

Johns Hopkins IRE
Potential DURC - PEPP Reporting Form

Please complete a separate form for each agent that may require DURC-PEPP Assessment

PI Name _____

PI Email _____

Click the applicable box or boxes:

I am reporting the possession or use of a Category 1 Agent

The Category 1 Agent or Agents I possess or will work with are:

If reporting a Category 1 agent, please complete the questions listed on page 2.

I am reporting that my research may be assessed as Category 2

The Pathogen(s) with Pandemic Potential or Enhanced Pandemic Potential I possess or will work with are:

If reporting potential Category 2 research, please complete the questions on page 3

Category 1 Research Potential Experimental Outcomes Query

Does your research program involving the Category 1 Agent(s) you listed on page 1 have the potential to do any of the following? Click all that apply. Leave blank if none apply.

- 1. Increase transmissibility of a pathogen within or between host species;
- 2. Increase the virulence (the ability of a pathogen to cause disease) 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; (for example, improving characteristics of the pathogen or toxin such as environmental stability and aerosolubility)
- 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; (for example, antimicrobials, antivirals, antitoxins, or vaccines)
- 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;
- 9. Enhance the susceptibility of a host population to a pathogen or toxin.

If you answered no to all of the above 9 potential experimental outcomes, please summarize your research involving the Category 1 agent below or on an attached sheet.

If you answered yes to any of the 9 potential experimental outcomes above, please explain in the space provided below or an attached sheet why you believe the experimental outcome or outcomes checked above may exist in your research program. The IRE may contact you for additional information:

Category 2 Research Potential Experimental Outcomes Query

Which Category 2 Pathogen definition do you believe applies to your research program?

- 1. Pathogen with Pandemic Potential (PPP)
- 2. Pathogen with Enhanced Pandemic Potential (PEPP)
- 3. Eradicated or Extinct PPP

Does your research program involving the Category 2 Pathogen you listed on Page 1 have the potential to do any of the following? Click all that apply. Leave blank if none apply.

- 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;
- 4. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

If you answered no to all of the above 4 potential experimental outcomes, please summarize your research below or on an attached sheet and explain why you think your research may be Category 2 research.

If you answered yes to any of the 4 potential experimental outcomes above, please explain in the space provided below or on an attached sheet why you believe the experimental outcome or outcomes checked above may exist in your research program. The IRE may contact you for additional information.