*PI Self-Assessment Tool for DURC-PEPP Category 1 and Category 2 Research*

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| Name: |  | Date: |  |
| Sponsor: |  | ORBiT #: |  |
| Email: |  |

**Instructions:** Answer the questions in Sections A-C about your research project.

* If you are not using any of the biological agents or toxins listed in Section A, you do not need to complete this form.
* If you plan to use any of the biological agents or toxins listed in Section A, send a completed copy of this form to the ICDUR, Barry Rowan (rowan@research.ucsb.edu).
* If you answer "Yes" to any question in Sections A and B, your research may fall under Category 1 or 2 and must be referred to the Institutional Review Entity (IRE) for further assessment.

**Section A: Category 1 Dual Use Research of Concern (DURC)**

1. Does your research involve any of the following agents or toxins **AND** is the research reasonably anticipated to produce any of the following experimental effects?

☐ Yes

☐ No

**Agents and toxins**

* 1. All [Biological Select Agents and Toxins](https://www.research.ucsb.edu/sites/default/files/ri/DURC-PEPP/DURC-PEPP-Agents-Toxins.pdf), as 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.
	2. All Risk Group 4 pathogens listed in Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).
	3. A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines (except HIV, HTLV, SIV, Mtb (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 var. duboisii).
	4. Biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines but are agents that are recommended to be handled at BSL-3 or BSL-4 per the guidance in the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL).
	5. Agents for which no risk group or Biosafety Level has been assigned but the UCSB IBC has determined the agent requires handling at BSL-3 or BSL-4.

**Experimental effects**

* 1. Increase transmissibility of a pathogen within or between host species;
	2. Increase the virulence of a pathogen or convey virulence to a non-pathogen;
	3. Increase the toxicity of a known toxin or produce a novel toxin;
	4. Increase the stability of a pathogen or toxin in the environment or increase the ability to disseminate a pathogen or toxin;
	5. Alter the host range or tropism of a pathogen or toxin;
	6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
	7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
	8. 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; or
	9. Enhance the susceptibility of a host population to a pathogen or toxin.

**Section B: Category 2 Pathogens with Enhanced Pandemic Potential (PEPPs)**

1. Does your research involve a pathogen that is likely capable of wide and uncontrollable spread in human populations and would likely cause moderate to severe disease and/or mortality in humans?

☐ Yes

☐ No

1. Is your research reasonably anticipated to result in any of the experimental outcomes listed below?

☐ Yes

☐ No

* 1. Enhance transmissibility of the pathogen in humans;
	2. Enhance the virulence of the pathogen in humans;
	3. 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; or
	4. Generate, use, reconstitute, or transfer an eradicated or extinct pathogen with pandemic potential, or a previously identiﬁed pathogen with enhanced pandemic potential.

**Section C: Risk Assessment**

1. Based on current understanding, could your research be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied to pose a signiﬁcant threat to public health, agriculture, the environment, or national security?

☐ Yes

☐ No

1. If you answered "Yes" to any question in Sections A or B, please brieﬂy describe the nature of your research and the speciﬁc concerns and share these with the ICDUR (rowan@research.ucsb.edu):

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**Section D: Next Steps**

If you answered "Yes" to any question in Sections A or B, your research may involve DURC-PEPP. Please take the following actions:

1. If you are currently submitting a federal funding proposal for this project, answer “Yes” to any questions asking if you are potentially conducting DURC-PEPP or Category 1 or 2 research.
2. Contact your Institutional Review Entity (IRE) via the ICDUR for a comprehensive review of your planned work. The UCSB ICDUR is Barry Rowan, (rowan@research.ucsb.edu).
3. Be prepared to work with the IRE to put together the needed documents for IRE review.
4. Do not proceed with the research until you receive guidance from the IRE and, if necessary, the relevant funding agency.

If you answered "No" to all questions and are not using any of the biological agents or toxins listed in Section A, your research likely does not fall under Category 1 or 2 at this time and you do not need to send this document to the ICDUR. However, continue to monitor your research for any changes that might alter this assessment and notify the ICDUR prior to proceeding with any research that may fall under Category 1 or 2.

Reminder: This self-assessment tool is a preliminary screening device. The ﬁnal determination of whether research falls under Category 1 or 2 will be made by the IRE and/or the relevant funding agency.