Assessment of Research That Requires Institutional Review

The US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (USG Policy) identifies two Categories of research that must be proactively assessed by the PI when described as part of a federal grant application:

Category 1 Research
(1) Involves one or more biological agents and toxins from a pre-determined list[1].
(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 PPP[2].
(2) Is reasonably anticipated to result in, or does result in, one or more experimental outcomes or actions.

Complete and save this self-assessment tool to determine whether your proposal involves research that is potentially within scope of Category 1 or Category 2. Please note:

- You will be required to declare the results of your assessment in your funding proposal.
- If the federal funding agency is considering your proposal for award, the PSU Institutional Review Entity (IRE) will be required to review this assessment and make their own determination of whether the proposed research in within the scope of Category 1 or Category 2.
  **For that reason, please retain this assessment for later use.*

For questions or assistance completing this form: orp-biosafety@psu.edu

1. Contact Information
   PI Name:
   PI Email:
   PI Phone:

   Submitter Name (if different):
   Submitter Email:
   Submitter Phone:

2. Funding Information
   Sponsor:
   Title of Proposal:
   Performance Site:
   Submission Date:

3. Date of Assessment:

4. Does the proposed research involve, or is it reasonably anticipated to result in, a pathogen with pandemic potential? □ **NO** □ **YES** **If yes, describe:**

[1] All Select Agents and Toxins, Risk Group 4 pathogens, and a subset of Risk Group 3 pathogens. See Appendix for complete list.
[2] A pathogen with pandemic potential (PPP) is 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.

5. Is the proposed research anticipated to result, or does result, in one or more of the following experimental outcomes or actions:
   (a) Enhance transmissibility of the pathogen in humans. □ **NO** □ **YES**
   (b) Enhance the virulence of the pathogen in humans. □ **NO** □ **YES**
   (c) 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. □ **NO** □ **YES**
   (d) Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP[3]. □ **NO** □ **YES**

   If yes to any of the above, describe:

IRE USE ONLY:
Based on current understanding, the research is 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. □ **NO** □ **YES**

6. Does your research involve:
   (a) The use of a Select Agent or Select Toxin? □ **NO** □ **YES** **If yes, what agent/toxin?**

   (b) A pathogen categorized in the NIH Guidelines as Risk Group 4? □ **NO** □ **YES** **If yes, what pathogen?**

   (c) A pathogen categorized in the NIH Guidelines as Risk Group 3? □ **NO** □ **YES** **If yes, what pathogen?**

7. Is the proposed research anticipated to result, or does result, in any of the following experimental outcomes:
   (a) Increase transmissibility of a pathogen within or between host species. □ **NO** □ **YES**
   (b) Increase the virulence of a pathogen or convey virulence to a non-pathogen. □ **NO** □ **YES**
   (c) Increase the toxicity of a known toxin or produce a novel toxin. □ **NO** □ **YES**

[3] A pathogen with enhanced pandemic potential (PEPP) is 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 pose a significant threat to public health, the capacity of health systems to function, or national security.

(d) Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin. □ **NO** □ **YES**
(e) Alter the host range or tropism of a pathogen or toxin. □ **NO** □ **YES**
(f) Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods. □ **NO** □ **YES**
(g) Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions. □ **NO** □ **YES**
(h) 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. □ **NO** □ **YES**
(i) Enhance the susceptibility of a host population to a pathogen or toxin. □ **NO** □ **YES**

If yes to any of the above, describe:

IRE USE ONLY:
Based on current understanding, the research is 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. □ **NO** □ **YES**

Appendix: Category 1 Agents and Toxins

HHS Select Agents and Toxins

1. Abrin
2. *Bacillus cereus* Biovar *anthracis*
3. Botulinum neurotoxins
4. Botulinum neurotoxin producing species of *Clostridium*
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol
9. Eastern Equine Encephalitis virus
10. Ebola virus
11. *Francisella tularensis*
12. Lassa fever virus
13. Lujo virus
14. Marburg virus
15. Mpox virus
16. 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)
17. Ricin
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)
20. 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
21. Saxitoxin

South American Haemorrhagic Fever viruses:

22. Chapare
23. Guanarito
24. Junín
25. Machupo
26. Sabia
27. Staphylococcal enterotoxins (subtypes A,B,C,D,E)
28. T-2 toxin
29. Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:

30. Far Eastern subtype
31. Siberian subtype
32. Kyasanur Forest disease virus
33. Omsk hemorrhagic fever virus
34. Variola major virus (Smallpox virus)
35. Variola minor virus (Alastrim)
36. *Yersinia pestis*

