



PI Assessment of Research – Institutional Review for DURC/PEPP

The US Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) requires proactive assessment to determine if the research falls into a category of research described in the policy as part of a federal funding application.

Complete and save this self-assessment tool to determine whether your proposal involves research that is potentially within the scope of the DURC/PEPP policy.

- You will be required to indicate the results of your assessment in your funding proposal.
- Please forward this form to the IRE if the research may fall into Category 1 or Category 2 research. (biosafety@case.edu)
- If the federal funding agency is considering your proposal for award, then the CWRU Institutional Review Entity (IRE) may need to review this assessment and make a determination of whether the research falls into Category 1 or Category 2 research.

Category 1 Research

- 1) Involves one or more biological agents and toxins from a specified list (see Appendix - list of category 1 agents), which includes select agents and toxins, risk group 4 pathogens and a subset of risk group 3 pathogens.
- 2) Is reasonably anticipated to result, or does result, in one of nine experimental outcomes.

Category 2 Research

- 1) Involves, or is reasonably anticipated to result in, a Pathogen of Pandemic Potential (PPP) - likely capable of wide and uncontrolled spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.
- 2) Is reasonably anticipated to result, or does result, in one (or more) of four experimental outcomes.

Definitions

Biological Agent: any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), infectious material, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious material, capable of causing:

- Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
- Deterioration of food, water, equipment, supplies, or material of any kind; or
- Deleterious alteration of the environment.

Pathogen of Pandemic Potential (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.

Reasonably Anticipated: an assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur with a non-trivial likelihood. It does not require high confidence that the outcome will definitely occur but excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely.

PI Information	
Name:	
Email:	Phone
Submitter information (if other than PI)	
Name:	
Email:	Phone

Funding Information
Sponsor:
Title of Proposal:

Category 1

Does the research involve a select agent or toxin?	Yes	No	Not sure
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What agent or toxin? Provide additional information if not sure.

Does the research involve a pathogen categorized as a risk Group 4 agent in the NIH Guidelines?	Yes	No	Not sure
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What agent or toxin? Provide additional information if not sure.

Does the research involve a pathogen categorized as a risk Group 3 agent in the NIH Guidelines, and is not listed as an exempt agent?	Yes	No	Not sure
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What agent or toxin? Provide additional information if not sure.

Does the research involve a pathogen not assigned a risk group in the NIH Guidelines, but has a recommended containment at BSL3 or BSL4 in the BMBL?	Yes	No	Not sure
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What agent or toxin? Provide additional information if not sure.

Is the research reasonably anticipated to result, or does result, in any of the following outcomes or actions?			
Increase transmissibility of a pathogen within or between host species.	Yes	No	Not sure
Increase the virulence of a pathogen or convey virulence to a non-pathogen.	Yes	No	Not sure
Increase the toxicity of a known toxin or produce a novel toxin.	Yes	No	Not sure
Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin.	Yes	No	Not sure
Alter the host range or tropism of a pathogen or toxin.	Yes	No	Not sure
Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods.	Yes	No	Not sure
Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions.	Yes	No	Not sure
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.	Yes	No	Not sure
Enhance the susceptibility of a host population to a pathogen or toxin,	Yes	No	Not sure

If yes or not sure, provide additional information:

Category 2

Does the research involve, or is reasonably anticipated to result in, a Pathogen of Pandemic Potential (PPP)?	Yes	No	Not sure
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If yes or not sure, provide additional information:

Is the research reasonably anticipated to result, or does result, in any of the following outcomes or actions?			
Enhance transmissibility of the pathogen in humans.	Yes	No	Not sure
Enhance the virulence of the pathogen in humans.	Yes	No	Not sure
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.	Yes	No	Not sure
Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.	Yes	No	Not sure

If yes or not sure, provide additional information:

IRE Use Only:

Category 1 Research

Based on current understanding, is research 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

Category 2 Research

Is research 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

Appendix

USG Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Category 1 Agents and Toxins

* There are no exempt quantities under this policy

HHS Select Agents and Toxins ¹	
<input type="checkbox"/>	Abrin
<input type="checkbox"/>	<i>Bacillus cereus</i> Biovar <i>anthracis</i>
<input type="checkbox"/>	Botulinum neurotoxins
<input type="checkbox"/>	<i>Clostridium botulinum</i> and neurotoxin-producing species of <i>Clostridia</i>
<input type="checkbox"/>	Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X ₁ CCX ₂ PACGX ₃ X ₄ X ₅ X ₆ CX ₇)
<input type="checkbox"/>	<i>Coxiella burnetii</i>
<input type="checkbox"/>	Crimean-Congo hemorrhagic fever virus
<input type="checkbox"/>	Diacetoxyscirpenol
<input type="checkbox"/>	Eastern equine encephalitis virus
<input type="checkbox"/>	Ebola virus
<input type="checkbox"/>	<i>Francisella tularensis</i>
<input type="checkbox"/>	Lassa fever virus
<input type="checkbox"/>	Lujo virus
<input type="checkbox"/>	Marburg virus
<input type="checkbox"/>	Mpox virus Clade I
<input type="checkbox"/>	1918-1919 H1N1 including reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
<input type="checkbox"/>	Ricin
<input type="checkbox"/>	<i>Rickettsia prowazekii</i>
<input type="checkbox"/>	Severe acute respiratory coronavirus (SARS-CoV)
<input type="checkbox"/>	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
<input type="checkbox"/>	Saxitoxin
<input type="checkbox"/>	Chapare virus

¹ Biological agents and toxins listed in this part of the list are controlled by Select Agent Regulations, please refer to the Select Agents and Toxins list for any relevant strain exclusions.

