Principal Investigator Assessment of Research for Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential- Instructions and Form

Purpose of Form: This questionnaire is designed to help you assess whether your research falls within the scope of the US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential ("Policy"). The Policy requires that principal investigators and senior/key personnel submitting federal grant proposals for life sciences research self-assess their research proposals for dual use research of concern (DURC) and pathogens with enhanced pandemic potential (PEPP) prior to submitting a federal grant application. A copy of this assessment must be provided to SRS.

If you answer "yes" to any of the questions regarding experimental outcomes and "yes" to any of the questions regarding biological agents, please contact Ms. Susan Gater, the designated Institutional Contact for Dual Use Research (ICDUR) via e-mail at ire@tamu.edu before submitting your proposal. **Do not delay.** If you are uncertain or need assistance completing this form, please contact biosafety@tamu.edu

If the federal funding agency is considering your proposal for award, the Texas A&M University Institutional Review Entity (IRE) will be required to review this assessment and the proposal. NIH will require the following documentation be provided as part of Just-in-Time Materials, as applicable:

- Confirmation of IRE review and category determination
- Risk-benefit assessment
- Risk mitigation plan, if research is confirmed to be Category 1 or Category 2

Category 1 Research	**Category 2 Research**
Involves one or more biological agents and toxins from a pre-determined list[1]; and	Involves, or is reasonably anticipated to result in, a Potential Pandemic Pathogen[2]; and
Is reasonably anticipated to result, or does result, in one of nine experimental outcomes[3].	Is reasonably anticipated to result in, or does result in, one of four experimental outcomes[3] or actions.

[1] See Appendix for a complete list
[2] Defined 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. PPPs are often those with little to no pre-existing immunity in the human population.
[3] Experimental outcomes are listed in questions 1-10 below. Category 2 experimental outcomes are underlined below. Any research that meets the definition of both categories is designated as Category 2 research.

ASSESSMENT FOR DUAL USE RESEARCH OF CONCERN AND PATHOGENS WITH ENHANCED PANDEMIC POTENTIAL

Name:
E-mail:
Phone:
Proposal Title: Sponsor:
Date of Assessment:

Experimental Outcomes

Does your proposed life sciences research aim to result in, or is it reasonably anticipated to result in, any of the following outcomes:

1. Increase transmissibility of a pathogen within or between host species, including enhancing the transmissibility of the pathogen in humans;

   ◯ Yes ◯ No ◯ Unknown

2. Increase the virulence (e.g. the ability of a pathogen to cause disease) of a pathogen or convey virulence to a non-pathogen, including enhancing the virulence of the pathogen in humans;

   ◯ Yes ◯ No ◯ Unknown

3. Increase the toxicity of a known toxin or produce a novel toxin;

   ◯ Yes ◯ No ◯ Unknown

4. 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 aerosolubility);

   ◯ Yes ◯ No ◯ Unknown

5. Alter the host range or tropism of a pathogen or toxin;

   ◯ Yes ◯ No ◯ Unknown

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

   ◯ Yes ◯ No ◯ Unknown

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

   ◯ Yes ◯ No ◯ Unknown

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, including enhancing 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 ◯ No ◯ Unknown

9. Enhance the susceptibility of a host population to a pathogen or toxin; or

◯ Yes ◯ No ◯ Unknown

10. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified Pathogen with Enhance Pandemic Potential (PEPP)[4].

◯ Yes ◯ No ◯ Unknown

Biological Agents

Does your proposed research involve one or more of the following biological agents and toxins[1]:

1. Any of the Select Agents and Toxins listed in the Select Agent Regulations, all Risk Group 4 pathogens and a subset of Risk Group 3 pathogens listed in the *NIH Guidelines*.

◯ Yes ◯ No ◯ Unknown

2. Any biological agent that the current edition BMBL recommends be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4).

◯ Yes ◯ No ◯ Unknown

3. Any biological agent that the Institutional Biosafety Committee (IBC) has determined require BSL-3 or BSL-4 containment based on a risk assessment.

◯ Yes ◯ No ◯ Unknown

4. A potential pandemic pathogen.

◯ Yes ◯ No ◯ Unknown

5. Any pathogen modified such that it is reasonably anticipated to result in a potential pandemic pathogen.

◯ Yes ◯ No ◯ Unknown

[4] 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.