DUAL USE RESEARCH OF CONCERN AND PATHOGENS WITH PANDEMIC POTENTIAL SURVEY

The new United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) has significantly expanded the scope of the original DURC policy with a larger list of applicable agents and toxins, an increase in potential experimental outcomes of concern, oversight of pathogens with pandemic potential, and a requirement that all future federal funding applications be assessed for DURC/PEPP. The policy also applies to existing federally funded research.

The survey below will walk you through all the pathogens and biological toxins currently covered in the new policy for what is classified as Category 1 Research as well as the scope and potential outcomes that need to be considered for what is classified as Category 2 Research. **Contact the JHU Biosafety Office or JH IRE if you determine that your research program may be considered Category 1 or Category 2 research**.

Category 1 Research: Research of this type involves one or more of the materials listed below. To determine if your research program falls under Category 1 Research, review the materials listed below and check all that apply.

	Biological Agents (Human and Animal)
☐	African horse sickness virus
☐	African swine fever virus
☐	Avian influenza virus[3]
☐	*Bacillus anthracis* Pasteur strain
☐	*Bacillus anthracis**
☐	*Bacillus cereus* Biovar *anthracis*
☐	*Bartonella*
☐	Botulinum neurotoxin producing species of *Clostridium**
☐	*Brucella* including *B. abortus, B. canis, B. melitensis, B. suis* (all strains)
☐	*Burkholderia mallei**
☐	*Burkholderia pseudomallei**
☐	Chikungunya virus except the vaccine strain 181/25
☐	Classical swine fever virus
☐	*Coxiella burnetii*
☐	Crimean-Congo haemorrhagic fever virus
☐	Eastern Equine Encephalitis virus[3]
☐	Ebola virus*
☐	Flexal virus
☐	Foot-and-mouth disease virus*
☐	*Francisella tularensis**
☐	Goat pox virus
☐	Hantaviruses, including Hantaan virus
☐	Hemorrhagic fever agents and viruses as yet undefined
☐	Hendra virus
☐	Herpesvirus simiae (herpes B or monkey B virus)

☐	Highly pathogenic avian influenza A virus H5Nx strains within the Goose/Guangdong/96-like H5 lineage (e.g., H5N1, H5N6, H5N8 etc.)
☐	Human influenza A virus H2N2 (1957-1968)
☐	Japanese encephalitis virus except strain SA 14-14-2
☐	Kyasanur Forest disease virus
☐	Lassa fever virus
☐	Lujo virus
☐	Lumpy skin disease virus
☐	Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
☐	Marburg virus*
☐	Middle East respiratory syndrome coronavirus (MERS-CoV)
☐	Monkeypox virus[3]
☐	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
☐	*Mycoplasma capricolum*[3]
☐	*Mycoplasma mycoides*[3]
☐	Newcastle disease virus[2,3]
☐	Nipah virus
☐	Omsk hemorrhagic fever virus
☐	*Orientia tsutsugamushi* (was *R. tsutsugamushi)*
☐	*Pasteurella multocida* type B -"buffalo" and other virulent strains
☐	Peste des petits ruminants virus
☐	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)
☐	*Rickettsia akari, R. australis, R. canada, R. conorii, R. rickettsii, R, siberica, R. typhi (R. mooseri)*
☐	*Rickettsia prowazekii*
☐	Rift Valley fever virus
☐	Rinderpest virus*
☐	SARS-associated coronavirus (SARS-CoV)
☐	SARS-associated coronavirus 2 (SARS-CoV-2)
☐	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
☐	Semliki Forest virus
☐	Sheep pox virus
☐	South American Haemorrhagic Fever viruses:
☐	Chapare
☐	Guanarito
☐	Junin
☐	Machupo
☐	Sabia
☐	St. Louis encephalitis virus
☐	Swine vesicular disease virus

☐	Tick-borne encephalitis complex (flavi) viruses:
☐	Far Eastern subtype
☐	Siberian subtype
☐	Tick-borne encephalitis virus complex including Far Eastern Subtype, Siberian Subtype, Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, and Russian spring-summer encephalitis viruses
☐	Variola major virus (Smallpox virus)*
☐	Variola minor virus (Alastrim)*
☐	Venezuelan equine encephalitis virus[3]
☐	West Nile virus
☐	Yellow fever virus
☐	*Yersinia pestis**
Biological Agents (Plant)	
☐	*Coniothyrium glycines (*formerly *Phoma glycinicola* and *Pyrenochaeta glycines)*
☐	*Peronosclerospora philippinensis (Peronosclerospora sacchari)*
☐	*Ralstonia solanacearum*
☐	*Rathayibacter toxicus*
☐	*Sclerophthora rayssiae*
☐	*Synchytrium endobioticum*
☐	*Xanthomonas oryzae*
Biological Toxins	
☐	Abrin
☐	Botulinum neurotoxins*
☐	Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)
☐	Diacetoxyscirpenol
☐	Ricin
☐	Saxitoxin
☐	Staphylococcal enterotoxins A,B,C,D,E subtypes
☐	T-2 toxin
☐	Tetrodotoxin
Biological Agents (Prions)	
☐	Transmissible spongiform encephalopathy (TSE) agents (e.g., Creutzfeldt-Jacob disease and kuru agents), Prions
Other	
☐	Any attenuated pathogen or vaccine strain (noted in the Select Agent Regulations) that is currently excluded from the Select Agent Regulations that exhibits the recovery of virulence at or near the wild-type