<input type="checkbox"/>	Guanarito virus
<input type="checkbox"/>	Junín virus
<input type="checkbox"/>	Machupo virus
<input type="checkbox"/>	Sabía virus
<input type="checkbox"/>	Staphylococcal enterotoxins (subtypes A, B, C, D, E)
<input type="checkbox"/>	T-2 toxin
<input type="checkbox"/>	Tetrodotoxin
<input type="checkbox"/>	Tick-borne encephalitis complex virus: Far Eastern subtype
<input type="checkbox"/>	Tick-borne encephalitis complex virus: Siberian subtype
<input type="checkbox"/>	Kyasanur Forest disease virus
<input type="checkbox"/>	Omsk hemorrhagic fever virus
<input type="checkbox"/>	Variola major virus (Smallpox virus)
<input type="checkbox"/>	Variola minor virus (Alastrim)
<input type="checkbox"/>	<i>Yersinia pestis</i>
Overlap Select Agents and Toxins	
<input type="checkbox"/>	<i>Bacillus anthracis</i>
<input type="checkbox"/>	<i>Bacillus anthracis</i> Pasteur strain
<input type="checkbox"/>	<i>Brucella abortus</i>
<input type="checkbox"/>	<i>Brucella melitensis</i>
<input type="checkbox"/>	<i>Brucella suis</i>
<input type="checkbox"/>	<i>Burkholderia mallei</i>
<input type="checkbox"/>	<i>Burkholderia pseudomallei</i>
<input type="checkbox"/>	Hendra virus
<input type="checkbox"/>	Nipah virus
<input type="checkbox"/>	Rift Valley fever virus
<input type="checkbox"/>	Venezuelan equine encephalitis virus
USDA Veterinary Services (VS) Select Agents and Toxins	
<input type="checkbox"/>	African horse sickness virus
<input type="checkbox"/>	African swine fever virus
<input type="checkbox"/>	Avian influenza virus [this is included here as a veterinary select agent in 9 CFR 121.3. Low pathogenicity strains are excluded.]
<input type="checkbox"/>	Classical swine fever virus
<input type="checkbox"/>	Foot-and-mouth disease virus
<input type="checkbox"/>	Goat pox virus
<input type="checkbox"/>	Lumpy skin disease virus
<input type="checkbox"/>	<i>Mycoplasma capricolum</i>
<input type="checkbox"/>	<i>Mycoplasma mycoides</i>
<input type="checkbox"/>	Newcastle disease virus
<input type="checkbox"/>	Peste des petits ruminants virus
<input type="checkbox"/>	Rinderpest virus

<input type="checkbox"/>	Sheep pox virus
<input type="checkbox"/>	Swine vesicular disease virus
USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins	
<input type="checkbox"/>	<i>Coniothyrium glycines</i>
<input type="checkbox"/>	<i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)
<input type="checkbox"/>	<i>Ralstonia solanacearum</i>
<input type="checkbox"/>	<i>Rathayibacter toxicus</i>
<input type="checkbox"/>	<i>Sclerophthora rayssiae</i>
<input type="checkbox"/>	<i>Synchytrium endobioticum</i>
<input type="checkbox"/>	<i>Xanthomonas oryzae</i>
Other Risk Group 4 Pathogens²	
<input type="checkbox"/>	Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, and Kumlinge
<input type="checkbox"/>	Herpesvirus simiae (herpes B or monkey B virus)
<input type="checkbox"/>	Hemorrhagic fever agents and viruses as yet undefined
Other Risk Group 3 Pathogens³	
<input type="checkbox"/>	<i>Bartonella</i>
<input type="checkbox"/>	<i>Brucella</i>
<input type="checkbox"/>	<i>Orientia tsutsugamushi</i>
<input type="checkbox"/>	<i>Pasteurella multocida</i> type B - "buffalo" and other virulent strains
<input type="checkbox"/>	<i>Rickettsia akari</i> , <i>R. australis</i> , <i>R. canada</i> , <i>R. conorii</i> , <i>R. rickettsii</i> , <i>R. siberica</i> , <i>R. typhi</i> (<i>R. mooseri</i>)
<input type="checkbox"/>	Chikungunya virus except the vaccine strain 181/25
<input type="checkbox"/>	Semliki Forest virus
<input type="checkbox"/>	Flexal virus
<input type="checkbox"/>	Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
<input type="checkbox"/>	Hantaviruses, including Hantaan virus
<input type="checkbox"/>	Middle East respiratory syndrome coronavirus (MERS-CoV)
<input type="checkbox"/>	Japanese encephalitis virus except strain SA 14-14-2
<input type="checkbox"/>	Yellow fever virus
<input type="checkbox"/>	Human influenza A virus H2N2 (1957-1968)
<input type="checkbox"/>	Highly pathogenic avian influenza A virus H5Nx strains within the Goose/Guangdong/96-like H5 lineage (e.g., H5N1, H5N6, H5N8 etc.)
<input type="checkbox"/>	Transmissible spongiform encephalopathy (TSE) agents (e.g., Creutzfeldt-Jacob disease and kuru agents)

² Pathogens listed in this part of the list are Risk Group 4 but not controlled by the Select Agent Regulations, please refer to the *NIH Guidelines* for any relevant strain exclusions.

³ Pathogens listed in this part of the list are Risk Group 3 but not controlled by the Select Agent Regulations, please refer to the *NIH Guidelines* for any relevant strain exclusions.

Other	
<input type="checkbox"/>	Any attenuated pathogen or vaccine strain that is currently excluded from the Select Agent Regulations that exhibits the recovery of virulence at or near the wild-type
<input type="checkbox"/>	Mpox virus clade I/II chimeric viruses resulting from any deliberate manipulation of clade II to incorporate nucleic acids coding for clade I virulence factors

Exempt Risk Group 3 Agents

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