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| Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) ApplicationIt is the policy of the U.S. Government that federally funded intramural or extramural research that meets the scope of Category 1 or Category 2 research within this policy is subject to federal and institutional oversight. The purpose of this oversight is to preserve the benefits of such research while minimizing the biosafety and biosecurity risks, including risks that the knowledge, information, products, or technologies generated by the research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security. The full policy is linked below.  |
| 1. Complete the [online DURC-PEPP Training](https://www.ehs.washington.edu/training/durc-pepp-training-online).
 |
| 1. Complete all questions in this application as they apply to your research that may be within the scope of the DURC-PEPP policy. Answer all questions and provide descriptions even if answered “no.” Fields will expand as needed.
 |
| 1. Submit completed application and any supplemental documents to EH&S Biosafety at ehsbio@uw.edu.
 |
| 1. Helpful resources for completing this application:
 |
| * + [EH&S DURC-PEPP webpage](https://www.ehs.washington.edu/biological/biological-research-approval/durc-pepp)
	+ [Self-Assessment Worksheet for DURC-PEPP](https://www.ehs.washington.edu/system/files/resources/assess-durc-pepp.docx)
	+ [DURC Biological Agents and Toxins List](https://www.ehs.washington.edu/system/files/resources/durc-agents-toxins.pdf)
	+ [USG Policy for Oversight of DURC-PEPP](https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf)
	+ [FAQs for DURC-PEPP Policy](https://aspr.hhs.gov/S3/Pages/DURC-and-PEPP-FAQ.aspx)
 | * + [NIH Implementation of DURC-PEPP Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-061.html)
	+ [NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)
	+ [Select Agents and Toxins List](https://www.selectagents.gov/sat/list.htm)
	+ [Biosafety in Microbiological and Biomedical Laboratories (BMBL)](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf)
 |
| **EH&S Biological Safety ·** **ehsbio@uw.edu** **· Box 354990 · 206-221-7770**  |

**General Project Information**

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| **Date Submitted**       | **Project Title**      [ ]  Check here if the title has changed | **Anticipated start date:**       |
| **Application Type**[ ]  New [ ]  Update[ ]  Ongoing assessment | **Biological** [**Use Authorization (BUA) Number**](https://www.ehs.washington.edu/biological/biological-research-approval)Provide only if applicable to the project described in this application    -    | [**IACUC Protocol Number**](https://www.ehs.washington.edu/biological/biological-research-approval/biological-use-authorization-bua-application-faqs#GP3)Provide only if applicable to the project described in this application    -   |
|  | **Name** | **Daytime Phone** | **Preferred Email** | **UW NetID** | **Advanced Degree(s)** | **Position** **or Title** |
| **Principal Investigator** |       |       |       |       |       |       |
| **Lab Contact** if applicable |       |       |       |       |       |       |
| **PI’s Emergency Contact Number:**      Provide a PI’s phone number other than office number to be used in case of emergencies. |
| **Department**       | **Division** if applicable       | **Box Number**       |

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| **Assessment Context** |
| 1. Did a federal funding agency request that you obtain an IRE assessment for your research?

