Utah State University Summary: Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) in Research Summary of Federal Policy Document

Purpose
The purpose of this United States Government (USG) policy is to outline Utah State University's (USU) plan for identification, review and oversight of research that may fall into the categories of Dual Use Research of Concern (DURC), Pathogens with Pandemic Potential (PPP) or Pathogens with Enhanced Pandemic Potential (PEPP).

Covered Parties
This policy applies to all University Principal Investigators (PI) engaged in or proposing research with DURC identified biological agent or toxins (see list of Category 1 agents below) that provides knowledge, information, products or technologies that could be misapplied to do harm. This policy also applies to PI conducting research with agents that enhance a pathogen's transmissibility, virulence or disrupts the effectiveness of pre-existing immunity.

PI Responsibilities
The PI makes an initial assessment of whether their proposed or ongoing research may be within the scope of Category 1 research (see Category 1 research criteria and experiments below), and/or Category 2 (see Category 2 research criteria and experiments below). If the PI initial assessment indicates the research could be within the scope of Category 1 and/or 2, research they will make an initial report to the University's Biological Safety Officer (BSO) and Institutional Biosafety Committee (IBC). For new proposed research this assessment will be made through the Service Now IBC protocol review/approval system. If the research involves DURC or PEPP the PI must also work to ensure that an appropriate risk mitigation plan is in place. A PI working with BSL-2, Risk Group (RG)-3 or RG-4 infectious agents must review Category 1 and 2 agents and experiments for DURC/PEPP involvement. A PI working with BSL-2 RG-2 agents must review Category 2 agents and experiments for DURC/PEPP involvement.

Regulatory Background.
In May 2024, the Federal government issued the "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" (https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf referred to as "the USG Policy" herein). They also issued an accompanying implementation guidance document, https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf. The USG policy requires funding agencies and institutional oversight of DURC and PEPP including policies, practices, and procedures to ensure this research is identified and risk mitigation measures must be implemented, where applicable. This USG policy was enacted as a unified federal oversight framework for conducting and managing certain types of federally funded life sciences research on biological agents and toxins. DURC/PEPP research is now grouped into two separate categories (Category 1 and Category 2). This 2024 USG policy supersedes the previous 2012 USG policies and guidance on DURC, the 2014 USG policy for Institutional Oversight of DURC that covered research using 15 specific agents, and the 2017 Recommended Policy Guidance for Potential Pandemic Pathogen Care and Oversight (P3CO) that covered research on highly transmissible, virulent agents.

Scope
This USG Policy applies to federal departments and agencies that fund or sponsor intramural or

extramural research at research institutions in the United States and internationally with biological agents or toxins where the research is within “Category 1” or “Category 2” under this USG Policy

Definitions

Biological agents - are any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), infectious material, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious material, capable of causing:

- Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
- Deterioration of food, water, equipment, supplies, or material of any kind; or
- Deleterious alteration of the environment.

Biosafety - is the application of practices, controls, and containment infrastructure that reduces the risk of unintentional exposure to, contamination with, release of, or harm from pathogens, toxins, and other associated biological materials.

Biosecurity - is the application of security measures designed to prevent the loss, theft, misuse, diversion, unauthorized possession or material introduction, or intentional release of pathogens, toxins, biological materials, and related information and/or technology.

Dual use research - is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

Dual use research of concern (DURC) - is life sciences research that, based on current understanding, can be reasonably anticipated to 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, materiel, or national security.

Federal funding agency - is a federal department, agency, institute, center, or office that funds or sponsors intramural or extramural research at research institutions in the United States or internationally, with biological agents or toxins where the research is within Category 1 or Category 2 under this USG Policy, as described in Section 4.

Pathogen with enhanced pandemic potential (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) - is 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.

Principal investigator (PI) - is the senior/key person seeking or receiving federal research and development funding (i.e., extramural funding). This includes researchers at federal agency laboratories and facilities, as well as researchers at government-owned, contractor operated laboratories and facilities (i.e., intramural researchers, whether or not federally employed). There may be more than one PI on a research grant or project within a single or multiple institution(s).

Reasonably anticipated - describes an assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur with a non-trivial likelihood. It does not require high confidence that the outcome will definitely occur but excludes experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely.

Categories of Research Subject to This USG Policy: Category 1, Category 2

Category 1 Research

Category 1 research meets all the following three criteria:

1. Involves one or more of the biological agents or toxins within scope of Section 4.1.1 of the USG Policy. https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf. (a summary of the Biological Agents and Toxins within the scopes of Category 1 are listed below)
    a. 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 and/or HHS.
    b. All Risk Group 4 pathogens listed in Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).
    c. A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines - Classification of Human Etiologic Agents on the Basis of Hazard.
    d. For biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines, refer to the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). In such cases, agents affecting humans that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL guidance are subject to this Policy.
    e. Biological agents added during future updates to the Implementation Guidance as specified in Sections 7 and 8.
2. Is reasonably anticipated to result, or does result, in one or more of the experimental outcomes listed in Section 4.1.2 of the USG Policy (pdf); and
3. Based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC, as specified in Section 4.1.3 of the USG Policy (pdf).

