UNIVERSITY OF FLORIDA DURC/PEPP ASSESSMENT FORM

The "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" (the "Policy") requires oversight of Category 1 (DURC) and Category 2 (PEPP) research. This form is intended to allow PIs, the Environmental Health & Safety Biosafety Office, and UF's Institutional Review Entity (IRE) to determine:

a) Applicability of Category 1 and/or Category 2 oversight criteria to the PI's research; and
b) The nature of the PI's research and proposed biological agents for further assessment and development of a risk-mitigation assessment and risk mitigation plan, if required.

If you have not used the DURC/PEPP Quick Assessment Tool available here, consider doing so before to determine whether it is necessary for you to complete this form. Complete Sections I, II, and II.

SECTION I – PRINCIPAL INVESTIGATOR AND FUNDING

Principal Investigator Information			
Name:		Department:	
Phone:		Email:	
Project Information			
Sponsor:		Title:	
Site of Performance:		Submission Date:	

Date of Assessment:

Additional Information:

SECTION II – CATEGORY 2 ASSESSMENT

Does the proposed research involve, or is it reasonably anticipated to result in, a pathogen with pandemic potential[1]? ☐ Yes ☐ No

If yes, describe:

Is the proposed research anticipated to result, or does result, in one or more of the following experimental outcomes or actions?

(a)	Enhances the transmissibility of the pathogen in humans	☐ Yes ☐ No
(b)	Enhances the virulence of the pathogen in humans	☐ Yes ☐ No
(c)	Enhances 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
(d)	Generates, uses, reconstitutes, or transfers and eradicated or extinct PPP, or previously identified PEPP	☐ Yes ☐ No

If yes to any of the above, describe:

[1] A pathogen with pandemic potential (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.

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IRE USE ONLY:
Based on current understanding, the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security. ☐ Yes ☐ No

Rationale:

SECTION III – CATEGORY 1 ASSESSMENT

Does the proposed research involve:

(a) The use of a Select Agent or Select Toxin? See the list of Select Agents and Toxins on www.selectagents.gov.

☐ Yes ☐ No	***If yes, list select agents/toxins:***

(b) A pathogen categorized in the NIH Guidelines as Risk Group 4? See "Additional Information" on page 4.

☐ Yes ☐ No	***If yes, list pathogen(s):***

(c) A non-excluded pathogen categorized in the NIH Guidelines as Risk Group 3? See "Additional Information" on page 4.

☐ Yes ☐ No	***If yes, list pathogen(s):***

(d) An agent not listed in the NIH Guidelines which otherwise requires BSL-3/4 containment? See "Additional Information" on page 4.

☐ Yes ☐ No	***If yes, list pathogen(s):***

Is the proposed research reasonably anticipated to result, or does result, in any of the following experimental outcomes?

(a)	Increase in the transmissibility of a pathogen within or between host species	☐ Yes ☐ No
(b)	Increase in the virulence of a pathogen or conveyance of virulence to a non-pathogen	☐ Yes ☐ No
(c)	Increase in the toxicity of a known toxin or production of a novel toxin	☐ Yes ☐ No
(d)	Increase in the stability of a pathogen or toxin in the environment, or increase in the ability to disseminate a pathogen or toxin	☐ Yes ☐ No
(e)	Alteration of the host range or tropism of a pathogen or toxin	☐ Yes ☐ No
(f)	Decrease in the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods	☐ Yes ☐ No
(g)	Increase in the resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions	☐ Yes ☐ No
(h)	Alteration of a human or veterinary pathogen or toxin to disrupt the effectiveness or preexisting immunity, via immunization or natural infection, against the pathogen or toxin	☐ Yes ☐ No
(i)	Enhancement of the susceptibility of a host population to a pathogen or toxin	☐ Yes ☐ No

If yes to any of the above, describe:

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IRE USE ONLY:
Based on current understanding, the research is 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

Rationale:

SECTION IV – IRE INFORMATION AND NOTES

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ADDITIONAL INFORMATION

Agents subject to Category 1 oversight:

i. Biological Agents or Toxins listed 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. (https://www.selectagents.gov/sat/list.htm)

ii. Risk Group 4 pathogens listed in Appendix B of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* - Classification of Human Etiologic Agents on the Basis of Hazard. (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)

iii. Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines - Classification of Human Etiologic Agents on the Basis of Hazard **except** HIV, HTLV, SIV, Mycobacterium tuberculosis (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, C. posadasii, Histoplasma capsulatum, and H. capsulatum var. duboisii.

iv. Agents not assigned a Risk Group in the NIH Guidelines in but are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL guidance (https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf)

For more detail regarding the research outcomes subject to Category 1 oversight, see the Implementation Guidance for the USG DURC/PEPP Policy, section B.1.2, Table 2.

For determination on whether a biological agent meets the definition of a potential pandemic pathogen (PPP), see the Implementation Guidance for the USG DURC/PEPP Policy, section B.2.1.

For more detail regarding the research outcomes subject to Category 2 oversight, see the Implementation Guidance for the USG DURC/PEPP Policy, section B.2.4, Table 3.

SUBMIT THIS COMPLETED FORM TO DURC@RESEARCH.UFL.EDU