[ ]  Yes [ ]  No |
| 1. What prompted you to apply for this IRE assessment?
 |
| [ ]  Required by funding agency after self-assessing research to be potentially within the policy scope[ ]  Required by funding agency for an existing grant[ ]  Required for grant application materials[ ]  Other:       |
| **Funding Source(s)** |
|  | **eGC1 number** | **Funding Agency** | **Grant/Contract** **Number or Identifier** | **Funding Agency** **Point of Contact** |
|  |       |       |       |       |
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| **Research Description**In language that scientific colleagues outside of your discipline would understand, please provide a narrative answer to the questions below. Describe your research only as it relates to the biological agents and toxins involved in the research specific to this assessment. |
| 1. Describe the goals or aims of your research.
 |
| 1. Describe the experimental manipulations you will perform.
 |
| 1. Describe the anticipated outcome of your research.
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| **Category 2 Research Assessment**Questions 7-9 are used to assess research for Category 2 or Pathogen with Enhanced Pandemic Potential (PEPP). Answer all questions and explain your answer even if answered “no.” Use a new or completed [Self-Assessment Worksheet for DURC-PEPP](https://www.ehs.washington.edu/system/files/resources/assess-durc-pepp.docx) for more detailed assessment descriptions. |
| 1. Does your research involve a pathogen with pandemic potential (PPP) or is it reasonably anticipated to result in a PPP? A PPP is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.
 |
|  |  | Yes | No |  |
|  |  | [ ]  | [ ]  | 1. Modifying any pathogen to result in a PPP? Explain:
 |
|  |  | [ ]  | [ ]  | 1. Use of an existing PPP: SARS-CoV, SARS-CoV-2, or Ebolaviruses? Explain:
 |
|  |  | [ ]  | [ ]  | 1. Generation, use, reconstitution, or transfer or an extinct/eradicated PPP: Variola major, Variola minor, and 1918 influenza virus? Explain:
 |
| *If no, skip to Question 10.* |
| 1. Is the PPP involved being modified in such a way that is reasonably anticipated to result in any of the following experimental outcomes:
 |
|  |  | Yes | No |  |
|  |  | [ ]  | [ ]  | 1. Enhance transmissibility of the pathogen in humans? Explain:
 |
|  |  | [ ]  | [ ]  | 1. Enhance the virulence of the pathogen in humans? Explain:
 |
|  |  | [ ]  | [ ]  | 1. 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? Explain:
 |
| 1. Do you believe that this research is reasonably anticipated to result in the development, use, or transfer for a PEPP or an eradicated or extinct PPP that may post a significant threat to public health, the capacity of health system to function, or national security?
 |
| Yes | No |  |
|[ ] [ ]  Explain:       |

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| **Category 1 Research Assessment**Questions 10-12 are used to assess research for Category 1 or Dual Use Research of Concern (DURC). Answer all questions and explain answers even if answered “no.” Use a new or completed [Self-Assessment Worksheet for DURC-PEPP](https://www.ehs.washington.edu/system/files/resources/assess-durc-pepp.docx) for more detailed assessment descriptions. |
| 1. Does your research involve any of the biological agents or toxins within the policy scope?
	* Select agents and toxins, including toxins in any amount
	* Risk Group 4 and a subset of Risk Group 3 pathogens per the NIH Guidelines
	* Any biological agent affecting humans recommended to be handled at BSL-3 or BSL-4 per Biosafety in Microbiological and Biomedical Laboratories (BMBL)

Use the [list](#list) at the end of the application to select from a list of all agents and toxins within the policy scope and indicate here if any are used in your research. Review the [excluded Risk Group 3 agents](#excludedlist). |
| Yes | No |  |
| [ ]  | [ ]  | Explain:       |
| 1. Is your research anticipated to result, or does it result, in any of the following experimental outcomes:
 |
| Yes | No |  |
| [ ]  | [ ]  | 1. Increase transmissibility of a pathogen within or between host species?

Explain:       |
| [ ]  | [ ]  | 1. Increase the virulence of a pathogen or convey virulence to a non-pathogen? Explain:
 |
| [ ]  | [ ]  | 1. Increase the toxicity of a known toxin or produce a novel toxin? Explain:
 |
| [ ]  | [ ]  | 1. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin? Explain:
 |
| [ ]  | [ ]  | 1. Alter the host range or tropism of a pathogen or toxin? Explain:
 |
| [ ]  | [ ]  | 1. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods? Explain:
 |
| [ ]  | [ ]  | 1. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions? Explain:
 |
| [ ]  | [ ]  | 1. 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? Explain:
 |
| [ ]  | [ ]  | 1. Enhance the susceptibility of a host population to a pathogen or toxin?

Explain:       |
| 1. Do you believe that this research can be reasonably anticipated to provide, or does 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 |  |  |  |
| [ ]  | [ ]  | Explain:       |

