

Principal Investigator Self-Assessment of Category 1 and 2 Research Activities

Dual Use Research of Concern (DURC) and Pathogens of Enhanced Pandemic Potential (PEPP)

For more information, please see:

[USG Policy](#)

[USG Implementation Guide](#)

1A. Does your research involve, or is it reasonably anticipated to result in, a pathogen with pandemic potential (PPP)?

PPP: 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. Examples include H5N1 influenza viruses, SARS-CoV and SARS-CoV-2, and MERS.

☐ NO - **Proceed to Question 2A**

☐ YES - **Proceed to Question 1B**

1B. Is your research anticipated to result in any of the following experimental outcomes?

- Enhanced transmissibility of the pathogen in humans
- Enhanced virulence of the pathogen in humans
- Enhanced 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
- To generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP

☐ NO - **Proceed to Question 2A**

☐ YES -

Explain why you anticipate the outcomes selected above:

Based on your responses, it is likely that your research falls within Category 2 research covered by the US Government Policy. Please submit this self-assessment to ibc@nd.edu, and provide the Cayuse Proposal ID for the proposal that is intended to fund this work. The Institutional Review Entity (IRE) will review this form and make a determination about the applicability of the US Government Policy, and communicate their decision to you.

2A. Does your research involve the use of any of the following? (Select all that apply)

☐ A Select Agent or Toxin (See complete list below)

Identify the Select Agent(s) or Toxin(s):

Proceed to Question 2B

☐ A pathogen categorized in the NIH Guidelines as Risk Group 4 (See complete list below)

Identify the pathogen(s):

Proceed to Question 2B

☐ A pathogen categorized in the NIH Guidelines as Risk Group 3 (See complete list below)

Are the only Risk Group 3 pathogens that will be used listed here?

- Human immunodeficiency virus (HIV) types 1 and 2
- Human T cell lymphotropic virus (HTLV) types 1 and 2
- Simian immunodeficiency virus (SIV)
- Mycobacterium tuberculosis, Mycobacterium bovis
- Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors
- Vesicular stomatitis virus
- Coccidioides immitis (sporulating cultures; contaminated soil)
- Histoplasma capsulatum, H. capsulatum var. duboisii

☐ YES - **FORM COMPLETE**

☐ NO -

Identify pathogen(s) not listed above that will be used:

Proceed to Question 2B

☐ None of the above - **FORM COMPLETE**

2B. Is your research anticipated to result in any of the following experimental outcomes?

- Increased transmissibility of a pathogen within or between host species
- Increased virulence of a pathogen or convey virulence to a non-pathogen
- Increased toxicity of a known toxin or produce a novel toxin
- Increased stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin
- Alteration of the host range or tropism of a pathogen or toxin
- Decreased ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
- Increased resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions
- Alteration of a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin
- Enhanced susceptibility of a host population to a pathogen or toxin

☐ NO - **FORM COMPLETE**

☐ YES -

Explain why you anticipate the outcomes selected above:

Based on your responses, it is likely that your research falls within Category 1 research covered by the US Government Policy. Please proceed to the Dual Use Risk Potential section below, then submit this self-assessment to ibc@nd.edu, and provide the Cayuse Proposal ID for the proposal that is intended to fund this work. The Institutional Review Entity (IRE) will review this form and make a determination about the applicability of the US Government Policy, and communicate their decision to you.

Dual Use Risk Potential identification

If your above responses indicate that your project likely falls within Category 1 research covered by the US Government Policy, please answer the following question.

Please select which of the following potential risks could be reasonably anticipated for the knowledge, information, products, or technologies resulting from your project (Select all that apply):

- ☐ Can be readily misused without significant additional scientific advances to facilitate its misapplication
- ☐ Can be misapplied with no, or only minor, modification to cause harm
- ☐ Can be misused in the near-future
- ☐ Can be misused with a low degree of technical skill and sophistication
- ☐ Can be misused with easily accessible materials, reagents, or equipment
- ☐ Access to the research knowledge, information, products or technologies will be openly shared or easily accessible by individuals with harmful intent
- ☐ Results from similar research are readily available and present an opportunity, when combined with results from this research, for misuse
- ☐ Highlights or consolidates existing vulnerabilities in medical countermeasures, public health approaches, or agricultural infrastructure
- ☐ Could be used to threaten public health, agriculture, food security, economic security, or national security
- ☐ Could be used to harm large populations of humans, plants or animals
- ☐ Could be used to cause severe harm, disease, or consequences
- ☐ Limited medical countermeasures exist to help mitigate potential consequences of misuse
- ☐ Medical countermeasures are not readily and widely available
- ☐ Administering medical countermeasures would significantly impact the healthcare system

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