Virginia Tech Life Sciences Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential Policy

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Policy Owner:
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Affected Parties:
Undergraduate
Graduate
Faculty
Staff
Other

1.0 Purpose

This policy establishes requirements for the identification and oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) within the research conducted at Virginia Tech. This policy is in accordance with the requirements of the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

2.0 Policy

Virginia Tech is actively committed to complying with federal and state laws and regulations regarding the use of dual use research of concern and pathogens with enhanced pandemic potential. It is recognized that use of agents and experiments that could be considered as dual use research of concern may be necessary to fulfill the objectives of life sciences research.

To implement compliance with the *United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)* and other federal and state laws and regulations, Virginia Tech has designated the Institutional Contact for DURC and the Institutional Review Entity (IRE) as the institutional entities that oversee the review and mitigation of DURC-PEPP-related research.

2.1 Applicability of Policy

This policy, as well as its amendments and additions, applies to all Virginia Tech faculty, staff, students, and visitors engaged in research or instructional activities.

Research that (i) uses one or more of the agents/toxins listed in Section 5.1.1, and 5.2.1 of this policy, and (ii) involves, or can be reasonably anticipated to result in, one or more of the experimental outcomes or actions listed in Sections 5.1.2 and 5.2.2 of this policy, will need to follow the procedures described in the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations.

3.0 Oversight

3.1 Virginia Tech, The Institution

Virginia Tech will implement compliance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and with approved risk mitigation plans, and other federal and state laws and regulations involving the handling and use of agents considered life sciences DURC and PEPP.

Virginia Tech will provide resources and training to guide the principal investigator (PI) in the

identification of research applicable to the policy and a mechanism to refer a project to the IRE as soon as: (i) The PI has identified that the research involves one or more of the agents or toxins listed in Sections 5.1.1 or 5.2.1 of this policy; and (ii) The PI's research involves, or can be reasonably anticipated to result in, one or more of the experimental outcomes or actions listed in Sections 5.1.2 or 5.2.2 of this policy

3.2 Senior Vice President for Research and Innovation

The Senior Vice President for Research and Innovation serves as the Institutional Official (IO) for the university and is responsible for oversight of compliance activities involving life sciences DURC or PEPP.

The IO will appoint members to the Institutional Review Entity.

3.3 Institutional Contact for Dual Use Research

The Associate Vice President for Scholarly Integrity and Research Compliance (SIRC)will serve as the Institutional Contact for Dual Use Research (ICDUR) for Virginia Tech. The ICDUR will serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section 2.0 of this policy or meets the definition of DURC or PEPP.

If questions arise regarding compliance, implementation of this policy, or when guidance is needed about identifying DURC or PEPP or developing risk mitigation plans, the ICDUR serves as the liaison, as necessary, between the institution and the relevant program officers at the federal funding agencies. The ICDUR, with the help of the Institutional Review Entity (IRE), will help to implement compliance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential,* and with approved risk mitigation plans.

The ICDUR will assist the IRE in reporting instances of noncompliance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations, as well as mitigation measures undertaken by Virginia Tech to prevent recurrences of similar noncompliance.

3.4 Institutional Review Entity

The Virginia Tech Institutional Biosafety Committee (IBC) has been appointed as the Institutional Review Entity (IRE) for Virginia Tech. The IRE is responsible for reviewing life sciences research identified as DURC or PEPP, and to execute the review and mitigation plan process described in the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. All IBC and IRE meetings will be conducted as independent meetings.

The IRE, with assistance from the ICDUR, will implement compliance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations, and with approved risk mitigation plans.

The IRE, with assistance from the ICDUR, will report any occurrence of non-compliance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations, as well as mitigation measures undertaken by Virginia Tech to prevent recurrences of similar noncompliance, as applicable and required.

The Virginia Tech IRE is composed of a minimum of 5 members and

(i) is sufficiently empowered by the institution to execute the requirements of Virginia Tech's research oversight policies.

