

Category 2 Research

The research can be reasonably anticipated to result in the development, use, or transfer of a pathogen with pandemic potential (PPP), enhanced pandemic potential (PEPP), or an eradicated or extinct pathogen with pandemic potential (PPP) that may pose a significant threat to public health, the capacity of health systems to function, or national security, through the potential accidental or deliberate introduction of a PEPP or an eradicated or extinct PPP into a human population. Category 2 research may also have dual use risks. Please review the definitions below and the experimental outcomes that follow.

The DURC/PEPP policy defines a pathogen with pandemic potential (PPP) 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."

The DURC/PEPP policy defines a pathogen with enhanced pandemic potential (PEPP) as "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 post a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs, but may be considered PPs because of their pandemic potential. "

The DURC/PEPP policy oversight includes research involving eradicated or extinct PPP.

"Category oversight is also required for experiments that generate, use, reconstitute, or transfer an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function or national security, regardless of whether the experiment enhances the PPP. Current eradicated and extinct PPPs include Variola major and minor, and Influenza A virus subtypes H1N1 (1918) and H2N2 (1957-1968). Any research with these PPPs is considered Category 2 because of the heightened consequences of biosafety or biosecurity incidents that could occur from directly handling or possessing such pathogens, even without any enhancement to virulence or transmissibility. "

The 4 experimental outcomes are listed below

1. Enhance transmissibility of the pathogen in humans

Examples:

- Creates a pathogen more transmissible than the wild-type pathogen such that it is able to spread widely and uncontrollably in the human population.
- Creates a pathogen able to survive outside the host and/or withstand environmental conditions longer than the wild-type pathogen, facilitating transmission such that it is able to spread widely and uncontrollably in the human population.
- Creates a pathogen with altered tropism (i.e., tissue tropism or host range), that could change the route of transmission, resulting in increased transmissibility relative to the wild-type pathogen such that it is able to spread widely and uncontrollably in the human population.
- Increases transmissibility of an animal or zoonotic pathogen, such that it can now utilize new non-human vectors or reservoirs to spread widely and uncontrollably in the human population.

2. Enhance the virulence of the pathogen in humans

Example: Creates a pathogen more virulent than the wild-type pathogen (i.e., resulting in higher morbidity or mortality) such that it is able to cause moderate to severe disease in humans.

3. 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

Example: Modifies a pathogen such that it is able to spread widely and uncontrollably in the human population, and cause moderate to severe disease, despite existing population immunity against the wild-type pathogen.

4. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP

Examples:

- Reconstitutes or creates a pathogen for which little or no natural immunity exists.
- Transfers a reconstructed eradicated or extinct PPP or a previously identified PEPP to another laboratory with or without further experimentation.