RISK MITIGATION PLAN

1. Purpose:

The purpose of risk mitigation plan is to identify, assess, and address potential biohazards associated with research activities that falls under DURC-PEPP policy. This document outlines specific strategies to minimize the likelihood and impact of identified risks, ensuring the safe and responsible conduct of scientific studies.

2. Responsibility

If the research is assessed to be Category 1 or Category 2, Risk Mitigation Plan should be developed by principal Investigator, IRE which provides a framework for maintaining biosafety and biosecurity standards throughout the research lifecycle. The federal funding agency (for Category 1) or federal department (for Category 2) will evaluate the Risk Mitigation Plan prior to the funding decision.

3. Contact Information:

Principle Investigator (PI)	
Name	
Laboratory Address	
Department	
Email	

Authorized Institutional Official (RO for Select Agent or Toxin)	
Name	
Address	
Email	

Institutional Contact for Dual Use Research (ICDUR)	
Name	
Address	
Email	

4. Review and Assessment Dates and Details:

PI's Assessment of The Research	
Initial Review Date and Details	
Ongoing Review Date and Details	

UAB DURC Committee's Assessment of The Research	
Reviews and assessments of the research Date and Details	

5. Information About the Biological Agent and Research:

Provide background information about the biological agents/toxin

Information about Biological Agent/Toxin	
Name of Agent/Toxin	
Risk group	☐ RG-2 ☐ RG-3
Category	☐ Category 1 ☐ Category 2
Host Range	
Mode of Transmission	
Biosafety Level Assigned	☐ BSL-1 ☐ BSL-2 ☐ BSL-3

Title of the grant	
Aim of the study	
Brief description of experimental design	

6. Experimental Outcomes:

Select the appropriate experimental outcomes that can be reasonably anticipated to occur as a consequence of the proposed experimental design.

Research within the scope of **Category 1** are those experimental outcomes with a biological agent or toxin that are reasonably anticipated to:	
☐	Increase transmissibility of a pathogen within or between host species
☐	Increase the virulence of a pathogen or convey virulence to a non-pathogen
☐	Increase the toxicity of a known toxin or produce a novel toxin
☐	Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin
☐	Alter the host range or tropism of a pathogen or toxin

☐	Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
☐	Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions
☐	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
☐	Enhance the susceptibility of a host population to a pathogen or toxin

Research within the scope of **Category 2** are those experimental outcomes or actions with a pathogen that are reasonably anticipated to:	
☐	Enhance transmissibility of the pathogen in humans
☐	Enhance the virulence of the pathogen in humans
☐	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
☐	Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

Brief description of experimental outcome:

7. Risks Identified:

Details of the risks identified by the UAB DURC committee, IRE following review and explanation of the risk mitigation strategies that will be implemented by the Principal Investigator to address those risks

Risks Identified	Risk Mitigation Strategies

8. Risk Mitigation Measures:

The researchers are required by the terms and conditions of the grant or contract to adhere to the following

Yes/No	Menu of Risk Mitigation Measures that May Be Applicable to Your Research
☐ ☐	The research is being conducted in compliance with the select agent regulations (42 CFR part 73, 9 CFR part 121) biosafety and biosecurity requirements.
☐ ☐	Well-established biosafety and containment practices and procedures in the NIH Guidelines and BMBL.
☐ ☐	Biosafety aspects of the research be reviewed and approved by an Institutional Biosafety Committee as per NIH Guidelines.
☐ ☐	Conduct the research at the appropriate Biosafety level.
☐ ☐	The research has been reviewed for its Category 1 or Category 2 potential by an appropriately constituted IRE.
☐ ☐	Undergo training in the safe conduct of research with the biological agent(s) or toxin(s) in question.
☐ ☐	Undergo training in the responsible conduct of research and/or research ethics as required by the institution and federal guidelines.
☐ ☐	Enrolled in an occupational health surveillance program, when appropriate.
☐ ☐	Designated management plan for the full life-cycle a biological agent(s) or toxin(s) generated from the research; from time of creation, appropriate inventory and access controls, tracking (if transferred to or shared with third parties), and ultimate safe destruction.

9. Supporting Document:

Other materials, such as proposals and progress reports related to the research, that may be requested by the federal government.

1	
2	
3	
4	
5	

10. Containment Controls:

Administrative: (Improving safety through the implementation of policies, practices, and procedures)	
Engineering: (Protect workers by placing a barrier between the worker and the biohazard)	
Workplace: (Safe practices are procedures in laboratory to reduce the potential risks while handling biohazard)	
PPE: (Specialized clothing worn by worker to minimize exposure to biohazards)	

11. Lab Personnel:

	Name of The Person	Training Date
1		
2		
3		
4		
5		

12. Incident Reporting:

Every individual handling biological agents/toxins has the responsibility to report any exposures to their supervisor and the PI/Manager. Employee must get first aid immediately following exposure and report the incident to "The Needlestick and Exposure Team" at **205-934-3411**.

The Employee/Supervisor is responsible for reporting the incident to UAB Employee Health (ehocchealth@uab.edu) and EH&S Biosafety (biosafety@uab.edu). Employee Health team will communicate with employee and take care of necessary medical treatment and follow up. Biosafety team will investigate the circumstances surrounding the exposure, and work with the Employee/Supervisor to modify work practices and/or develop additional prevention strategies. UAB Human Resources On-the-Job Injury and Illness (OJI) Program houses instructions and forms.