FOR OFFICE USE ONLY: DUR Protocol # Status:

Training Complete:

KANSAS STATE UNIVERSITY

Office of Research Integrity, Compliance, and Security

Dual Use Research Concern (DURC) and/or Pathogen with Enhanced Pandemic Potential (PEPP)

Assessment Form

Please send your completed document to comply@k-state.edu

INSTRUCTIONS

Be sure to save the PDF form to your computer *before* you begin completing the form. You may not be able to save your changes if you edit this form in a web browser.

Please identify any life sciences research you conduct at this institution that directly involves nonattenuated forms of one or more of the agents/toxins listed here (please use a separate form for each identified project). If none of the agents are identified, your research is not subject to institutional DURC oversight. However, PIs should be aware that, if at any time, research is initiated that involves any of the below listed agents, he or she will need to immediately notify the institutional review entity (IRE) (or appropriate institutional authority), per the policy of this institution.

Institutional Review Entity (IRE) / Institutional Contact for Dual Use Research:

The K-State associate vice president for research compliance has been designated as the ICDUR. If you have questions about dual-use research, contact Brad Woods at comply@ksu.edu or 785-532-3224.

If you need help or have questions about how to complete this application, please contact the Office of Research Integrity, Compliance, and Security (ORICS) (532-3224, or email: comply@ksu.edu).

FAILURE TO PROVIDE THE INFORMATION REQUESTED WILL LEAD TO A DELAY IN PROCESSING YOUR REQUEST!

Please proof read and check spelling BEFORE submitting the form.
To use Acrobat spelling check, press F7 or select EDIT, CHECK SPELLING

PLEASE CONTINUE TO THE NEXT PAGE TO BEGIN COMPLETING THE FORM

1. Contact Information

1.1 Institutional Review Entity

Date(s) of Review:

Name (Last, First, MI):

Campus Address:

E-mail:

Campus Phone: Fax #:

1.2 Principle Investigator:

Name (Last, First, MI):

Department:

Campus Address:

E-mail:

Campus Phone: Fax #:

1.3 Person Preparing This Document (If Not the PI):

Name (Last, First, MI):

E-mail:

Campus Phone: Fax #:

2. Project information

2.1 Title of Project:

2.2 List the Agent (s) or Toxin (s) Involved in Project (check the list here)

2.3 Review(s) of Research by PI

Please list prior dates of reviews or assessments by the PI of research for DURC potential. For each date, please include a copy of the review or assessment with your submitted form.

Review Date(s)		

Add Row Delete Row

3. Assessment by the IRE for Experimental Effects

PIs are required to assess whether any research directly involving nonattenuated forms of the listed agents/toxins produces, aims to produce, or is reasonably anticipated to produce 1 or more of the experimental effects listed in Section 4 of the Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (relisted below). Note: the research and this assessment must be submitted to the IRE for review regardless of whether any of the following experimental effects apply.

3.1 Category 1

a. ☐ Increase transmissibility of a pathogen within or between host species.
If checked, please explain below:

b. ☐ Increase the virulence of a pathogen or convey virulence to a non-pathogen.
If checked, please explain below:

c. ☐ Increase the toxicity of a known toxin or produce a novel toxin.
If checked, please explain below:

d. ☐ Increase the stability of a pathogen or toxin in the environment or increase the ability to disseminate a pathogen or toxin.
If checked, please explain below:

e. ☐ Alter the host range or tropism of a pathogen or toxin.
If checked, please explain below:

f. ☐ Enhances the susceptibility of a host population to the agent or toxin.
If checked, please explain below:

g. ☐ Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions.
If checked, please explain below:

h. ☐ Enhance the susceptibility of a host population to a pathogen or toxin.
If checked, please explain below:

i. ☐ 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.
If checked, please explain below:

3.2 Category 2

a. ☐ Enhance transmissibility of the pathogen to humans.
If checked, please explain below:

b. ☐ Enhance virulence of the pathogen in humans.
If checked, please explain below:

c. ☐ Enhance 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.
If checked, please explain below:

d. ☐ Generate, use, reconstitute or transfer an eradicated or extinct PPP, or a previously identified PEPP.
If checked, please explain below:

If none of the above experimental effects applies, the research does not meet the scope of the Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, and the IRE does not need to continue with this assessment. The PI should be informed that at any time the reviewed research produces or can be reasonably anticipated to produce a previously unanticipated experimental effect listed in Sections 4.1.2 and 4.2.2 of the Policy, or if the reviewed research may meet the definition of DURC/PEPP, he or she will refer it again to the IRE for review.

