DURC-PEPP RESEARCH DECLARATION FORM

(A separate form must be completed for each ongoing grant)

The United States Government Policy (USG) for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) is going into effect on May 6th, 2025. The purpose of this form is investigators must report ongoing research that may fall under the scope of this policy. Declaration is for ongoing work (not part of a grant application or progress report, which are reported on the grant forms directly).

Please complete the following fields to help Biosafety and the IRE to properly document and assess the nature of the work. Send to: biosafety@uab.edu

Contact Information	
Name of Principal Investigator	
Department	
Laboratory Location	
Phone Number; Email	
UAB IBC Project Reg. No.	

Funding Information	
Funding Agency	
Title of the Grant	
Start Date of Funding	
Duration of Grant	

CATEGORY 1 RESEARCH: Dual Use Research of Concern (DURC)

Answer questions 1-3 for ANY of the microbial agents (RG3, Select Agents or Select Toxins) you are currently working with

1. My work involves one or more of the following agent categories:

☐Yes ☐No	A. Biological Select Agents and Toxins[#] Listed by the Federal Select Agent Program
☐Yes ☐No	B. Any Risk Group 3 (RG-3) pathogens listed in Appendix B of the NIH Guidelines **except** the following: HIV (Human Immunodeficiency Virus); HTLV (Human T-cell Lymphotropic Virus); SIV (Simian Immunodeficiency Virus); Mtb (including mycobacterium bovis);Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors; Vesicular stomatitis virus; Coccidioides immitis; Coccidioides Posadasii; Histoplasma capsulatum; Histoplasma capsulatum var. duboisii
☐Yes ☐No	C. Biological agents affecting humans that have not been assigned a risk group in NIH guidelines but are recommended to be handled at Biosafety Level 3 (BSL-3) per the BMBL guidance. *Examples: Newly emerging pathogen or chimeric agent etc.*

Name of the Microbial Agent/Toxin:
Category 1 oversight considers the anticipated experimental outcomes, regardless of the amount of toxin involved. Note: RG-4 pathogens, or those requiring Biosafety Level-4 (BSL-4*) containment are not allowed at UAB.

2. If you selected "yes" to Question #1, is the work associated with the agent(s) expected (or reasonably anticipated[1]) to result in any of the following outcomes (check all that apply)?

☐Yes ☐No	Increase transmissibility of a pathogen within or between host species?
☐Yes ☐No	Increase the virulence of a pathogen or convey virulence to a non-pathogen?
☐Yes ☐No	Increase the toxicity of a known toxin or produce a novel toxin?
☐Yes ☐No	Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin?
☐Yes ☐No	Alter the host range or tropism of a pathogen or toxin?
☐Yes ☐No	Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods?
☐Yes ☐No	Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions?
☐Yes ☐No	Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of pre-existing immunity, via immunization or natural infection, against the pathogen or toxin?
☐Yes ☐No	Enhance the susceptibility of a host population to a pathogen or toxin?

3. If you selected "yes" for #1 and #2 (above), does the research provide, or is reasonably anticipated to provide, knowledge, information, products, or technologies that could be misapplied to do harm with no—or only minor—modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

☐ Yes ☐ No

If you selected Yes to all 3 questions for any agent, *"This work falls under the U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential as Category 1 Research*".

[1] *"Reasonably anticipated" means something that is likely or probable to occur, based on rational judgment and available information. This term is often used in legal or regulatory context to describe events or outcomes that can be logically foreseen or predicted with a reasonable degree of certainty, even if they are not guaranteed.*

4. Briefly explain (1-2 sentences) how the research could lead to DURC. What are the potential outcomes that could arise from these experiments?

Please work with Biosafety and Institutional Review Entity (IRE) to develop a Risk-benefit Assessment and a Risk Mitigation Plan. Work may not continue until UAB's IRE and the funding agency has approved the plan.

CATEGORY 2 RESEARCH: Pathogens with Enhanced Pandemic Potential (PEPP)

Answer questions 5-7 for ANY of the microbial agents you are currently working with

5. My work involves microbial agent/agents as described below

☐ Yes ☐ No	Involves, or is reasonably anticipated to result in, a Pathogen with Pandemic Potential (PPP), the development, use, or transfer of a Pathogen with Enhanced Pandemic Potential (PEPP), or an eradicated or extinct PPP that may pose a significant public health threat.
Name of the Microbial Agent/Toxin:	
Note: Please reach out to biosafety@uab.edu if you need help answering this question.	

6. Work with this/these agents is expected (or reasonably anticipated[2]) to result in any of the following outcomes (check all that apply)

☐ Yes ☐ No	Enhance the transmissibility of the pathogen in humans
☐ Yes ☐ No	Enhance the virulence of the pathogen in humans
☐ Yes ☐ No	Enhance the 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	Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or previously identified pathogen with enhanced pandemic potential

[2] *"Reasonably anticipated" means something that is likely or probable to occur, based on rational judgment and available information. This term is often used in legal or regulatory context to describe events or outcomes that can be logically foreseen or predicted with a reasonable degree of certainty, even if they are not guaranteed.*

7. If you selected "yes" to questions 5 & 6 for any agent, does the research provide, or is reasonably anticipated to provide, knowledge, information, products, or technologies that could be misapplied to do harm with no—or only minor—modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

☐ Yes ☐ No

If selected Yes to above 3 questions, "*This work falls under the U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential as Category 2 Research".*

8. Briefly explain (1-2 sentences) how the research could lead to PEPP/PPP. What are the potential outcomes that could arise from these experiments?

Please work with Biosafety and Institutional Review Entity (IRE) to develop a Risk-benefit Assessment and a Risk Mitigation Plan. A Federal Multidisciplinary Review Entity will notify the funding agency of any recommendations. Work may not begin or continue until notified of approval by the funding agency.

ATTESTATION:

I am familiar with the relevant provisions of the current USG Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and agree to comply with these relevant provisions and all UAB Institutional Policies and Procedures. I understand that I will be responsible to comply with federal, state and local regulations that pertain to all my research and laboratory activities.

I understand that I will need to submit amendments for my approved research if there are any changes or additions to pathogens, vectors, inserts, or hosts. I accept responsibility for providing training to all personnel involved in my laboratory.

Principal Investigator Signature	