(ii) includes persons with sufficient breadth of expertise, including biosafety and biocontainment expertise, to assess the applicability of the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations to the range of relevant life sciences research conducted at a given research facility and to understand the biosafety and biosecurity implications of such research.

(iii) has knowledge of potential pandemic pathogens, pathogens with enhanced pandemic potential, dual use concerns, and related federal and state laws and regulations.

(iv) understands risk assessment and risk management considerations, including awareness of a variety of risk mitigation measures and that designating research as DURC or PEPP research does not necessarily mean that the research should not be conducted or communicated.

(v) on a case by case basis, recuses any member of an IRE who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity.

(vi) engages in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan.

(vii) will assess whether submitted research is within the scope of the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations.

(viii) will work with the PI to conduct a risk-benefit assessment and develop a risk mitigation plan, as necessary; assist with and oversee implementation of the plan; and notify the federal funding agency when the plan is reviewed, approved, and implemented prior to the initiation of the research.

(ix) will evaluate risk mitigation plans annually, and work with the PI to modify them as necessary for the duration of the research.

(x) within 30 calendar days of the IRE review, will assist the PI in notifying the federal funding agency of any research within the scope of the USG Policy and other federal and state laws and regulations, including whether it meets or does not meet the definition of DURC research.

(xi) within 90 calendar days from the determination that the research does meet the definition of DURC or PEPP research, will assist the PI in providing a copy of the risk mitigation plan to the federal funding agency.

3.5 Institutional Biosafety Committee Program

The Institutional Biosafety Committee Program (IBCP) is an administrative unit within the division of Scholarly Integrity and Research Compliance. The IBCP is responsible for administrative support to the IRE. The IBCP is charged with supporting the IRE in fulfilling their responsibility for implementing individual research and instructional compliance with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and other federal and state laws and regulations* for the use of, and mitigation strategies approved for, activities designated as DURC or PEPP.

4.0 Responsibilities of Researchers and Instructors

Faculty, staff, students, and visitors engaged in research activities at Virginia Tech are required to comply with the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations. Anyone participating in such research has the responsibility to:

(i) be knowledgeable about and comply with all applicable laws and regulations, requirements, and policies for oversight of biological agent and toxin research.

(ii) assess their research at the proposal stage, and continuously throughout the research lifecycle of any project, to identify whether there is research reasonably anticipated to be within the scope of research as described in Section 5 of this policy.

(iii) communicate DURC and PEPP research, as required. Communication of research and research findings is an essential activity for all researchers and occurs throughout the research process, not only at the point of publication.

(iv) If research is identified as meeting the scope of research as described in Section 5 of this policy, researchers must

a. immediately notify the federal funding agency and the Virginia Tech IRE. This notification is to be made regardless of the point at which the research is determined to meet the scope of this policy.

b. halt any active work that is determined to meet the scope of this policy after the experiments have been started until a risk mitigation plan has been approved by the federal funding agency following the framework outlined in the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

c. work with the IRE to assess the risks and benefits of the proposed research and to develop a risk-benefit assessment and draft risk mitigation plan.

d. submit the risk-benefit assessment and draft risk mitigation plan to the federal funding agency.

e. conduct the research in accordance with the provisions identified in the risk mitigation plan approved by the federal funding agency.

f. provide annual progress reports for DURC research and semiannual progress reports for PEPP research, and as requested by the federal funding agency, for review, evaluation, assessment, and, where necessary, clarification or confirmation.

g. provide all lab personnel (e.g., co-investigators, and those under the supervision of laboratory leadership including students, postdoctoral fellows, research technicians, laboratory staff, visiting scientists, and volunteers) participating in research applicable to this policy with initial and maintenance education and training on all research oversight policies and processes, and have requirements for demonstrated competency from such personnel.