4 Risk Assessment by the IRE and Determination of DURC/PEPP

When considering whether the research in question meets the definition of DURC or PEPP, the IRE should first identify the risks associated with the potential misuse of the information, technologies, or products that may be generated. Although risk assessments may be either quantitative or qualitative, the assessment process outlined below is qualitative in nature and requires the consideration and judgment of the IRE on the following:

- The ways in which knowledge, information, technologies, or products from the research could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel, or national security.
- The ease with which the knowledge, information, technologies, or products might be misused and the feasibility of such misuse. The magnitude, nature, and scope of the potential consequences of misuse.
- The magnitude, nature, and scope of the potential consequences of misuse.

4.1 Points to Consider in Assessing Research for Its Dual Use Potential

Consider the points below to assess the potential risks associated with conducting the research in question or communicating its results. These points address some of the aspects of potential DURC/PEPP that could be considered, but they are not exhaustive – IREs should augment these points to if their needs and the research under consideration. This risk assessment is intended to assist IREs in determining whether the research in question meets the definition of Category 1 and Category 2 agents. In cases where the research is determined to be DURC/PEPP, this assessment will also inform the subsequent process of identifying strategies for mitigating those risks.

1. The ways in which knowledge, information, technologies, or products from the research could be misused. Address the following questions and considerations regarding the nature and disposition of the knowledge, information, technology, or products that could be generated by the research under consideration:

a. What types of knowledge, information, technology, or products are anticipated to be generated through the research?

b. How will the results or products of the research in question be shared or distributed? *Knowledge, information, technology, or products that are freely available and widely distributed may be more easily accessed by individuals with harmful intent.*

- Who will have access to the knowledge, information, technology, or final products?

- Will it be shared openly or remain within the laboratory?

c. What is the novelty of the information provided by the research or of the research methods? *Research that adds novel information or consolidates information in novel ways may be of greater concern, whereas information that is already widely available is generally of lower concern.*

- Have the results of the research been previously described or shared?

- If so, at what venues and in what detail?

- How readily available are these results?

d. Are the products of the research under consideration applicable to other more common or less pathogenic organisms or agents? *Knowledge, information, technology, or products generated from research that could be applied to more commonly available organisms to increase their associated risks may be of greater concern.*

e. Does the research highlight vulnerabilities in existing countermeasures or public health or agricultural infrastructure?

- Does the research highlight weaknesses in the ability to prepare for and respond to disease outbreaks that could impact public, agricultural, or environmental health?

- Does the research consolidate existing information in ways that highlight vulnerabilities in public health and/or safety preparedness?

2. Assess the likelihood and feasibility of the knowledge, information, technologies, or products from this research being directly misused. While IRE members are not expected to have national security expertise, they, along with investigators, are well-positioned to evaluate the technical aspects of potential misuse. This assessment should consider factors such as technical feasibility, the level of expertise required, the availability of necessary reagents, and whether additional scientific advances or technologies would be needed for misuse to occur.

   a. Consider the technical expertise and/or physical resources that would be needed to apply the knowledge, information, technology, or product for malevolent purposes. *The risk of misuse may be lower for knowledge, information, technologies, or products that would be expensive, difficult to procure, or that require a high degree of technical skill to facilitate such misuse.*

      - Would it require a low or high degree of technical skill and sophistication to misuse information from Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential for harmful purposes?

      - Would its misuse require materials, equipment, or reagents that are expensive or difficult to procure?

   b. Consider whether the products of the research in question could be directly misused to pose a threat to public health and safety, agriculture, plants, animals, the environment, material, or national security. *The risk of misuse may be higher for research information that can be directly misused than for research information that requires significant additional scientific advances to facilitate its misapplication.*

      - Can the products, information, or technologies generated from the research be directly misapplied? If so, how?

- If not, do these outcomes of the research need to be combined with other knowledge, information, technology, or products in order to pose a threat? If so, is that other information already available?

c. Consider the time frame in which information from the research might be misused. *Information that can be misused in the near term may be of greater concern.*

- Is there concern about immediate or near-future potential use, or is the concern about misuse in the distant future?

d. Given your responses to the preceding questions, how readily could the knowledge, information, technology, or products from the research be used to threaten public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

3. **Potential consequences of misuse**. When considering the potential consequences of the misuse of scientific knowledge, information, technology, or products obtained from research, think broadly about the potential impacts on public health, agriculture, the environment, and/or the economy from the intentional misapplication of the results from the research in question. In general, information that could be misused to harm large populations of humans, plants, or animals; cause public panic; or require costly response efforts would be considered a greater risk.

a. Consider the nature of the potential consequences (e.g., harm to the economy, the environment, agriculture, or public health; public terror) that might result from misuse of the research results in question. Information that could be misused to harm numerous sectors of society or the environment may be of greater concern.

- Could the impact on people, plants, and/or animals be considered minor, moderate, or major?

b. Consider the scope and magnitude of the potential consequences. Research or research information that could be misused to cause severe harm, disease, or consequences is generally considered to be of greater concern.

