# PI Self-Assessment Form for DURC Determination

The US Government Policy for Oversight of Dual Use Research of Concern and Pathogens (DURC) with Enhanced Pandemic Potential (USG Policy) identifies two Categories of research that must be proactively assessed by the PI:

Category 1 Research

(1) Involves one or more biological agents and toxins from a pre-determined list including Federal Select Agents and Toxins as well as Risk Group 4 and some Risk Group 3 agents from the NIH *Guidelines* (*see Appendix*).
(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 with Pandemic Potential (PPP). PPPs are pathogens that are likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe diseases and/or mortality in humans. Examples include H5N1 influenza viruses, SARS-CoV and SARS-CoV-2, and MERS.
(2) Is reasonably anticipated* to result in, or does result in, one or more experimental outcomes or actions.

* Reasonably anticipated describes "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 and excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely."

**Instructions:**
This form is intended to be a tool to determine whether a project meets Category 1 or Category 2 research. Funding agencies will require this determination for submissions.

**Complete and save this self-assessment form** 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 funding agency is considering your proposal for award, the Temple University Institutional Review Entity (IRE) will be required to review this assessment at that time and make their own determination of whether the proposed research is within the scope of Category 1 or Category 2. This form must be submitted to the IRE at that time.
- This form will be required with the IBC Annual Renewal Review for any projects that were initiated prior to May 6, 2025.

For questions or assistance completing this form: ibc@temple.edu or klmurray@temple.edu

**Section I. Contact Information**

1. Contact Information
   Principal Investigator (PI):
   Name:
   Email:
   Phone:

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

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

3. Date of Assessment:

**Section II. Category 1 Determination**

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

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

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

**If the answer to any item in Question 1 is YES, complete Question 2. Otherwise, proceed to Section III.**

2. 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**
   (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) Enhance the susceptibility of a host population to a pathogen or toxin. □ **NO** □ **YES**

   **If yes to any of the above, describe:**

**If the answer to any of the items in Question 1 and any of the items in Question 2 is Yes, this project will meet the definition of Category 1 research under the DURC policy.**

**Section III. Category 2 Determination**

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

2. 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 pathogen with enhanced pandemic potential (PEPP). □ **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**

**If yes to any of the above, describe:**

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| |

**If the answer to Question 1 and any of the items in Question 2 is Yes, this project will meet the definition of Category 2 research under the DURC policy.**

**Section IV. Tool Results**

**If the responses to Category 1 and Category 2 are both NO:** the project does not fall under DURC requirements at this time. The project should be continually evaluated throughout the work to ensure no changes warrant reconsideration of the status of the project.

**If the responses to Category 1 and Category 2 are both YES**: the project must be reported to the funding agency as Category 2 research. If the funding agency is considering the project for funding, they will request the University and PI provide additional consideration. For additional information, see the *Temple University Guidance on Institutional Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.* ***For that reason, please retain this assessment for later use****.*

I**f the response to either Category 1 or Category 2 is YES**: the project must be reported to the funding agency under that Category. If the funding agency is considering the project for funding, they will request the University and PI provide additional consideration. For additional information, see the *Temple University Guidance on Institutional Oversight of Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.* ***For that reason, please retain this assessment for later use****.*

**Section V. PI Signature**

I certify the information provided in this DURC Self-Assessment is complete and accurate. I acknowledge my responsibility for the safe conduct of this research. I will notify the IBC Office as to any changes in the project which may impact the inclusion/exclusion of the project in the DURC program.

PI Signature:

**This Section is for IRE Use Only**

*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. **Project meets Category 1 research**: □ **NO** □ **YES**

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. **Project meets Category 2 research**: □ **NO** □ **YES**

**Institutional Review Entity**
DURC Registration Number:
IRE Chair
Print Name:
Signature:
Email:
Phone:

## Appendix: Category 1 Agents and Toxins

**I. Federal Select Agent Program - CDC and USDA Select Agents and Toxins**

**HHS Select Agents and Toxins**

-Abrin
-*Bacillus cereus* Biovar *anthracis*
-Botulinum neurotoxins
-Chapare virus
-*Clostridium botulinum* and neurotoxin-producing species of *Clostridia*
-Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1 CCX2 PACGX3 X4 X5 X6 CX7 )
-*Coxiella burnetii*
-Crimean-Congo hemorrhagic fever virus
-Diacetoxyscirpenol
-Eastern equine encephalitis virus
-Ebola virus
-*Francisella tularensis*
-Guanarito virus
-Junín virus
-Kyasanur Forest disease virus
-Lassa fever virus
-Lujo virus
-Machupo virus
-Marburg virus
-Mpox virus Clade I
-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)
-Omsk hemorrhagic fever virus
-Ricin
-*Rickettsia prowazekii*
-Sabía virus
-Severe acute respiratory coronavirus (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
-Saxitoxin
-Staphylococcal enterotoxins (subtypes A, B, C, D, E)
-T-2 toxin
-Tetrodotoxin
-Tick-borne encephalitis complex virus: Far Eastern subtype
-Tick-borne encephalitis complex virus: Siberian subtype
-Variola major virus (Smallpox virus)
-Variola minor virus (Alastrim)
-*Yersinia pestis*

**Overlap Select Agents and Toxins**

-*Bacillus anthracis*
-*Bacillus anthracis* Pasteur strain
-*Brucella abortus*
-*Brucella melitensis*

-*Brucella suis*
-*Burkholderia mallei*
-*Burkholderia pseudomallei*
-Hendra virus
-Nipah virus
-Rift Valley fever virus
-Venezuelan equine encephalitis virus

**USDA Veterinary Services (VS) Select Agents and Toxins**
-African horse sickness virus
-African swine fever virus
-Avian influenza virus [this is included here as a veterinary select agent in 9 CFR 121.3. Low pathogenicity strains are excluded.]
-Classical swine fever virus
-Foot-and-mouth disease virus
-Goat pox virus
-Lumpy skin disease virus
-*Mycoplasma capricolum*
-*Mycoplasma mycoides*
-Newcastle disease virus
-Peste des petits ruminants virus
-Rinderpest virus
-Sheep pox virus
-Swine vesicular disease virus

**USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins**
-*Coniothyrium glycines*
-*Peronosclerospora philippinensis (Peronosclerospora sacchari)*
-*Ralstonia solanacearum*
-*Rathayibacter toxicus*
-*Sclerophthora rayssiae*
-*Synchytrium endobioticum*
-*Xanthomonas oryzae*

## II. NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH *Guidelines*), Appendix B, Risk Group 4 and subset of Risk Group 3

**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) - 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