PI Self-Assessment Tool for Category 1 and Category 2 Research

Instructions: Answer the following questions about your research project. If you answer "Yes" to any question in Sections A and B, your research may fall under Category 1 or 2 and must be referred to your Institutional Review Entity (DURC-IRE) for further assessment.

Section A: Category 1 Pandemic Potential Pathogens (PPP)

1. Does your research involve any of the following agents or toxins? [ ] Yes [ ] No
    - List of agents/toxins (e.g., highly pathogenic avian influenza H5N1, SARS-CoV, etc.)
2. Is your research reasonably anticipated to produce, or does it intentionally produce, any of the following experimental effects? [ ] Yes [ ] No
    1. Increase transmissibility of a pathogen within or between host species;
    2. Increase the virulence of a pathogen or convey virulence to a non-pathogen;
    3. Increase the toxicity of a known toxin or produce a novel toxin;
    4. Increase the stability of a pathogen or toxin in the environment or increase the ability to disseminate a pathogen or toxin;
    5. Alter the host range or tropism of a pathogen or toxin;
    6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
    7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
    8. 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; or
    9. Enhance the susceptibility of a host population to a pathogen or toxin.

Section B: Category 2 Potential Enhanced Pandemic Pathogens (PEPPs)

3. Does your research involve a pathogen that is likely capable of wide and uncontrollable spread in human populations? [ ] Yes [ ] No
4. If yes to question 3, is this pathogen likely to cause significant morbidity and/or mortality in humans? [ ] Yes [ ] No
5. Is your research reasonably anticipated to create, transfer, or create any of the results below? [ ] Yes [ ] No

    i. Enhance transmissibility of the pathogen in humans;
    ii. Enhance the virulence of the pathogen in humans;
    iii. 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; or
    iv. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

Section C: Risk Assessment

6. Based on current understanding, could your research be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied to pose a significant threat to public health, agriculture, the environment, or national security? [ ] Yes [ ] No

7. If you answered "Yes" to any question in Sections A or B, please briefly describe the nature of your research and the specific concerns and share these with the DURC research coordinator (contact information): [Text entry box]

Section D: Next Steps

If you answered "Yes" to any question in Sections A or B:

1. If you are currently completing the compliance section of a sponsored project, answer yes to the question “Question from RASS-need to add text”
2. Contact your Institutional Review Entity (DURC-IRE) via the DURC Research Coordinator for a comprehensive review of your planned work.
3. Be prepared to work with the DURC Research Coordinator to put together the needed documents for DURC-IRE review.
4. Do not proceed with the research until you receive guidance from your DURC-IRE and, if necessary, the relevant funding agency.

If you answered "No" to all questions: Your research likely does not fall under Category 1 or 2 at this time. However, continue to monitor your research for any changes that might alter this assessment.

Reminder: This self-assessment tool is a preliminary screening device. The final determination of whether research falls under Category 1 or 2 will be made by your DURC-IRE and the relevant funding agency.

List of Agents and Toxins subject to DURC PPP/PEPP Policy:

1. Abrin
2. African horse sickness virus
3. African swine fever virus
4. Attenuated pathogen or vaccine strain that would be expected to regain full virulence
5. Bacillus anthracis
6. Bacillus anthracis Pasteur strain
7. Bacillus cereus Biovar anthracis
8. Bartonella spp.
9. Botulinum neurotoxins
10. Brucella spp.
11. Burkholderia mallei
12. Burkholderia pseudomallei
13. Chapare virus
14. Chikungunya virus (excludes vaccine strain 181/25)
15. Classical swine fever virus
16. Clostridium botulinum and neurotoxin-producing species of Clostridia
17. Coniothyrium glycines
18. Conotoxins
19. Coxiella burnetii
20. Crimean-Congo hemorrhagic fever virus
21. Diacetoxyscirpenol
22. Eastern equine encephalitis virus
23. Ebola virus
24. Flexal virus
25. Foot-and-mouth disease virus
26. Francisella tularensis
27. Goat Pox virus
28. Guanaritovirus
29. Hantavirus including Hantaan virus
30. Hemorrhagic fever agents and viruses as yet undefined
31. Hendra virus
32. Herpes simiae (Herpes B or monkey B virus)
33. Highly pathogenic avian influenza A virus (HPAI H5Nx)
34. Human influenza virus H2N2 (1957-1968)
35. 1918/1919 H1N1
36. Junin virus
37. Kyasanur Forest disease virus
38. Lass fever virus
39. Lujo virus
40. Lumpy skin disease virus
41. Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
42. Machupo virus
43. Marburg virus
44. Middle East respiratory syndrome coronavirus (MERS-Cov)
45. Mpox virus Clade I
46. Mpox virus clade I/II chimeric viruses
47. Mycoplasma capricolum
48. Mycoplasma mycoides

49. Newcastle disease virus
50. Nipah Virus
51. Omsk hemorrhagic fever virus
52. Orientia tsutsugamushi
53. Pasteurella multocida Type B- “buffalo” and other virulent strains
54. Peronosclerospora philippinensis (Peronosclerospora sacchari)
55. Peste des petits ruminants virus
56. Ralstonia solanacearum
57. Rathayibacter toxicus
58. Ricin
59. Rickettsia akari, R. australis, R. canada, R. conorii, R. rickettsii, R. siberica, R. typhi (R. mooseri)
60. Rickettsia prowazekii
61. Rift Valley Fever virus
62. Rinderpest virus
63. Sabia virus
64. SARS-CoV/SARS-CoV-2 chimeric viruses
65. Saxitoxin
66. Sclerophthora rayssiae
67. Semliki Forest virus
68. Sever acute respiratory coronavirus (SARS-CoV)
69. Sheep pox virus
70. St. Louis encephalitis virus
71. Staphylococcal enterotoxins (subtypes A, B, C, D, E)
72. Swine Vesicular disease virus
73. Synchytrium endobioticum
74. T-2 toxin
75. Tetrodotoxin
76. Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, and Kumlinge
77. Tick-borne encephalitis complex virus: Far Eastern subtype
78. Tick-borne encephalitis complex virus: Siberian subtype
79. Transmissible spongiform encephalopathy (TSE) agents (Creutzfeldt-Jocob disease and kuru agents)