UGA Institutional Biosafety Committee

Protocol Review Form

UNIVERSITY OF GEORGIA
Office of Research

For questions about this form, contact:
UGA Office of Biosafety
https://research.uga.edu/biosafety/
Email: biosfty@uga.edu
Phone: 706-542-2697
Return by E-mail to: ibc@uga.edu

Principal investigator (PI)	Phone	Fax	E-mail
Center/Institute/Department		College	
Co-Investigator **(enter N/A if none)**	Phone		E-mail
Project/Grant Title			Account NO. (If internally funded)
			Account NO. (If Externally funded)
Alternate Title			
			Funding Source (If externally funded)
2nd Alternate Title			Anticipated Starting Date

- I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted to external funding agencies.
- I agree that I will not begin this project until receipt of official approval from the appropriate committee(s).
- I agree that modifications to the originally approved project will not take place without prior review and approval by the appropriate committee(s), and that all activities will be performed in accordance with all applicable federal, state, local and University of Georgia policies.
- I will follow applicable biosafety level requirements, comply with all shipping requirements and required waste management practices.
- I will ensure that all personnel have appropriate training including but not limited to: biosafety principles and techniques, accidental spills, shipping regulations, proper handling of biohazardous materials and waste management.
- I will complete the training on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.
- I am aware that the IBC reserves the right to conduct inspections of the research facilities at any time.

Signature of Principal Investigator	**Date**

Signature of Department Chair	**Date**

For Institutional Biosafety Committee (IBC) Use Only

Protocol #:

Date Received:

☐ rDNA ☐ Infectious agents
☐ Exempt ☐ Expedited review
☐ Full Committee Review
☐ IRE Review

◯ Protocol Approved ◯ Protocol Denied

Completion of this section is a requirement for all protocols submitted to the UGA IBC. Failure to complete this section will result in the protocol not being submitted for IBC review.

Refer to the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential for definitions of Category 1 and Category 2 research and to Executive Order 14292 for the definition of Dangerous Gain of Function Research.

1. **Work in my laboratory involves or could result in a pandemic potential pathogen (PPP) or a pathogen with enhanced pandemic potential (PEPP).** If yes, please list the pathogen names and identify experimental outcome(s) or action(s). ◯ Yes ◯ No

   Pathogen name(s):

   This work is reasonably anticipated to result, or does result in, one of the following Category 2 experimental outcomes or actions:

   Enhanced transmissibility of the pathogen in humans. ◯ Yes ◯ No

   Enhanced virulence of the pathogen in humans. ◯ Yes ◯ No

   Enhanced immune evasion of the pathogen in humans (such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection. ◯ Yes ◯ No

   Generation, use, reconstitution, or transfer of an eradicated or extinct PPP, or a previously identified PEPP. ◯ Yes ◯ No

2. **Work in my laboratory involves an agent or toxin within the scope of Category 1 research.** If yes, please list the pathogen name(s) and indicate whether the work is anticipated to result in, or does result in, one or more of the experimental outcome(s) or action(s) specified for Category 1 research. ◯ Yes ◯ No

   Pathogen name(s):

   Work in my laboratory is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified for Category 1 Research. If yes, please specify the experimental outcome(s) or action(s) below. ◯ Yes ◯ No

   Experimental outcome(s) or action(s):

3. **Work in my laboratory involves an infectious agent or toxin that could result in significant societal consequences.** If yes, please list the pathogen name(s) and indicate whether the work is anticipated to result in, or does result in, one or more of the experimental outcome(s) or action(s) specified for Dangerous Gain of Function Research. ◯ Yes ◯ No

   Pathogen name(s):

   Work in my laboratory is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified for Dangerous Gain of Function research. If yes, please specify the experimental outcome(s) or action(s) below. ◯ Yes ◯ No

   Experimental outcome(s) or action(s):

For any "Yes" answers to prompts in questions 1, 2, or 3, please fill out the DURC/PEPP Research Review and the Risk/Benefit Assessment and Risk Mitigation Plan Forms.