5.0 Procedures

During planning of a research project, while performing experiments for active projects, and during development of a proposal, the principal investigator (PI) shall first assess the research to identify if it (1) uses one or more of the agents or toxins listed in Sections 5.1.1 or 5.2.1 of this policy, and (2) involves, or can be reasonably anticipated to result in, one or more of the experimental outcomes or actions listed in Sections 5.1.2

or 5.2.2. If it is determined that the research meets the definition of Category 1 or Category 2 research, the following will occur, as applicable.

(i) For a proposal, the PI will submit the proposal to the federal funding agency including notification that the research may be within the scope of Category 1 or Category 2.

(ii) For a proposal, the federal funding agency will notify the institution after they have completed the merit review of the proposed research and are considering funding the research.

(iii) For research at any point, the PI will submit an application to the IRE to review the research and to confirm if the proposed or ongoing research is within the scope of Category 1 or Category 2 research.

(iv) The institution will notify the federal funding agency of the results of the IRE review within 30 days, and the federal funding agency will evaluate the assessment to verify the determination.

(v) If within the scope of Category 1 or Category 2 research, a risk-benefit assessment and draft mitigation plan will be developed for the conduct and communication of the research. The assessment and mitigation plan are submitted to the federal funding agency within 90 days of (iv).

(vi) The federal funding agency will review the assessment and mitigation plan following the framework outlined in the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and other federal and state laws and regulations.

5.1 Category 1 Research

Category 1 research is subject to oversight by Virginia Tech and the federal funding agencies. If any research meets the definition of both Category 1 and Category 2, it is designated as Category 2.

Category 1 research meets the following criteria:

(i) it involves one or more of the biological agents or toxins listed in Section 5.1.1 of this policy;

(ii) it is reasonably anticipated to result, or does result, in one or more of the experimental outcomes or actions listed in Section 5.1.2 of this policy; and,

(iii) it has been assessed by the Virginia Tech IRE or federal funding agency to constitute DURC as described in Section 5.1.3 of this policy.

5.1.1 Biological Agents and Toxins within the Scope of Category 1 Research

For detailed lists of agents and toxins, refer to the Federal Select Agent Program list, Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), and Appendix C of the Implementation Guidance for the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

(i) All Select Agents and Toxins listed in 9 CFR 121.3-121.4, 42 CFR 73.3-73.4, and 7 CFR 331.3, and regulated by USDA or HHS

(ii) All Risk Group 4 Pathogens

(iii) A subset of Risk Group 3 Pathogens

(iv) All agents required or recommended to be handled using BSL/ABSL/ACL-3 or BSL/ABSL/ACL-4

(v) Biological agents stated as meeting the definition of Category 1 by federal or state guidelines, regulations, or laws.

5.1.2 Category 1 Research Experimental Outcomes

(i) Increases the transmissibility of a pathogen within or between host species.

(ii) Increases the virulence (e.g., ability to cause disease) of a pathogen or convey virulence to a non-pathogen.

(iii) Increases the toxicity of a known toxin or produces a novel toxin.

(iv) Increases the stability of a pathogen or toxin in the environment or increases the ability to disseminate a pathogen or toxin.

(v) Alters the host range or tropism of a pathogen or toxin.

(vi) Decreases the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods.

(vii) Increases resistance of a pathogen or toxin to clinical or veterinary prophylactic or therapeutic interventions

(viii) Alters a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin.

(ix) Enhances the susceptibility of a host population to a pathogen or toxin.

5.1.3 Category 1 Research Risk Assessment

The following information is further defined and detailed in the *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

Based on current understanding, the research can be reasonably anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

5.2 Category 2 Research

Category 2 research is subject to oversight by Virginia Tech, the federal funding agencies, and their federal department if applicable. This research has a heightened potential for biosafety and biosecurity risks.