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| **DURC-PEPP Training Records**The Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Policy requires that the principal investigator and any laboratory personnel conducting research within the scope of the policy receive education and training on the responsibilities and requirements of the policy. List the names of all laboratory personnel involved in this project and the date that the 2025 DURC-PEPP Policy training was completed. You can look up training record reports on the EH&S website at [Track Training Progress](https://www.ehs.washington.edu/track-training-progress). |
| **14**. | **Name** | **Title/Role** | **UW Net ID** | **Completion Dates** |
|  |       |       |       |       |
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| Principal Investigator Acknowledgment of Responsibility**As Principal Investigator (PI) for this project, I am aware of the PI responsibilities per the DURC-PEPP policy:**1. Be knowledgeable about and comply with all applicable institutional and U.S. government policies, requirements, and regulation for the oversight of biological agent and toxin research.
2. Assess my research at the proposal stage and continuously throughout the research lifecycle for the potential of Category 1 or Category 2 research.
3. Notify the federal funding agency, research institution, and IRE upon identifying potential Category 1 or Category 2 research.
4. If research is assessed to be Category 1 and/or 2:
	1. Work with the IRE to develop and submit a risk-benefit assessment and draft risk mitigation plan to the funding agency.
	2. Conduct Category 1 or Category 2 research in accordance with the provisions identified in the risk mitigation plan approved by the IRE and funding agency.
	3. Provide research progress reports to the funding agency annually for Category 1 research, semiannually for Category 2 research, and as requested.
	4. Communicate Category 1 or Category 2 research in a responsible manner. The communication of research and research findings is an essential activity for all researchers. It occurs throughout the research process, not only at the point of publication. Researchers planning to communicate Category 1 or Category 2 research should do so in compliance with the approved risk mitigation plan.
5. Ensure laboratory personnel under the supervision of laboratory leadership have received and maintain education and training on all research oversight policies and processes and demonstrated competency.
* **To the best of my knowledge, the information reported on this form is correct and accurately reflects my proposed or current research.**
* **I will notify the UW IRE if the scope of my research changes or if I plan to initiate research that may be subject to the DURC-PEPP policy.**
* **I have completed the required DURC-PEPP online training course and will ensure that any laboratory personnel working on this project also complete the training course.**

     Principal Investigator Name (printed or typed)           Principal Investigator Signature/Electronic Signature Date |
| Submit completed application and any supplemental documents to EH&S Biosafety at ehsbio@uw.edu.**EH&S Biosafety ·** **ehsbio@uw.edu** **· Box 354990 · 206-221-7770** |