4. I have reviewed and understand the information provided in the information sheet on the Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential Policy and Dangerous Gain of Function Research. ◯ Yes ◯ No

5. I understand that it is my responsibility to continuously assess my research for Category 1, Category 2, and Dangerous Gain of Function research throughout the research lifecycle. ◯ Yes ◯ No

Type of Funding Source(s) for this Project:

☐ Department/institutional funds
☐ Foundation
☐ Federal funds
☐ Business/industry
☐ Other

If project is supported with federal funds, name of funding agency and grant or contract number:

Key Personnel. List all project personnel and relevant experience. This information is intended to inform the committee of the training and background of the investigators and key personnel. The PI and Co-PI name will automatically populate in the first and second boxes – if there is no Co-PI, please be certain that the second name listed is "N/A". For additional personnel, please list one name per row.

Name	Degree	Specific Duties on Project	Number of Years Training and Description of Experience
PI:			
Co-PI:			

Non-Technical Synopsis. Please give a brief description of your project easily understood by nonscientists. **Explain the overall goal, anticipated outcomes, and potential benefits.** Do not use abbreviations and technical vocabulary or phrases.

Technical Synopsis. Provide a detailed description of specific experiments that will be conducted. In addition, provide details on how infectious agents(s), rDNA material(s), human or NHP material(s), or toxin(s) will be used/handled. Include the following information, as it applies: *in vitro* and/or *in vivo* procedures used; maximum volumes and titers of cultures to be grown at any given time; method(s) of transportation for samples and inoculum; procedures that may create a splash or aerosol hazard and the mitigation plan for these procedures.

If different Biosafety containment levels are used, clarify what will be done at each level.

Part A: Transgenic Animals

Will this project involve the use of transgenic animals? ○ Yes ○ No

1. **Describe how these animals are genetically altered.**

2. **Please indicate how these animals will be procured.** This information is intended to inform the committee if animals will be purchased from a vendor, transferred from another institution, or produced here at UGA.

3. **Describe the type and frequency of evaluations to be performed** on the animals in this project.

4. **Describe the marking system to be used** to individually identify all transgenic animals in this project and any resulting offspring.

Part B: Transgenic Plants

Will this project involve the use of transgenic plants? ○ Yes ○ No

5. **Does your work with transgenic plants require a permit?** Refer to the USDA APHIS import/transport permit for information on transgenic plant permit requirements. ○ Yes ○ No

   If the appropriate permit(s) have already been obtained, **please list the applicable permit number(s)** and provide a copy with this submission, otherwise, indicate "pending".

   Permit: **Permit:** **Permit:**

Part C: Recombinant DNA

Will this project involve the use of recombinant DNA? PIs working with recombinant material are required to understand and follow the NIH Guidelines and must determine what sections of the NIH guidelines apply to their work. ○ Yes ○ No

6. **Please specify the relevant guidelines that cover this work** (for example, III-E-1, III-D-1-a, etc.) See the **NIH Guidelines** for more information.

7. Please describe the source(s) of the DNA including the type of organism, species, strain, cultivar/cell line.

8. **Please list genes to be cloned and describe the nature of the inserted DNA sequences**, including regulatory or coding region, entire genome, synthetic antisense sequences, etc. If specific genes have yet to be identified, please provide a description of the types of genes to be used. Once identified, specific genes must be provided as an addendum *via* a protocol modification request.

9. **Please describe the recipient organism(s) for the DNA.** Specify the type of organism, species, strain, cultivar/cell line, origin, animal, plant, etc**.**

10. **List vectors to be used**, such as expression vectors, and briefly specify which genes will be cloned into which vector(s) for introduction of foreign DNA/RNA into the host. Provide vector maps with this submission.

11. **Will there be a deliberate attempt to express a foreign gene?** If yes, describe how expression of the inserted DNA sequences will result in differences from the nonmodified parental organism (for example, morphological or structural characteristics, physiological activities and processes, growth characteristics). Indicate possible toxicity or other hazards, if any. ○ **Yes** ○ **No**

12. **Will the work involve the importation, movement, and/or field release of genetically engineered (GE) plants, insects, microorganisms**, and another organism that is known to, or could, be a plant pest? ○ **Yes** ○ **No**

Does this work require a USDA-APHIS permit? See APHIS eFile for more information. ○ **Yes** ○ **No**

If the appropriate permit(s) have already been obtained, please list the applicable permit number(s) and provide a copy with this submission, otherwise, indicate "pending".

