Policy and Guidance for Oversight of
Dual Use Research of Concern (DURC) &
Pathogens with Enhanced Pandemic Potential (PEPP)

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The *U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (herein referred to as the DURC/PEPP Policy requires institutional oversight for "conducting and managing certain types of federally funded life sciences research on biological agents and toxins."

The DURC/PEPP Policy defines and outlines oversight requirements for two categories of research: Category 1 research, which involves dual use research of concern (DURC), and Category 2 research, which involves pathogens with enhanced pandemic potential (PEPP).

The DURC/PEPP Policies defines PEPP as "a type of pathogen with pandemic potential (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. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential."

The DURC/PEPP Policy expands oversight of DURC to a wider scope of agents including all *Select Agents and Toxins*, all Risk Group 4 and most Risk Group 3 agents listed in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, and biological agents added during future updates to the DURC/PEPP Policy Implementation Guidance.

Researchers must identify and mitigate biosafety, biosecurity, and information risks associated with manipulation of certain pathogens that could cause significant harm to society, be it accidental or intentional. For NIH applicants, researchers must assess whether or not their research falls under the scope of Category 1 and/or Category 2 research at the proposal stage and continuously throughout the research life cycle.

If you are proposing to use *any* quantity of these agents and toxins, Vassar must evaluate for DURC or PPP potential. (Note these attenuated select agent strains or less toxic select toxins are not subject to the requirements of the select agent regulations.) Depending on the need, Vassar's Grants Office will identify an Institutional Review Entity (IRE) and/or an Institutional Contact for Dual Use Research (ICDUR) to review and determine the proposed use and category; conduct a risk-benefit assessment; and, if research is determined to be Category 1 or Category 2, create a risk mitigation plan.

Note: No work with agents requiring BSL3 or 4 facilities is permitted at Vassar.