If you did not click YES to any of the agents listed above, then your research program does not fall under Category 1 Research as currently defined. **However, you must continue to page 5 to assess whether your research program falls under Category 2 Research.**

If you clicked YES to one or more agents above, you must answer the questions below to complete your assessment of Category 1 Research. Please also contact the JHU Biosafety Office or JH IRE so they can review your answers to the section below.

Please indicate below if any of the research you do with the items you checked above are reasonably anticipated to result, or do result in one or more of the experimental outcomes listed below

☐ Increases transmissibility of a pathogen within or between host species

☐ Increase the virulence of a pathogen or convey virulence (i.e., the ability of a pathogen to cause disease) to a non-pathogen

☐ Increase the toxicity of a known toxin or produce a novel toxin

☐ Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin (e.g., improving characteristics of the pathogen or toxin such as environmental stability and ability to be aerosolized)

☐ Alter the host range or tropism of a pathogen or toxin

☐ Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods

☐ Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions (e.g., antimicrobials, antivirals, antitoxins, vaccines)

☐ Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of pre-existing immunity, via immunization or natural infection, against the pathogen or toxin

☐ Enhance the susceptibility of a host population to a pathogen or toxin

Please Indicate the Type of Funding Source(s) for this Project:

☐ Department/Institutional Funds

☐ Business/Industry

☐ Foundation

☐ Other: _____

☐ Federal Funds

Category 2 Research: The research can be reasonably anticipated to result in the development, use, or transfer of a pathogen with pandemic potential (PPP), enhanced pandemic potential (PEPP), or an eradicated or extinct pathogen with pandemic potential (PPP) that may pose a significant threat to public health, the capacity of health systems to function, or national security, through the potential accidental or deliberate introduction of a PEPP or an eradicated or extinct PPP into a human population. Category 2 research may also have dual use risks. Please review the definitions below and the experimental outcomes that follow.

The DURC/PEPP policy defines a pathogen with pandemic potential (PPP) as 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."

The DURC/PEPP policy defines a pathogen with enhanced pandemic potential (PEPP) as "a type of PPP resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may post a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs, but may be considered PPs because of their pandemic potential. "

The DURC/PEPP policy oversight includes research involving eradicated or extinct PPP. "Category oversight is also required for experiments that generate, use, reconstitute, or transfer an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function or national security, regardless of whether the experiment enhances the PPP. Current eradicated and extinct PPPs include Variola major and minor, and Influenza A virus subtypes H1N1 (1918) and H2N2 (1957-1968). Any research with there PPPs is considered Category 2 because of the heightened consequences of biosafety or biosecurity incidents that could occur from directly handling or possessing such pathogens, even without any enhancement to virulence or transmissibility. "

Please indicate below if any of the research you do with the items is reasonably anticipated to result, or do result in one or more of the experimental outcomes listed below

☐ Enhance transmissibility of the pathogen in humans

Examples:

- Creates a pathogen more transmissible than the wild-type pathogen such that it is able to spread widely and uncontrollably in the human population.
- Creates a pathogen able to survive outside the host and/or withstand environmental conditions longer than the wild-type pathogen, facilitating transmission such that it is able to spread widely and uncontrollably in the human population.
- Creates a pathogen with altered tropism (i.e., tissue tropism or host range), that could change the route of transmission, resulting in increased transmissibility relative to the wild-type pathogen such that it is able to spread widely and uncontrollably in the human population.
- Increases transmissibility of an animal or zoonotic pathogen, such that it can now utilize new non-human vectors or reservoirs to spread widely and uncontrollably in the human population.

☐ Enhance the virulence of the pathogen in humans

Example: Creates a pathogen more virulent than the wild-type pathogen (i.e., resulting in higher morbidity or mortality) such that it is able to cause moderate to severe disease in humans.

☐ 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

Example: Modifies a pathogen such that it is able to spread widely and uncontrollably in the human population, and cause moderate to severe disease, despite existing population immunity against the wild-type pathogen.

☐ Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP

Examples:

- Reconstitutes or creates a pathogen for which little or no natural immunity exists.
- Transfers a reconstructed eradicated or extinct PPP or a previously identified PEPP to another laboratory with or without further experimentation.

Please Indicate the Type of Funding Source(s) for this Project:

☐ Department/Institutional Funds

☐ Business/Industry

☐ Foundation

☐ Other: _____

☐ Federal Funds

Principal Investigator Name

Principal Investigator Email Address