Permit: **Permit:** **Permit:**

Part D: Infectious Agent and Biological Toxins Use

Will this project involve infectious agents (human pathogens, animal pathogens, plant pathogens) or biological toxins? ○ Yes ○ No

13. **Please list all infectious agents and biological toxins,** including genus, species, and any additional subclassifications which may help in determining the biosafety level of the agent. Indicate **yes** or **no** for each hazard category (humans, animals, and plants).

Infectious Agent or Biological Toxin	Human Hazard		Animal Hazard		Plant Hazard	
	Yes	No	Yes	No	Yes	No
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
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	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
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	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○

14. **Will the work involve a human pathogen or human material that originated outside the United States?** ○ Yes ○ No

Does this work require a CDC permit? See the CDC Import Permit website for more information. ○ Yes ○ No

If the appropriate permit(s) have already been obtained, please list the applicable permit number(s) and provide a copy with this submission, otherwise, indicate "pending".

Permit: _____ **Permit:** _____ **Permit:** _____

15. For every agent listed as human hazard or animal hazard, please describe symptoms, severity of disease, and mode of transmission in **laboratory or animal workers.** Include descriptions of any procedures in the lab/animal room which could result in a potential exposure.

16. **If you will be using a human infectious agent or biological toxin, is a vaccine available?** If a vaccine is available, all potentially exposed personnel must be informed of the potential hazards and benefits and offered the option of receiving the vaccine. ○ Yes ○ No

Please list each vaccine and confirm whether it will be offered to potentially exposed personnel.

Name of vaccination	Will this vaccination be offered to potentially exposed personnel?	
	Yes	No
	○	○
	○	○
	○	○
	○	○

17. **Are any of the agents or toxins listed above Select Agents or Toxins?** ○ Yes ○ No

18. **Will the work involve an animal or plant pathogen that originated outside of Georgia or the United States?** ○ Yes ○ No

Does this work require a USDA-APHIS permit? See the USDA APHIS import/transport permit website for more information. ○ Yes ○ No

If the appropriate permit(s) have already been obtained, please list the applicable permit number(s) and provide a copy with this submission, otherwise, indicate "pending".

Permit: _____ **Permit:** _____ **Permit:** _____

Part E: Non-Infectious Agent Use

Will this project involve: non-infectious agents? For example, lab strains such as *E. coli* K-12, *E. coli* BL21, vaccine strains, lentivirus/adenovirus vector systems, etc. ○ Yes ○ No

19. Please list any non-infectious (risk group 1) **lab strains or non-lentiviral vector systems or agents** you are using for this project.

20. Please list any **lentiviral vector systems** you are using and indicate what generation they are.

Lentiviral vector system name	1st generation	2nd generation	3rd generation	4th generation
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○

21. Please list any **vaccine strains** you are using.

Part F: Biological Safety Levels

22. **For recombinant DNA and/or transgenic animals,** refer to the NIH Guidelines for research involving recombinant DNA molecules. **Please indicate proposed biosafety containment level(s) to be used for recombinant work in this project.**

rDNA Biosafety Level 1 (BL1)
rDNA Biosafety Level 2 (BL2)
rDNA Biosafety Level 3 (BL3)

rDNA Animal Biosafety Level 1 (BL1-N)
rDNA Animal Biosafety Level 2 (BL2-N)
rDNA Animal Biosafety Level 3 (BL3-N)

rDNA Large Scale Biosafety Level 1 (BL1-LS)
rDNA Large Scale Biosafety Level 2 (BL2-LS)
rDNA Large Scale Biosafety Level 3 (BL3-LS)

rDNA Plant Biosafety Level 1 (BL1-P)
rDNA Plant Biosafety Level 2 (BL2-P)
rDNA Plant Biosafety Level 3 (BL3-P)

For risk group 1, risk group 2, or risk group 3 organisms, refer to the CDC publication Biosafety in Microbiological and Biomedical Laboratories and A Practical Guide to Plant Containment. Please indicate proposed biosafety containment level(s) to be used in this project.

Biosafety Level 1 (BSL-1)
Biosafety Level 2 (BSL-2)
Biosafety Level 3 (BSL-3)

Animal Biosafety Level 1 (ABSL-1)
Animal Biosafety Level 2 (ABSL-2)
Animal Biosafety Level 3 (ABSL-3)
Agricultural Animal Biosafety Level 3 (ABSL-3Ag)

Plant Biosafety Level 1 (BSL-1P)
Plant Biosafety Level 2 (BSL-2P)
Plant Biosafety Level 3 (BSL-3P)

23. Please check beside any BSL-1, BSL-2, or BSL-3 standard procedures you will use for decontamination of biohazardous waste, contaminated equipment, and surfaces.

