Institutional Biosafety Committee

**DURC & PEPP Inclusion Form for New Protocols**

Please complete this additional form if you are intending to include any Dual Use of Research Concern (DURC) and/or Pathogens with Enhanced Pandemic Potential (PEPP) substances in your new biosafety protocol.

1. **General Information**

**Principal Investigator:**

**Date Completed:**

**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 how the DURC and/or PEPP substances will be used on this project.

1. **Certification: Unexpected or Adverse Events**

Please certify that you will intend to report any unexpected or adverse events compromising biosafety that may occur during your new project per 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.

[ ]  **Yes, I certify that as the Project Investigator, I will report any unexpected or adverse events that compromise the biosafety of my project per 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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**Intention for DURC & PEPP Substances on Project**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Y | N | n/a | Complete all sections that apply or mark as not applicable (n/a): |
|  |  |  |  | **Category 1** |
|  | Y | N | n/a | **Select which Category 1 types of pathogens in scope are reasonably anticipated to be in your new protocol:** |
| 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 | **Select which Category 1 experimental outcomes or actions with a pathogen are reasonably anticipated to be in your new protocol:** |
| 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 | **Select which Category 2 types of pathogens in scope are anticipated to be in your new protocol:**  |
| 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 | **Select which Category 2 experimental outcomes or actions with a pathogen are reasonably expected to be anticipated in your new protocol:** |
| 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 | **Select which project outcomes are 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 here is accurate and complete regarding the intent of this project. I am also 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