Overlap Select Agents and Toxins

37. *Bacillus anthracis*
38. *Bacillus anthracis* Pasteur strain

39. *Brucella abortus*
40. *Brucella melitensis*
41. *Brucella suis*
42. *Burkholderia mallei*
43. *Burkholderia pseudomallei*
44. Hendra virus
45. Nipah virus
46. Rift Valley fever virus
47. Venezuelan equine encephalitis virus

USDA Veterinary Services (VS) Select Agents and Toxins

48. African horse sickness virus
49. African swine fever virus
50. Avian influenza virus
51. Classical swine fever virus
52. Foot-and-mouth disease virus
53. Goat pox virus
54. Lumpy skin disease virus
55. *Mycoplasma capricolum*
56. *Mycoplasma mycoides*
57. Newcastle disease virus
58. Peste des petits ruminants virus
59. Rinderpest virus
60. Sheep pox virus
61. Swine vesicular disease virus

USDA Plant Protection And Quarantine (PPQ) Select Agents and Toxins

62. *Coniothyrium glycines*
    (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
63. *Peronosclerospora philippinensis (Peronosclerospora sacchari)*
64. *Ralstonia solanacearum*
65. *Rathayibacter toxicus*
66. *Sclerophthora rayssiae*
67. *Synchytrium endobioticum*
68. *Xanthomonas oryzae*

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Appendix B, Risk Group 4 and subset of Risk Group 3
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Risk Group 4 (RG4) - Bacterial Agents
None

Risk Group 4 (RG4) - Fungal Agents
None

Risk Group 4 (RG4) - Parasitic Agents
None

Risk Group 4 (RG4) - Viral Agents

- Arenaviruses
    - Guanarito virus
    - Lassa virus
    - Junin virus (except the candid #1 vaccine strain listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
    - Machupo virus
    - Sabia
- Bunyaviruses (Nairovirus)
    - Crimean-Congo hemorrhagic fever virus
- Filoviruses
    - Ebola viruses
    - Marburg viruses
- Flaviruses - Group B Arboviruses
    - Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses
- Herpesviruses (alpha)
    - Herpesvirus simiae (Herpes B or Monkey B virus)
- Paramyxoviruses
    - Equine Morbillivirus (Hendra virus)
- Hemorrhagic fever viruses as yet undefined

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia*

- Bartonella
- Brucella including B. abortus, B. canis, B. suis
- Burkholderia (Pseudomonas) mallei, B. pseudomallei
- Coxiella burnetii (except the Phase II, Nine Mile strain listed in Appendix B-II-A, Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)
- Francisella tularensis (except those strains listed in Appendix B-II-A, Risk Group 2 (RG2) – Bacterial Agents Including Chlamydia)
- Orientia tsutsugamushi (was R. tsutsugamushi)
- Pasteurella multocida type B -"buffalo" and other virulent strains
- Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. typhi (R. mooseri)
- Yersinia pestis (except those strains listed in Appendix B-II-A, Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)

Risk Group 3 (RG3) - Fungal Agents*

None

Risk Group 3 (RG3) - Parasitic Agents

None

Risk Group 3 (RG3) - Viruses and Prions*

- Alphaviruses (Togaviruses) - Group A Arboviruses
    - Chikungunya virus (except the vaccine strain 181/25 listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
    - Semliki Forest virus
    - Venezuelan equine encephalomyelitis virus (except the vaccine strains TC-83 and V3526,

see Appendix B-II-D (RG2) – Viruses)
    - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Arenaviruses
    - Flexal
    - Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
- Bunyaviruses
    - Hantaviruses including Hantaan virus
    - Rift Valley fever virus
- Coronaviruses
    - SARS-associated coronavirus (SARS-CoV)
    - Middle East respiratory syndrome coronavirus (MERS-CoV)
- Flaviviruses - Group B Arboviruses
    - Japanese encephalitis virus (except those strains listed in Appendix B-II-D Risk Group2 (RG2) - Viruses)
    - Yellow fever virus
    - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Orthomyxoviruses
    - Influenza viruses 1918-1919 H1N1 (1918 H1N1), human H2N2 (1957-1968), and highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1).
- Poxviruses
    - Monkeypox virus (Clade I & Clade II containing nucleic acids coding for clade I MPVX virus virulence factors)
- Prions
    - Transmissible spongiform encephalopathies (TSE) agents (Creutzfeldt-Jacob disease and kuru agents) (see Section V-C, Footnotes and References of Sections I through IV, for containment instruction)

EXCLUDED RG3 Agents:

- 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