- Could the impact on people, plants, and/or animals be considered minor, moderate, or major?

c. Consider the available countermeasures. *Adequate countermeasures may help to decrease concern about the consequences of misuse. Countermeasures may include drugs, biological products, public health practices, pesticides, or devices intended for diagnosis, detection, mitigation, prevention, or treatment.*

- Are there currently any countermeasures to help mitigate the potential consequences?

- Are they readily available?

4.2 Apply the DURC Definition

The IRE should consider the identified risks in determining whether the research in question meets the definition of dual use research of concern (DURC), Pathogen with pandemic potential (PPP) and Pathogen with enhanced pandemic potential (PEPP):

- DURC: life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
- Pathogen with pandemic potential (PPP): 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.
- Pathogen with enhanced pandemic potential (PEPP): 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.

If the IRE determines that the research does not meet these definitions, the research is not subject to additional institutional DURC oversight. However, the institution must still notify the appropriate USG funding agency of the findings of the institutional review. If significant concerns remain, the ICDUR should be informed. The ICDUR and the IRE may choose to consult with a representative of the USG department or agency that is funding the research in question.

If the IRE determines that the research does meet the DURC/PPP/PEPP definition, the research is subject to additional DURC oversight as defined in the Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. The IRE should inform the PI of its findings and proceed with the review process, which includes the development of a draft risk mitigation plan. The institution must notify the appropriate USG funding agency of the IRE's findings within 30 calendar days of review.

5 Risk-Benefit Assessment of DURC/PEPP

For research that has been identified as DURC/PEPP, it is important to assess the research for its anticipated benefits and to weigh those benefits with the risks identified in Step 4. This process will help determine the acceptable level of risk and inform the most appropriate mitigation strategies. The IRE should use the answers to Step 4 and Step 5 in developing a risk mitigation plan for conducting the research and communicating its findings.

5.1 Points to Consider in Assessing Research for Its Dual Use Potential

The benefits inherent to scientific research are many. Such benefits may impact various sectors of society and be realized over different time frames. The points below address some of the aspects of the research that could be considered, but they are not exhaustive – IREs should augment these points to fit their needs and the research under consideration.

a. Are there potential benefits to the public's health and/or safety from the research?

b. Are there potential benefits of the research for agriculture, plants, animals, the environment, materiel, or national security?

– What potential solution does it offer to an identified problem or vulnerability?

c. Will this research be useful to the scientific, public health, or public safety communities? If so, how?

d. Because scientific research can have broad impacts, it is important to consider the scope of the potential benefits.

– Will the knowledge, information, or technology generated from the research be broadly applicable (e.g., to human health, multiple scientific fields, populations of organisms)?

– What populations of plants or animals might be positively affected?

e. If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might this research benefit science, public health, agriculture, plants, animals, the environment, materiel, or national security?

5.2 Points to Consider for Weighing the Risks and Benefits of the DURC

This can be the most challenging step in the risk-benefit assessment; it is often described as a step that entails "weighing" or "balancing" the risks with or against the benefits of research with DURC/PEPP. This language, however, suggests that risks and benefits can be quantified and that they are commensurable. This is rarely, if ever, the case.

The process of weighing the risks and benefits is an exercise in making defensible, rational judgments in the midst of unavoidable uncertainty. Uncertainty can best be managed by ensuring that the process draws on the expertise and perspectives of a group of individuals of diverse backgrounds and experience. Discussion and debate within such a group can help to (a) identify and mitigate the biases that individuals inevitably bring to the challenges of this sort, (b) uncover often implicit assumptions in arguments, (c) scrutinize and test the basis for judgments, and (d) yield conclusions that represent a consensus (literally, "a thinking together") and are optimally defensible.

a. Could the information of concern be more readily applied to improvements in surveillance or to the development of countermeasures than to malevolent applications? What reasons or evidence support the answer to this question?

b. What is the time frame in which potential benefits or anticipated risks might be realized?

c. How might the potential benefits and the anticipated risks be distributed across different populations (humans and animals)?

– Who or what will be the likely beneficiaries of the potential benefits? Will the potential benefits be distributed equally or disproportionately across different populations? (Here, it will be helpful to keep in mind that, for example, human populations may differ in terms of size: The potential benefits may accrue to a large or, alternatively, to a small number of individuals. Or, human populations may differ along socioeconomic or cultural lines: The potential benefits may accrue to or have little impact on a vulnerable or low- resourced population versus a well-resourced population.)

– Who or what will bear the anticipated risks? Is it likely that one or more specific populations will bear the burden of the anticipated risks?

– Is it likely that the distribution of the anticipated risks and the potential benefits will be fair or just?

d. Considering the anticipated risks in tandem with the potential benefits, are the risks of such a feasibility and magnitude that they warrant proceeding after developing and implementing a risk mitigation plan? Are the potential benefits of significant magnitude to warrant proceeding despite the risks? What is the most responsible way to proceed? For the vast majority of cases of DURC/PEPP, an appropriate risk mitigation plan can be developed and effectively implemented.

6 Signature

PI Signature: Date: