Institutional Biosafety Committee

**DURC & PEPP Progress Report**

Please return this form, completed, and signed before      . Your reporting period is for       to      .

1. **General Information**

**Principal Investigator:**

**Date Completed:**

**Protocol #:**

**Protocol Title:**

**Select what applies: Category 1**       **Category 2**       **DURC**

If federally funded, please provide:

**Sponsor Name**:

**Federal Award Number**:

1. **Summary of Project**

**Summary of Project**:

Please provide a brief summary of this project’s progress within the most recent reporting period.

**Summary of Unexpected or Adverse Events**:

If applicable, please provide a brief summary of any unexpected or adverse events compromising biosafety that have occurred during the most recent reporting period.

1. **Intent for Project**

Based on the information provided above, please select how you intend to proceed with this project:

      **Delete protocol**. This project has ended, and no further work will be done.

**Renew this protocol** **with revisions** using the attached protocol modification

request. Changes must be approved prior to implementing.

      **Renew this protocol with no changes**. It is still active and will be used with **no**

revisions.

Institutional Biosafety Committee

**Self-Audit of Approved DURC & PEPP Project\***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Y | N | n/a | Complete all sections that apply or mark as not applicable (n/a): |
|  |  |  |  | **Category 1** |
|  | Y | N | n/a | **Are the Category 1 types of pathogens in scope anticipated to remain the same from your originally approved protocol, or within your most recent reporting period?** |
| 1. |       |       |       | * All Biological Select Agents & Toxins in 9 CFR 121.3-121.4, 42 CFR 73.3-73.4, and 7 CFR 331.3 and regulated by USDA and/or HHS?
 |
| 2. |       |       |       | * All Risk Group 4 pathogens in Appendix B of the NIH Guidelines 1?
 |
| 3. |       |       |       | * A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines1?
 |
| 4. |       |       |       | * For biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines, agents affecting humans that are recommended to be handled at BSL3 or BSL4 per the BMBL2 (Section VIII)?
 |
| 5. |       |       |       | * Are another listed pathogen or toxin per the NIH Implementation Guidance, Appendix C. If other, please list:
 |
|  | Y | N | n/a | **Are the Category 1 experimental outcomes or actions with a pathogen reasonably anticipated to remain the same from your originally approved protocol, or within your most recent reporting period?** |
| 6. |       |       |       | * Increase transmissibility of a pathogen within or between host species?
 |
| 7. |       |       |       | * Increase the virulence of a pathogen or convey virulence to a non-pathogen?
 |
| 8. |       |       |       | * Increase the toxicity of a known toxin or produce a novel toxin?
 |
| 9. |       |       |       | * Increase the stability of a pathogen in the environment or increase the ability to disseminate a pathogen or toxin?
 |
| 10. |       |       |       | * Alter the host range or tropism of a pathogen or toxin?
 |
| 11. |       |       |       | * Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods?
 |
| 12. |       |       |       | * Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions?
 |
| 13. |       |       |       | * Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin?
 |
| 14. |       |       |       | * Enhance the susceptibility of a host population to a pathogen or toxin?
 |
|  |  |  |  | **Category 2** |
|  | Y | N | n/a | **Are the Category 2 types of pathogens in scope anticipated to remain the same from your originally approved protocol, or within your most recent reporting period?** |
| 15. |       |       |       | * Any pathogen modified in such a way that is reasonably anticipated to result in the development, use, or transfer of a PEPP. Includes development of new PPPs from non-PPPs as well as the enhancement of existing PPPs?
 |
| 16. |       |       |       | * Eradicated or extinct PPPs that may pose significant threat to public health, the capacity of health systems to function, or national security?
 |
|  | Y | N | n/a | **Are the Category 2 experimental outcomes or actions with a pathogen reasonably anticipated to remain the same from your originally approved protocol, or within your most recent reporting period?** |
| 17. |       |       |       | * Enhance transmissibility of the pathogen in humans?
 |
| 18. |       |       |       | * Enhance the virulence of the pathogen in humans?
 |
| 19. |       |       |       | * 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?
 |
| 20. |       |       |       | * Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP?
 |
|  |  |  |  | **DURC** |
|  | Y | N | n/a | **Project outcomes are still 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 the following:** |
| 21. |       |       |       | * Public health and safety?
 |
| 22. |       |       |       | * Agricultural crops and other plants?
 |
| 23. |       |       |       | * Animals?
 |
| 24. |       |       |       | * The environment?
 |
| 25. |       |       |       | * Material?
 |
| 26. |       |       |       | * National safety?
 |

\*Checklist developed based on the US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and corresponding NIH Implementation Guidance, Appendix C.

**PI Assurance**: I certify that the information contained in this IBC protocol review and self-audit is accurate and complete. I am familiar with and agree to abide by the current editions of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules; CDC Biosafety in Microbiological and Biomedical Laboratories; US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential; and the University of Wisconsin-La Crosse (UWL) Biosafety Manual.

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Signature of Principal Investigator Date

Please return completed documents **electronically** in Word format to: grants@uwlax.edu

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| *For IBC Use Only****:*****Institutional Biosafety Committee (IBC) Assurance***: The IBC certifies that this project is in compliance with the current editions of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules; CDC Biosafety in Microbiological and Biomedical Laboratories; US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential; and the University of Wisconsin-La Crosse (UWL) Biosafety Manual.* |

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Signature of IBC Chair or IBC Coordinator Date