboratory? (Should be able to provide upon request).

4. If you are working with risk group 2 or higher biological agents, how will health of the researchers be monitored?

Section 7. Reporting

I, **enter name here** , the principal investigator of this study, agree to abide by all university, local, state, and federal guidelines and regulations regarding the handling of biological materials, recombinant DNA or synthetic nucleic acid molecules, infectious agents, and/ or human tissues/ fluids in my research. I will follow my approved protocol. I agree to report the any of the following incidents, which are required by the UWM-Biological Safety Program, to the Biological Safety Officer:

- Accidental release or spills of any biological agents in or out of a BSC
- Accidental release of rDNA or synthetic nucleic acid molecules to the environment (including escape of a transgenic animal)
- Research-related incidents and illnesses (including needle sticks and bites from transgenic or infected animals)
- Spills and accidents involving wild-type pathogens, organisms containing rDNA or synthetic nucleic acids, or potentially infectious material.
- Spills and accidents in any NIH animal laboratory that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant or synthetic nucleic acid molecules.
- Any issues at any biosafety level pertaining to the operation and implementation of containment practices and procedures or violations of the NIH Guidelines or the UWM Biosafety Manual.

I also agree to provide the following for all personnel working in my laboratory(ies):

- Adequate training to use all equipment and perform all necessary procedures.
- Communicate biosafety training opportunities and maintain their training records.
- Correcting work errors and unsafe laboratory practices.

As a responsible researcher, I will maintain a biological inventory and a laboratory safety manual outlining policies, procedures, and approved protocols, and will require all personnel to review it and sign that they have reviewed it.

By signing this, I also verify that this form is complete, all attachments are included in my submission, and I will make myself or a co-investigator available for protocol review. I certify that I have read the above statements and agree that I and all listed participants will abide by those statements as well as all university and campus policies and procedures governing the use of infectious agents and other biological materials as outlined in this application and in the campus specific Biosafety Manual. If there are any changes to personnel or the protocol, I will submit the appropriate request for

changes to the protocol. I understand that the approval of this protocol expires in 3 years, at which time I will be expected to submit a renewal form or a new protocol form if I am changing my protocol.

Principal Investigator E-signature (Type Name) **Date**

Appendix A: Recombinant and Synthetic Nucleic Acid Molecule Experiments

Link: NIH Guidelines for Research With Recombinant DNA or Synthetic Nucleic Acid Molecules
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Animal Activities Table

1. Review the chart below. If you answer yes to any of these questions, you must have Institutional Biosafety Committee approval **PRIOR** to commencing or continuing experiments per the NIH Guidelines, Sections III-A, III, B, III-C, and III-D.

Experimental Questions	Yes	No
Section III-A: Will any experiments involve the transfer of a drug resistance trait to an organism for a therapeutically useful antibiotic used in human or veterinary medicine? (Check "no" for standard laboratory procedures- such as ampicillin into *E.coli*). If yes, must also attach NIH/ RAC approvals.		
Section III-B: Does the experiment involve genes coding for molecules toxic to vertebrates (LD50< 100 ng/ kg body weight)? This would include biological toxins. If yes, complete Appendix B: Biological Toxins. If toxin is a select toxin, work is not permitted at this time at UWM with this material. Review www.selectagents.gov for more information.		
Section III-C: Will the recombinant or synthetic nucleic acids be used in human subjects for human gene transfer experiments? If yes, requires IRB approval and any other NIH approvals. Attach as supplements.		
Section III-D-1: Do the experiments involve using Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents as Host-Vector Systems? If a viral vector is used, complete Appendix C: Viruses and Viral Vectors		
Section III-D-2: Do the experiments involve human genes being cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems?		
Section III-D-2: Do the experiments involve experiments in which DNA from Risk Group 2, Risk Group 3, or Risk Group 4 Biological Agents are being cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems?		
Section III-D-3: Do any experiments involve the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of a helper virus in a tissue culture? If human cell culture, complete Appendix D: Human and Non-Human Primate Blood, Cells, Tissues If viral vector, complete Appendix C: Viruses and Viral Vectors		
Section III-D-4: Do your experiments involve whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals? Complete Appendix E: Animal Biosafety Note: There are limited exempt experiments for animals, and the only animals that have exemptions are rodents. These experiments also include introduction of modified microorganisms to whole animals. All transgenic zebrafish, transgenic *C.elegans*, and other transgenic animal experiments fall under this section. Exemptions include: Breeding/ purchase/ transfer of established rodent lines in ABSL-1 containment.		
Section III-D-5: Do your experiments include genetically engineering plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules in BL2-P or higher containment? Complete Appendix F: Plant Biosafety		

Section III-D-6: Will your experiments involve the creation of >10L of culture in a single culture vessel?		
Section III-D-7: Will your experiments involve the generation of influenza viruses by recombinant or synthetic methods?		