BSL-1 and BSL-2 standard procedures:

Autoclaving of solid waste: Solid waste is collected in double-biohazard bags placed or a single biohazard bag at least 3 mil thick within a solid-walled, leakproof container. When ~¾ full, the bag is closed for transportation to the autoclave and is labeled with PI name and/or lab room number and a chemical test indicator. The bag is opened in the autoclave room to ensure there is an opening at least 2-3" in diameter and the waste is autoclaved for at least 30 minutes at 121°C. When the run is complete, the chemical test indicator is taped into an established autoclave logbook and the results are recorded. If the chemical test indicator passed, the waste is disposed of in black bags which are tightly tied and brought to the dumpster. Autoclave logs are kept for a minimum of 3 years.

Chemical decontamination of reusable labware: All liquid or solid waste is removed from the labware and decontaminated appropriately. The labware is then decontaminated by completely submerging it in 10% bleach (prepared fresh daily from at least 5.25% sodium hypochlorite) for at least 20 minutes prior to washing.

Surface/contaminated equipment decontamination: Surfaces are sprayed down with 70% ethanol and allowed to sit for a contact time of at least 2-3 minutes. A disposable paper towel will be used to wipe the surface down, after which the paper towel will be placed directly into the biohazard bin.

Liquid waste decontamination: Liquid waste is treated by adding bleach (at least 5.25% sodium hypochlorite) to the waste to reach a final concentration of 10% and allowing for a contact time of at least 20 minutes prior to disposal down the drain. All bleach solutions are prepared fresh daily.

BSL-3 standard procedures:

Autoclaving of solid waste: Solid waste is collected in double-biohazard bags placed or a single biohazard bag at least 3 mil thick within a solid-walled, leakproof container. When ~¾ full, the bag is closed tightly for transportation to the autoclave and is labeled with PI name and/or lab room number and a chemical test indicator. The bag is opened in the autoclave room to ensure there is an opening at least 2-3" in diameter and the waste is autoclaved for at least 90 minutes at 121°C. When the run is complete, the chemical test indicator is taped into an established autoclave logbook and the results are recorded. If the chemical test indicator passed, the waste is disposed of in black bags which are tightly tied and brought to the dumpster. Autoclave logs are kept for a minimum of 3 years.

24. If using modified standard procedures, please outline the modifications that your lab will use.

25. If working with plants, please outline the decontamination procedures your lab will use.

Decontamination and disposal of seeds, plant material and soil:

Decontamination of greenhouse/growth chamber spaces and surfaces:

26. **If using other procedures, please outline them.**

If using additional chemical disinfectants or any disinfectants that are not listed in the standard procedures above to disinfect waste or surfaces, for each disinfectant please indicate: disinfectant name, each item type being decontaminated with the disinfectant (solid waste, animal waste, carcasses, plants, soil, liquid waste, surface disinfection, contaminated equipment etc.), disinfectant concentration, contact time, and final disposal procedures for the disinfected material (if applicable).

Disinfectant Name	Waste stream type(s) or surface/contaminated equipment	Disinfectant concentration	Disinfectant contact time	Final Disposal

Part G: Training and Procedures for Laboratory Safety

27. **Please specify all personal protective equipment required in addition to lab coats and gloves for work in the BSL-1/BSL-2 laboratory**.

Eye/face/mouth/nose/respiratory protection (specify type):

Other (specify):

28. **Please check beside personal protective equipment required for work in the BSL-3 laboratory.** If your lab is not doing any BSL-3 work, please skip this question.

Eye/face/mouth/nose/respiratory protection (specify type):

Outer gown Double gloves (specify how the first layer is secured):

Booties Room-dedicated scrubs and socks Tyvek Suit

Other (specify):

29. **Please list any special precautions, in addition to the personal protective equipment and the regulatory guideline requirements that may be employed in the laboratory for safety**, i.e. sharps policy; enrollment in Occupational Health Program; hand washing policy; incident response and reporting procedures; transportation of biohazard waste to the autoclave room; training requirements; vaccination requirements, Lentivirus post exposure plan, Agent Specific training form, etc.