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| **Appendix: Biological Agents and Toxins with Scope of Category 1 (DURC)**Select any biological agents and/or toxins that are used as part of your research. Then indicate yes or no for each group in Question 10 in the application. [Return to Question 10](#Q10) |
| **Toxins** |
| [ ]  | Abrin |
| [ ]  | Botulinum neurotoxins |
| [ ]  | Conotoxins (Short, paralytic alpha conotoxins containing the amino acid sequence X1CCX2PACGX3X4X5X6CX7) |
| [ ]  | Diacetoxyscirpenol |
| [ ]  | Ricin |
| [ ]  | Saxitoxin |
| [ ]  | Staphylococcal enterotoxins (subtypes A,B,C,D,E) |
| [ ]  | T-2 toxin |
| [ ]  | Tetrodotoxin |
| **Bacteria and Rickettsia** |
| [ ]  | Bacillus anthracis |
| [ ]  | Bacillus anthracis Pasteur strain |
| [ ]  | Bacillus cereus Biovar anthracis |
| [ ]  | Bartonella |
| [ ]  | Botulinum neurotoxin producing species of Clostridium |
| [ ]  | Brucella including B. abortus, B. canis, B. suis |
| [ ]  | Burkholderia mallei |
| [ ]  | Burkholderia pseudomallei |
| [ ]  | Coxiella burnetti (except the Phase II, Nine Mile strain listed as Risk Group 2) |
| [ ]  | Francisella tularensis (except strains listed as Risk Group 2) |
| [ ]  | Mycoplasma capricolum |
| [ ]  | Mycoplasma mycoides |
| [ ]  | Orientia tsutsugamushi (formerly R. tsutsugamushi) |
| [ ]  | Pasteurella multocida type B – “buffalo” and other virulent strains |
| [ ]  | Ralstonia solanacearum |
| [ ]  | Rathayibacter toxicus |
| [ ]  | Rickettsia species: akari, australis, canada, conorii, prowazekii, rickettsii, siberica, typhi (mooseri) |
| [ ]  | Rickettsia prowazekii |
| [ ]  | Xanthomonas oryzae |
| [ ]  | Yersinia pestis (except strains listed as Risk Group 2) |
| [ ]  | Any other bacteria or rickettsia recommended to be handled at BSL-3 or BSL-4 per [Biosafety in Microbiological and Biomedical Laboratories (BMBL)](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf) |
| **Viruses** |
| [ ]  | African swine fever virus |
| [ ]  | Avian influenza virus |
| [ ]  | Chapare virus |
| [ ]  | Chikungunya virus (except the vaccine strain 181/25 listed as Risk Group 2) |
| [ ]  | Classical swine fever virus |
| [ ]  | Crimean-Congo hemorrhagic fever virus |
| [ ]  | Eastern equine encephalitis virus |
| [ ]  | Ebolaviruses |
| [ ]  | Far Eastern subtype tick-borne encephalitis virus |
| [ ]  | Flexal |
| [ ]  | Foot-and-mouth disease virus |
| [ ]  | Goat pox virus |
| [ ]  | Guanarito virus |
| [ ]  | Hantaviruses including Hantaan virus |
| [ ]  | Hemorrhagic fever viruses as yet undefined |
| [ ]  | Hendra virus (or Equine Morbillivirus) |
| [ ]  | Herpesvirus simiae (Herpes B or Monkey B virus) |
| [ ]  | Influenza viruses:* 1918-1919 H1N1 (1918 H1N1)
* Reconstructed 1918 influenza virus (Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments)
* Human H2N2 (1957-1968)
* Avian influenza virus
* Highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage
 |
| [ ]  | Japanese encephalitis virus (except strains listed as Risk Group 2) |
| [ ]  | Junin virus (except the candid #1 vaccine strain listed in as Risk Group 2) |
| [ ]  | Lassa virus (or Lassa fever virus) |
| [ ]  | Lujo virus |
| [ ]  | Lumpy skin disease virus |
| [ ]  | Lymphocytic choriomeningitis virus (LCMV) neurotropic strains (except lab-adapted strains) |
| [ ]  | Machupo virus |
| [ ]  | Marburg viruses |
| [ ]  | Middle East respiratory syndrome coronavirus (MERS-CoV) |
| [ ]  | Monkeypox virus (Clade I and Clade II containing nucleic acids coding for clade I MPVX virus virulence factors) |
| [ ]  | Newcastle disease virus |
| [ ]  | Nipah virus |
| [ ]  | Peste des petits ruminants virus |
| [ ]  | Rift Valley fever virus |
| [ ]  | Rinderpest virus |
| [ ]  | Sabia virus |
| [ ]  | SARS-associated coronavirus (SARS-CoV) |
| [ ]  | SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors |
| [ ]  | Semliki Forest virus |
| [ ]  | Sheep pox virus |
| [ ]  | Siberian subtype tick-borne encephalitis virus |
| [ ]  | Swine vesicular disease virus |
| [ ]  | Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses |
| [ ]  | Variola major virus (Smallpox virus) |
| [ ]  | Variola minor virus (Alastrim) |
| [ ]  | Venezuelan equine encephalitis virus (except the vaccine strains TC-83 and V3526) |
| [ ]  | Yellow fever virus |
| [ ]  | Any other virus recommended to be handled at BSL-3 or BSL-4 per [Biosafety in Microbiological and Biomedical Laboratories (BMBL)](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf) |
| **Fungi** |
| [ ]  | Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines) |
| [ ]  | Sclerophthora rayssiae |
| [ ]  | Synchytrium endobioticum |
| [ ]  | Any other fungus recommended to be handled at BSL-3 or BSL-4 per [Biosafety in Microbiological and Biomedical Laboratories (BMBL)](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf) |
| **Prions** |
| [ ]  | Transmissible spongiform encephalopathies (TSE) agents (Creutzfeldt-Jacob disease and kuru agents)  |
| [ ]  | Any other prion recommended to be handled at BSL-3 or BSL-4 per [Biosafety in Microbiological and Biomedical Laboratories (BMBL)](https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf) |
| **Excluded Risk Group 3 Biological Agents**These biological agents are excluded from the Category 1 biological agents in the DURC-PEPP policy. |
| Clade II of MPVX viruses (unless containing nucleic acids coding for clade I MPVX virus virulence factors ) |
| Coccidioides immitis |
| Coccidioides posadasii |
| Histoplasma capsulatum |
| Histoplasma capsulatum var. duboisii |
| Human immunodeficiency virus (HIV) types 1 and 2 |
| Human T cell lymphotropic virus (HTLV) types 1 and 2 |
| Mycobacterium bovis |
| Mycobacterium tuberculosis |
| Simian immunodeficiency virus (SIV) |
| Vesicular stomatitis virus |

[Return to Question 10](#Q10)