Category 2 research meets the following criteria:

(i) it involves, or is reasonably anticipated to result in, a Potential Pandemic Pathogen (PPP) as described in Section 5.2.1 of this policy;

(ii) it is reasonably anticipated to result, or does result, in one or more of the experimental outcomes or actions listed in Section 5.2.2 of this policy; and

(iii) It has been assessed by the Virginia Tech IRE or federal funding agency that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a threat to public health, the capacity of health systems to function, or national security as described in Section 5.2.3 of this policy.

5.2.1 Biological Agents and Toxins within the Scope of Category 2 Research

A Potential Pandemic Pathogen (PPP), or any pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP.

Examples of the types of pathogens that, with enhancement, could potentially be considered Category 2 research are provided in the *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

5.2.2 Category 2 Research Experimental Outcomes or Actions

The following information is further defined and detailed in the *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

(i) Enhances transmissibility of the pathogen in humans

(ii) Enhances the virulence (e.g., ability to cause disease) of the pathogen in humans

(iii) Enhances the immune evasion of the pathogen in humans (e.g., modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection)

(iv) Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP. Current eradicated and extinct pathogens include Variola major, Variola minor, and 1918 H1N1 Influenza virus.

5.2.3 Category 2 Research Risk Assessment

The following information is further defined and detailed, with additional guidance and examples, in the *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*.

Research can be considered to be Category 2 if the research can 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.

6.0 Definitions

Dual use research – Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies, or products that could be utilized for both benevolent and harmful purposes.

Life Sciences – The study of life sciences pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

Life sciences dual use research of concern – 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.

Institutional Biosafety Committee (IBC) – The IBC is a compliance oversight committee required by the *NIH Guidelines* charged with the review and approval of activities involving the use of recombinant and synthetic nucleic acid molecules, and other biohazardous materials, at Virginia Tech facilities.

Institutional contact for dual use research (ICDUR) – The ICDUR is the individual designated by Virginia Tech to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC and PEPP as well as the liaison, as necessary, between Virginia Tech and the relevant federal funding agency.

Institutional Review Entity (IRE) – The IRE is a committee established by Virginia Tech and empowered to execute the requirements, as described in the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. The IBC has been designated as the IRE for Virginia Tech.

Principal Investigator (PI) – The PI is an individual(s) who has been designated by Virginia Tech to direct a project or program and who is responsible to the federal funding agency or Virginia Tech for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within a single or multiple institution(s).

United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential – The "*USG DURC/PEPP Policy*" specifies the definition of DURC and PEPP, and the responsibilities of Institutions, researchers and USG funding agencies involved in life sciences research.

Pathogen with enhanced pandemic potential (PEPP) – PEPP is 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.

Pathogen with pandemic potential (PPP) – PPP is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease or mortality in humans. They are often pathogens with little to no pre-existing immunity in the human population.