2. Review the chart below. If you answer yes to any of these questions, you must have Institutional Biosafety Committee approval **CONCURRENT** with the commencement or when renewing experiments per the NIH Guidelines, Sections III-A, III, B, III-C, and III-D. All Section III-E experiments may be conducted in Biosafety Level 1. If your experiment requires higher containment, it is non-exempt.

Experimental Questions	**Yes**	**No**
Section III-E-1: Do your experiments involve the formation of a recombinant or synthetic nucleic acid molecule that contains no more than 2/3 of the genome of any eukaryotic virus in BL-1 containment?		
Section III-E-2: Do your experiments involve whole plants in BL1-P containment or research involving modified arthropods associated with plants that can be handled in BL1-P containment?		
Section III-E-3: Will you be creating knockout rodents, breeding knockout rodents from two strains, or breeding rodents from two strains (generating a new strain) in BL-1 containment?		

3. Do your experiments involve recombinant DNA not found in organisms or viruses, single monochromal or viral DNA sources, or host DNA transferred to the same host or related species, that can all be safely handled in BL-1 containment (including breeding/ transfer rodents)?
   - ☐ Yes- your protocol may not require IBC approval (still requires registration).
   - ☐ No

Recombinant DNA (rDNA) and Synthetic Nucleic Acid Molecule Chart

Supplement Request: Attach any supplemental information for your recombinant DNA/ synthetic nucleic acid and indicate supplemental attachments on the Checklist for Submission.

Source Species of Inserted DNA	**Host(s) to be Used**	**Plasmid and/ or Vector(s) to be Used**	**Gene or Transcription Product**	**Known Toxicity to Humans, Animals or Environment (If Yes, describe)**

Appendix B: Biological Toxins

Please identify the following characteristics for the Biological Toxin(s) you have included in the Biohazard Table. Note that if you plan to use a select toxin or DURC, the protocol cannot approved at this time as there is no Select Agent Program in place at UWM.

1. What is the LD50 of the biological toxin(s) listed?

2. What are the symptoms associated with exposure to the toxin(s)? How will lab personnel be monitored after handling the toxin(s)?

3. Describe the toxin inactivation procedures. How have these been verified to be effective in the inactivation of the toxin(s)?

Appendix C: Viruses and Viral Vectors

Note: If you are working with viral vectors, you are required to complete the NIH Guidelines (Appendix A) as well. If the viral vectors are being introduced to animal models, Appendix E is required.

1. What virus/viral vector will be used (make sure they are listed in the biohazard table)?

2. Are any of the vectors listed replication competent? If they are not replication competent, what tests were performed to verify their incompetence to replicate?

3. Could the viral vectors be complimented or recombine in the proposed experiments?

4. What experiments will be done using the viruses listed?

5. Will any procedures be done that could potentially extend the host range of the virus/ viral vector?

6. Will any procedures be done that could potentially enhance the pathogenicity of the viral vector(s)- such as insertion of oncogenes, toxin genes, etc.?

7. Could the viral vectors be complimented or recombine in the proposed experiments?

8. What will be done to minimize the risks associated with the viral vector(s) in the proposed experiments?

9. Is the free DNA/ RNA infectious to humans, animals, and/ or plants?

10. Are you using any helper viruses or packaging/producer cell lines? If yes, please describe. Identify the essential genes deleted from the vector.

11. Does the proposed/ used disinfection and decontamination procedures inactivate the virus/ vector being used?

Lentiviral Vectors

If using lentiviral vectors, answer the following questions and review the NIH Supplement: Biosafety Considerations for Research with Lentiviral Vectors.

12. What is the generation?

13. How was the lentivirus testing performed to determine replication competence?

Appendix D: Human and Non-Human Primate Cells, Tissues, and Fluids

Include all cell lines (primary and established) are listed in the Biohazard Table.

Use of human cells/ tissues requires the completion of Bloodborne Pathogens Training within the last calendar year. Indicate training in the training section.

All researchers using human blood, cells, or tissues must have a current exposure control plan for their research facility for bloodborne pathogens. A template is available at: http://uwm.edu/safety-health/bbp-2/

All researchers handling human or non-human primate materials must work in a minimum of BSL-2.

Human Cells, Tissue, Fluids

1. If working with human cell lines tissues or fluids (primary or established) , are there known bloodborne pathogens present in the cell lines?

2. If working with human bodily fluids, please identify any known pathogens that may be present. Describe how the fluids will be disposed of after use in experiments. Bodily fluids include: saliva, urine, stool samples, internal fluids such as CSF.

3. Will any of the human cells be purposely infected with human pathogens? If so, please describe precautions that will be taken to minimize risk to the researcher when handling infected human cells.

Non-Human Primate Cells, Fluids, Tissues

1. What species of primate is the source of the cells/ fluids/ tissues? If an IACUC protocol is tied to the collection of these tissues, please attach as a supplement and indicate as such.