30. **For each individual listed on this protocol, please indicate the date the following training was completed. If the training is not applicable, please enter "N/A".** Proficiency documentation is required for individuals (other than the PI and Co-PI) working in any microbiological lab. In addition, bloodborne pathogen training (UGA Right to Know: Bloodborne Pathogens Training available on PEP) is required for all individuals working with human-derived materials or non-human primate-derived materials. Personnel names will automatically populate to reflect the key personnel table.

Name	Proficiency documentation submitted?		Date of Bloodborne Pathogen Training (if required)
	Yes	No	
PI:			
Co-PI:			
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
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	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	
	○	○	

Part H: Study Location Information

31. Please list the location(s) where the project will be carried out. Include all laboratory and animal facilities as well as insectaries, core facilities, shared lab spaces, field locations, growth chambers, and greenhouses.

Building/Location Name	Room number(s)	Facility type

32. List location of each Biological Safety Cabinet(s) (BSC) and the most recent certification date(s). Please enter "failed" if the equipment did not pass certification testing.

Building name	Room number with BSC	Certification date

33. List location of each autoclave.

Building name	Room number(s) with autoclave

34. List location(s) of O-ring sealed centrifuge(s) and other aerosol-generating equipment. Indicate the frequency that O-ring seals are checked and replaced.

35. List location(s) of other containment equipment, including any BioBubbles and anaerobic chambers.

Part I: Shipping and Transportation

36. Please read and check beside every shipping and transportation requirement below.

Transporting biological materials via UGA-owned roads: Materials will be contained to prevent a release. Secondary and tertiary containers will be utilized and labeled with the biohazard symbol and the identity of the material inside. **If a vehicle is used, it will be a state vehicle.**

Transporting biological materials via a vehicle on public roadways: will follow DOT regulations for packaging and shipping dangerous goods, including filling out a shipper's declaration as applicable. An intracampus transport form will be completed for each intra-campus transportation. All individuals transporting biological material will be trained on applicable DOT regulations. Training is available through the Office of Biosafety. **Only state vehicles will be used for these transports**.

As applicable, transporting materials subject to a CDC or USDA permit or the Select Agent Program: will be performed only in accordance with the permit conditions or Select Agent Regulations.

Shipping of biological materials: will be in accordance with DOT, 49 CFR, and the IATA Hazardous Materials regulations. All dangerous goods, including biohazardous agents and dry ice, under DOT/IATA regulations, will be properly classified, packaged, documented and handled by trained personnel. Training is available through the Office of Biosafety.

For more information on Shipping and Transportation Requirements, please refer to the Institutional Biosafety Manual.

37. I understand and agree to the Shipping and Transportation Requirements outlined above and as outlined in the Institutional Biosafety Manual. ○ **Yes** ○ **No**

Part J: Projects involving animal studies

38. Does this project involve animals? ○ **Yes** ○ **No**

Please list the AUP numbers for all animal projects associated with this research.

What species of animals will be used?

At the end of the project, the animals will be:

Euthanized
Transferred to another project
Other (specify):

Please specify the final disposal method for carcasses (such as incineration or KOH treatment). As applicable, include information on decontamination cycle parameters.

39. **Please specify if or how inoculated animal species will shed the infectious agent or toxin.**

40. **Please check all personal protective equipment required in ABSL-1 and ABSL-2 animal facilities:**

Eye/face/mouth/nose/respiratory protection (specify type):

Boots/shoe covers Coveralls/lab coat

Rain suit Gloves

Other (specify):

41. **Please check all personal protective equipment required in ABSL-3 or ABSL-3Ag animal facilities:**

Eye/face/mouth/nose/respiratory protection (specify type):

Facility dedicated scrubs/socks Impervious outer gown

Facility dedicated footwear Shoe/boot covers

Double gloves (specify how first layer is secured):

Other (specify):

42. **Please describe any special precautions to be used in the animal facility (e.g., shower in/out).**
For ABSL-2 and higher animal studies, indicate that a pre-study meeting will be conducted so that animal resources staff will be familiar with the work being performed and what hazards may be present.

For questions or more information, contact:

UGA Office of Biosafety
310 East Campus Road, Room 217
Athens, GA 30606
Phone: 706-542-2967
E-mail: ibc@uga.edu
Fax: 706-583-8104

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