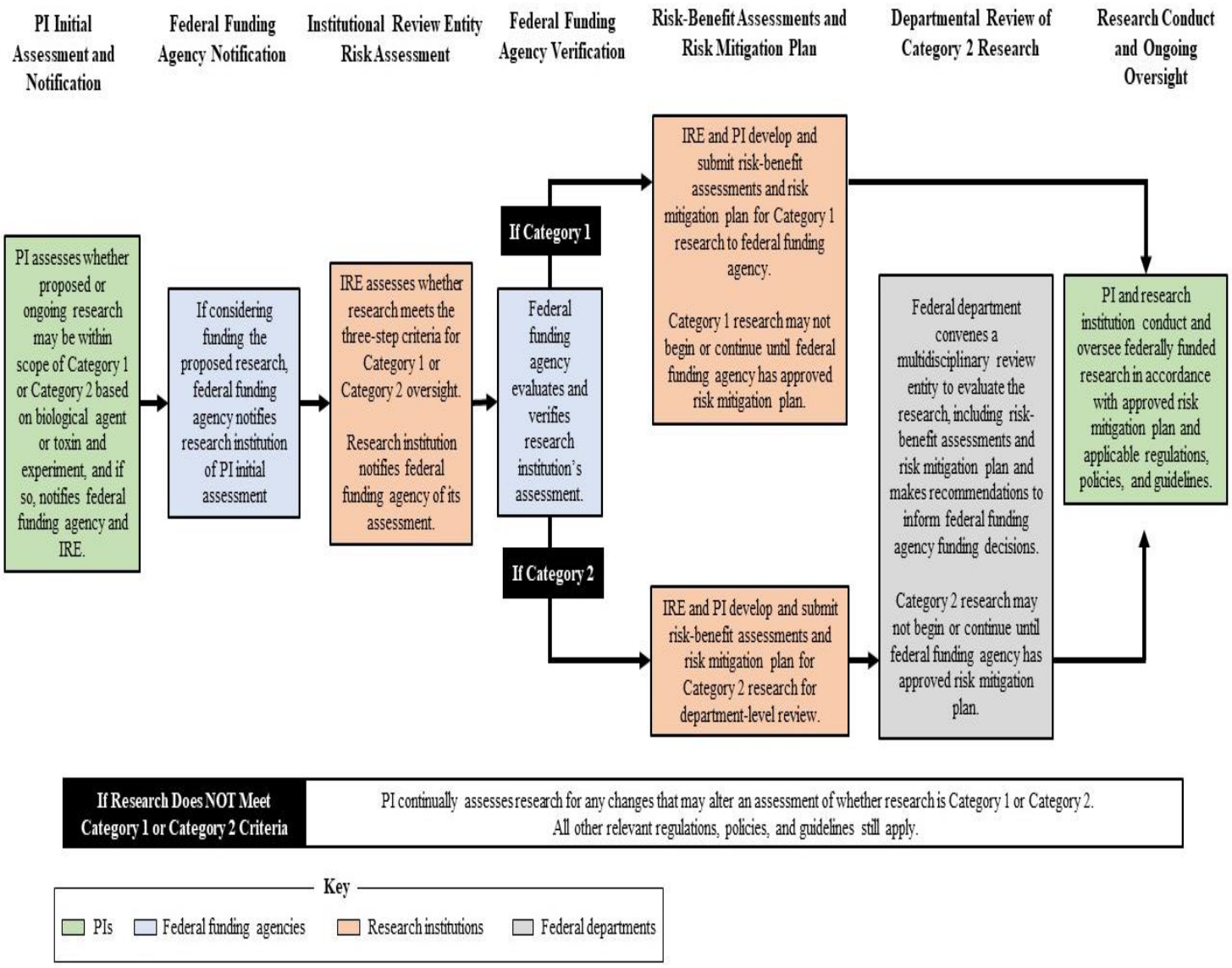
7.0 References

The United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. The policy can be downloaded from the U.S. Government Office of Science and Technology Policy website. The Virginia Tech IBC office (ibc@vt.edu) also maintains a copy of the policy.

Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. The guidance document can be downloaded from the U.S. Government Office of Science and Technology Policy website. The Virginia Tech IBC office (ibc@vt.edu) also maintains a copy of the document.

8.0 Appendix A

Figure 1. *United States Government Policy for Oversight of Dual Use Research of Concern* and Pathogens with Enhanced Pandemic Potential: An overview of the review process for Category 1 and Category 2 research.



9.0 Approval and Revisions

Approved September 25, 2015 by Interim Vice President for Research, Dr. Dennis Dean.

- Revision 1
  - Technical updates for titles.
  - Section 2.2.3: Clarified IBC and IRE meetings are held independently.

  Recommended November 13, 2019 by Director, IBCP and IBC Administrator, Regina Allen.

  Approved November 22, 2019 by Vice President for Policy and Governance, Kim O'Rourke.

- Revision 2

  This policy was completely revised to align with the May 6, 2024 United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, effective May 6, 2025.

  Approved May 5, 2025 by Senior Vice President for Research and Innovation, Dan Sui.