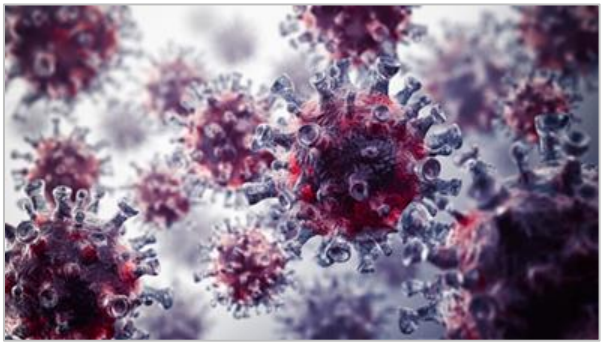
Biomaterials Research Subject to NSABB-related Policies

Life sciences research involving infectious agents has many benefits especially research focused on pandemic preparedness and understanding infectious diseases. However, biosafety and biosecurity concerns may arise when pathogens are intentionally modified to improve their ability to cause disease or a pandemic (sometimes called gain of function research). In these cases, the potential for lab accidents or releases during experimentation, and the potential for misuse of the research information or products require additional consideration.

To ensure that scientific research on infectious agents is conducted safely and securely, the U.S. Government has created several policies to assess and mitigate the risks of work that may produce biological threats to public health. These policies include:

- United States Government Policy for Institutional Oversight of Life Sciences DURC,
- United States Government Policy for Oversight of Life Sciences DURC,
- Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO), and the
- Framework for Guiding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens.



The National Science Advisory Board for Biosecurity (NSABB) consists of members with a broad range of expertise related to life science and security policy development. The NSABB was established to provide advice, guidance, and recommendations on this type of research and to assist in consolidating these policies, and their recommendations and reports are available online.

Investigator's "Need to Know" Definitions from U.S. Government Policies

Dual Use Research of Concern (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."

Research may meet the definition of DURC if it:

1. uses one or more of the 15 agents listed below, and
2. produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in the 7 categories below.

DURC-listed Biological Agents and Toxins:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

**These agents are also regulated for possession and use under the federal select agent regulations and require additional oversight beyond consideration for DURC.*

DURC Categories of Experiments:

1. Enhances the harmful consequences of the agent or toxin.
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification.
3. Confers to the agent or toxin resistant to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies.
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin.
5. Alters the host range or tropism of the agent or toxin.
6. Enhances the susceptibility of a host population to the agent or toxin.
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

Remember: The combination of any of the 7 activities/outcomes involving any of the 15 agents listed may be considered DURC and may require additional institutional oversight.

Potential Pandemic Pathogen (PPP):

A pathogen that is both:

1. likely highly transmissible and likely capable of wide and uncontrollable spread in human populations, and
2. likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

Enhanced PPP (ePPP):

A PPP that results from enhancement of the transmissibility and/or virulence of a pathogen that is not naturally occurring already in circulation or that was recovered from nature.

Investigator's Responsibility: Do your research plans (or collaborations) involve any agents or activities that reflect the definitions above in any way?

Contact the VU Biosafety Team for assistance!
If you are planning to do any research that is described in the above categories, contact VUBiosafety@vanderbilt.edu to discuss these activities **prior** to beginning the work or acquiring the biological agents or toxins. Experiments involving these materials or these research activities may be subject to the U.S. Government research regulations described in this document which require additional institutional review, oversight, risk mitigation measures, and reporting.