



**KANSAS STATE UNIVERSITY
RESEARCH EVALUATION CHECKLIST – PRINCIPAL INVESTIGATORS
DUAL USE RESEARCH OF CONCERN AND PATHOGENS WITH ENHANCED
PANDEMIC POTENTIAL**

CATEGORY 1

(A) Will this research use any of the **98 listed Category 1 agents or toxins**?

- a. If no, is the agent a human pathogen?
 - i. If no, the agent is not Category 1. No further action.
 - ii. If yes (the agent is a human pathogen), does the BMBL or the IBC recommend the agent be handled at BSL-3 or BSL-4?
 1. If no, the agent is not Category 1. No further action.
 2. If yes, the agent is Category 1. Go to **(B)**.
- b. If yes, the agent is Category 1. Go to **(B)**.

(B) Can this research with a Category 1 agent be reasonably anticipated to have any of the **9 listed research experimental outcomes**?

- a. If no, the anticipated experimental outcome is not Category 1. No further action.
- b. If yes, the anticipated experimental outcome is Category 1. Go to **(C)**.

(C) Could this research be reasonably anticipated to be able to be misapplied so as to pose a severe threat to public health and safety, agricultural crops and other plants, animals, the environment, materiel (*supplies or equipment used by the military*), or national security?

- a. If no, the research is not Category 1. No further action.
- b. If yes, the research is Category 1.
 - i. The PI notifies the federal funding agency and ORICS as part of their research proposal submission.
 - ii. The funding agency will notify the University if it is considering funding the proposal.
 - iii. The University IRE then evaluates whether the research is Category 1 or 2 and responds to the funding agency to verify.
 - iv. The funding agency will verify the University IRE's assessment.
 - v. The University IRE will develop a draft mitigation plan.
 - vi. The PI will submit the mitigation plan to the funding agency.
 - vii. Once the funding agency approves both funding and mitigation plan, research may proceed.

*If research is determined to be Category 1 or 2 while already ongoing, stop immediately and go through steps i-vii.

CATEGORY 2

- (A) Will this research use a Pathogen with Pandemic Potential (PPP), or any pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP?
- If no, the agent is not Category 2. No further action.
 - If yes, the agent is Category 2. Go to **(B)**.
- (B) Can this research with a Category 2 agent be reasonably anticipated to have any of the **4 listed research experimental outcomes**?
- If no, the anticipated experimental outcome is not Category 2. No further action.
 - If yes, the anticipated experimental outcome is Category 2. Go to **(C)**.
- (C) Could this research be 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?
Current eradicated and extinct pathogens include Variola major, Variola minor, and 1918 H1N1 Influenza virus.
- If no, the research is not Category 2. No further action.
 - If yes, the research is Category 2.
 - The PI notifies the federal funding agency and ORICS as part of their research proposal submission.
 - The funding agency will notify the University if it is considering funding the proposal.
 - The University IRE then evaluates whether the research is Category 1 or 2 and responds to the funding agency to verify.
 - The funding agency will verify the University IRE's assessment.
 - The University IRE will develop a draft mitigation plan.
 - The PI will submit the mitigation plan to the funding agency.
 - Once the funding agency approves both funding and mitigation plan, research may proceed.

*If research is determined to be Category 1 or 2 while already ongoing, stop immediately and go through steps i-vii.