myResearch Study ID #

Dual Use Research of Concern (DURC) and Pathogen with

Enhanced Pandemic Potential (PEPP) Application

**PROTOCOL TITLE:**

Response:

**PROTOCOL VERSION/AMENDMENT #:**

Response:

**PRINCIPAL INVESTIGATOR:**

Response:

**Funding:** [ ]  Seeking funding [ ]  Funded [ ]  Internally Funded

Agency:

**1.0 Agents or Toxins that are Involved in the Research:**

*Strains considered to be ‘attenuated’ and appearing on the Select Agent and Toxins Exclusions list:* [*http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html*](http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html) *do not need to be listed on this form as long as your project does not propose any manipulation that restores or enhances its virulence or toxic activity. Please see the list at the end of this document in Appendix A and list those pathogens being used here:*

**2.0 Personnel Training (DURC)**

One of the responsibilities of the principal investigator is to ensure that laboratory personnel under his/her supervision who are working with any of the agents listed in #1 above have received training and education on DURC. List all personnel involved in this research, and the dates of completion of DURC.

|  |  |  |  |
| --- | --- | --- | --- |
| Last Name | First Name | SBU Employee ID# (not SSN) | DURC Training Completion Date  |
| PI:       |  |       |        |
|       |  |       |        |
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**Category 1 Research**

**3.0 Does your research that involves one or more the agents or toxins above also produce, aim to produce, or is reasonably anticipated to produce the following effects:**

Increases transmissibility of a pathogen within or between host species

[ ]  Yes Explain why:

[ ]  No

Increases the virulence of a pathogen or convey virulence to a non-pathogen

[ ]  Yes Explain why:

[ ]  No

Increases the toxicity of a known toxin or produces a novel toxin

[ ]  Yes Explain why:

[ ]  No

Increases the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin

[ ]  Yes Explain why:

[ ]  No

Alters the host range or tropism of the agent or toxin

[ ]  Yes Explain why:

[ ]  No

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

[ ]  Yes Explain why:

[ ]  No

Increases resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions

[ ]  Yes Explain why:

[ ]  No

Alters 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 Explain why:

[ ]  No

Enhances the susceptibility of a host population to a pathogen or toxin

[ ]  Yes Explain why:

[ ]  No

NOTE: If any of the strains checked above are considered to be ‘attenuated’, but your research involves restoring or enhancing virulence or toxic activity, please explain:

**Category 2 Research**

1. It involves, or is reasonably anticipated to result in, a pathogen with pandemic potential (PPP), or a pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP.

[ ]  Yes Explain why:

[ ]  No

1. It is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified here:

Increases transmissibility of a pathogen within or between host species

[ ]  Yes Explain why:

[ ]  No

Increases the virulence of a pathogen or convey virulence to a non-pathogen

[ ]  Yes Explain why:

[ ]  No

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 Explain why:

[ ]  No

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

[ ]  Yes Explain why:

[ ]  No

**3. The research can be *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 the health systems to function, or national security.**

**4.0 Describe the aim(s) of your research:**

**5.0 Describe the experimental manipulations that will be performed:**

**6.0 Describe the anticipated outcome of your research:**

**7.0 Explain why you think that your research does or does not constitute dual use research of concern:**

**8.0 Risk Mitigation Plan**

It is the responsibility of the principal investigator to submit a Risk Mitigation Plan following identification of potential Category 1 or Category 2 research. Please see the Dual Research of Concern policies for more information.

**Appendix A**

**List of Category 1 Agents**

**Bacteria:**

* ***Bacillus anthracis***
* ***Bacillus anthracis* Pasteur *strain***
* ***Bacillus cereus* Blovar *anthracis***
* ***Bartonella***
* ***Brucella* including *B. abortus, B. melitensis, B. Suis***
* ***Burkholderia mallei***
* ***Burkholderia pseudomallei***
* ***Clostridium botulinum* and neurotoxin-producing species *of Clostridium***
* ***Coniothyrium glycines***
* ***Coxiella burnetiid***
* ***Francisella tularensis***
* ***Mycoplasma capricolum***
* ***Mycoplasma mycoides***
* ***Orientia tsutsugamushi***
* ***Pasteurella muitocida* type B – “buffalo” and other virulent strains**
* ***Ralstonia solanacearum***
* ***Rathaylbacter toxicus***
* ***Rickettsia akari, R. australis, R. Canada, R. conorii, r. prowazekii, R. rickettsii, r. siberica, R. typhi (R. mooseri)***
* ***Scerophthora rayssiae***
* ***Synchytrium endobioticum***
* ***Xanthomonoas oryzae***
* ***Yersinia pestis***

**Toxins (No Exempt Quantities):**

* **Abrin**
* **Botulinum neurotoxins**
* **Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)**
* **Diacetoxyscirpenol**
* **Ricin**
* **Saxitoxin**
* **Staphylococcal enterotoxins (subtypes A, B, C, D, E)**
* **T-2 toxin**
* **Tetrodotoxin**

**Viruses and Prions:**

* **African swine fever virus**
* **Alphaviruses (Togaviruses) – Group A Arboviruses**
* **Arenaviruses**
* **Avian influenzna virus (low pathogenity strains excluded)**
* **Bunyaviruses – Hantaviruses, including Hantaan virus**
* **Classical swine fever virus**
* **Coronaviruses – MERS-CoV**
* **Crimean-Congo hemorrhagic fever virus**
* **Eastern equine encephalitis virus**
* **Ebolavirus**
* **Flaviviruses – Group B Arboviruses (Powassan virus, West Nile virus, Yellow Fever virus, etc.)**
* **Foot-and-mouth disease virus**
* **Goat pox virus**
* **Hemorrhagic fever agents and viruses as yet unidentified**
* **Hendra virus**
* **Herpesvirus simiae (herpes B or monkey B virus)**
* **Lassa fever virus**
* **Lujo virus**
* **Lumpy skin disease virus**
* **Marburg virus**
* **Mpox virus Clade I**
* **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**
* **Newcastle disease virus**
* **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**
* **Nipah virus**
* **Orthomyxoviruses – Human influenza A virus H2N2, highly pathogenic avain influenza A virus H5Nx strains with the Goose/Guangdong/96-like H5 lineage (e.g. H5N1, H5N6, H5N8, etc.)**
* **Peste des pettis ruminant virus**
* **Prions**
* **Rift Valley fever virus**
* **Rinderpest virus**
* **SARS-CoV, 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**
* **Sheep pxo virus**
* **South American Hemorrhagic Fever viruses**
* **Swine vesicular disease virus**
* **Tick-borne encephalitis complex (flavi) viruses**
* **Variola major virus (Samllpox virus)**
* **Variola minor virus (Alastrim)**
* **Venezuelan equine encephalitis virus**

**DURC-PEPP Category 1 Exceptions**

* ***Coccidioides immitis***
* ***Coccidioides posadasii***
* ***Histoplasma capsulatum and Histoplasma capsulatum var. Duboisii***
* **Human immunodeficiency viruses (HIV) types 1 and 2**
* **Human t-lymphotrophic virus (HTLV) types 1 and 2**
* **Mpox virus clade II, unless containing nucleic acids coding for clade I Mpox virus virulence factors**
* ***Mycobacterium bovis, Mycobacterium tuberculosis***
* **Simian immunodeficiency virus (SIV)**
* **Vesicular stomatitis virus**
* **Excluded strains as listed in the NIH guidelines and Select Agents & Toxins Exclusions**