2. What are the known human pathogens this species of primate may carry, and how will the cells/ fluids/ tissues be safely handled to minimize the risk of accidental exposure to these potential pathogens that may be present?

3. Will any of the human cells be purposely infected with human pathogens? If so, please describe precautions that will be taken to minimize risk to the researcher when handling infected human cells.

Appendix E: Animal Biosafety

Identify animals that will be inoculated with pathogens, are genetically-modified, or will be genetically-modified in this protocol. IACUC will not approve any protocol that involves transgenic animals or the use of animals in biological agent research without the prior approval of the IBC- please attach the IACUC protocol as a supplement. Submit your IBC protocol with ample time for review. Additional measures may be required for containment when handling aquatic animals or arthropods (particularly insects and bugs).

Additional Training Required for Working with Vertebrate Animals from Animal Care, as well as record of Animal Biosafety Training completed through CITI Program within the last 3 years.

Include all biohazards in the biohazard table in the main form.

1. Are any animals being infected with human or animal pathogens in your proposed animal experiments? If yes, have the pathogens been previously studied in animals?

2. Will animals be exposed to human cells, tissues, blood, etc.? If yes, Identify all human materials in biohazard table and complete Appendix D as well and include record of bloodborne pathogens training in the training records.

3. If you answered yes to the previous question, has this material been previously tested and certified pathogen-free of bloodborne pathogens? Provide testing source information. Note: If it has not been tested for bloodborne pathogens, you are required to treat animals exposed to these tissues as also infected with bloodborne pathogens.

4. If infecting/ testing animals with a known human/ animal pathogen, describe how this information will be communicated to animal care staff (cage/ tank cards, door signage, etc.).

5. If infecting animals with a known human/ animal pathogen, please identify how the animal lab space will be routinely disinfected to minimize the risk of accidental exposure.

6. If working in ABSL-2 or higher, please describe the controls that will be taken to minimize the risk of accidental exposure to the research personnel and animal care staff.

7. What PPE should be worn when handling animals, including the cages or fish tanks?

8. Explain how animal waste is decontaminated/ disposed of, including carcasses, cleaning of housing units, and disposal of bedding/ feces/ waste. If using fish as a model, please describe how the wastewater is disposed of and how the tanks are cleaned. (Note: even if animal care is caring for your animals, you still need to provide how the waste bedding should be handled, decontamination procedures, etc.).

9. Do your proposed vertebrate animal experiments include non-exempt experiments under Section III of the NIH Guidelines? If yes, please summarize.

Non-Vertebrate Animals

1. Identify the non-vertebrate animals proposed for use in experiments in this protocol. Describe their origin, purpose for use, and include in the animal information table.

2. Are the animal species listed in this section an established species in the Milwaukee metro? If they are an exotic species, is there any risk that the animal could become temporarily or permanently established in the event of an accidental release event? How will these animals be contained to minimize the risk of accidental release into the surrounding environment?

3. Are these non-vertebrate animals known to be potential carriers of human, animal, and/ or plant diseases? If yes, identify the potential pathogens that they may carry. Identify if these are diseases that can also be found carried by native populations in the Milwaukee metro. Also identify if it is a mechanical or biological vector in the biological agent's life cycle.

4. Is there a means of controlling or eradicating the animal if it escapes containment? If so, please describe.

Animal Information Table

Animal species and source	Knockout (KO), Knock-In (KI), Transgene (T) or Not Applicable (NA)	Strain Name (needs to match IACUC nomenclature)	Gene Name and Biological Source	Where will the animals be housed? (Building, room, BSL)	Will the animal be inoculated with a pathogen? Specify

Appendix F: Plant Biosafety

Instructions: Per the NIH Guidelines, all research involving transgenic plants must be reported to the IBC. If the project requires BSL-1P containment than it may be initiated simultaneously with submission of this registration form (Section III-E). All other transgenic plant projects will require IBC review and approval prior to the initiation of research. Please review Appendix P of the NIH Guidelines, which outlines the Plant Biosafety Containment Levels.

1. Does your research involve the use of any transgenic plants? If yes, please provide the appropriate section of the NIH Guidelines in the space provided. If using transgenic plants, where will transgenic whole plants will be maintained? (Building, room, type of growth chamber) Be sure to clearly explain containment and care of the transgenic plants.

2. If you are not using/ creating transgenic plants, will you be infecting plants with any known plant pathogens? If yes, please attach any applicable USDA/ APHIS permits required for many plant pathogens. Summarize how the pathogen will be contained to minimize the risk of accidental release into the environment.

Plant Information Table

Plant (Species)	BSL-P	Gene(s) involved (if transgenic)	Native or Exotic Plant Species and Source	Location(s) of Plant Research	Containment Procedures