Category 1 Experiments

- Increase transmissibility of a pathogen within or between host species;
- Increase the virulence of a pathogen or convey virulence to a non-pathogen;
- Increase the toxicity of a known toxin or produce a novel toxin;

- Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin;
- Alter the host range or tropism of a pathogen or toxin;
- Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
- Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
- Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; or
- Enhance the susceptibility of a host population to a pathogen or toxin.

Category 1 Viruses and Prions

- African swine fever virus
- Alphaviruses (Togaviruses) - Group A Arboviruses
    - Chikungunya virus except the vaccine strain 181/25
    - Semliki Forest virus
    - St. Louis encephalitis virus
- Arenaviruses
    - Flexal virus
    - Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
- Avian influenza virus [included here as a veterinary select agent in 9 CFR 121.3. Low pathogenicity strains are excluded]
- Bunyaviruses
    - Hantaviruses, including Hantaan virus
- Classical swine fever virus
- Coronaviruses
    - Middle East respiratory syndrome coronavirus (MERS-CoV)
- Crimean-Congo hemorrhagic fever virus
- Eastern equine encephalitis virus
- Ebolavirus
- Flaviviruses - Group B Arboviruses
    - Japanese encephalitis virus except strain SA 14-14-2
    - Koutango virus
    - Louping Ill virus
    - Murray Valley encephalitis virus
    - Powassan virus
    - Rocio virus
    - Wesselsbron virus
    - West Nile virus
    - Yellow fever virus
- Foot-and-mouth disease virus
- Goat pox virus
- Hemorrhagic fever agents and viruses as yet undefined
- Hendra virus
- Herpesvirus simiae (herpes B or monkey B virus)
- Lassa fever virus
- Lujo virus
- Lumpy skin disease virus

- Marburg virus
- Mpox virus Clade I
- Mpox virus clade I/II chimeric viruses resulting from any deliberate manipulation of clade II to incorporate nucleic acids coding for clade I virulence factors
- Newcastle disease virus
- 1918-1919 H1N1 including reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- Nipah virus
- Orthomyxoviruses
    - Human influenza A virus H2N2 (1957-1968)
    - Highly pathogenic avian influenza A virus H5Nx strains within the Goose/Guangdong/96-like H5 lineage (e.g., H5N1, H5N6, H5N8, etc.)
- Peste des petits ruminants virus
- Prions
    - Transmissible spongiform encephalopathy (TSE) agents (e.g., Creutzfeldt-Jakob disease and kuru agents)
- Rift Valley fever virus
- Rinderpest virus
- Severe acute respiratory syndrome coronavirus (SARS-CoV) SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
- Sheep pox virus
- South American Haemorrhagic Fever viruses
    - Chapare virus
    - Guanarito virus
    - Junín virus
    - Machupo virus
    - Sabía virus
- Swine vesicular disease virus
- Tick-borne encephalitis complex (flavi) viruses
    - Absetterov
    - Central European encephalitis
    - Far Eastern subtype
    - Hanzalova
    - Hypr
    - Kyasanur Forest disease virus
    - Kumlinge
    - Omsk hemorrhagic fever virus
    - Siberian subtype
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- Venezuelan equine encephalitis virus

Category 1 Bacteria

- *Bacillus anthracis*
- *Bacillus anthracis* Pasteur *strain*
- *Bacillus cereus* Biovar *anthracis*

- *Bartonella*
- *Brucella* including *B. abortus, B. melitensis, B. Suis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- *Clostridium botulinum* and neurotoxin-producing species *of Clostridium*
- *Coniothyrium glycines*
- *Coxiella burnetii*
- *Francisella tularensis*
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- *Orientia tsutsugamushi*
- *Pasteurella multocida* type B -"buffalo" and other virulent strains
- *Ralstonia solanacearum*
- *Rathayibacter toxicus*
- *Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R, siberica, R. typhi (R.mooseri)*
- *Sclerophthora rayssiae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*
- *Yersinia pestis*

Category 1 Risk Assessment
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.

Category 2 Research
Category 2 research meets all of the following three criteria:
- Involves, or is reasonably anticipated to result in, a PPP as specified in Section 4.2.1 of the USG Policy (pdf);
- Is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified in Section 4.2.2 of the USG Policy (pdf); and
- Based on current understanding, the research institution, federal funding agency, and/or Departmental multidisciplinary review entity assesses 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 significant threat to public health, the capacity of health systems to function, or national security as specified in Section 4.2.3 of the USG Policy (pdf).

Category 2 Experiments - Research within the scope of Category 2 are those experimental outcomes or actions with a pathogen outlined in the USG Policy (pdf) that are reasonably anticipated to:
- Enhance transmissibility of the pathogen in humans;
- Enhance the virulence of the pathogen in humans;
- 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;

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

Category 2 Risk Assessment
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. See the Implementation Guidance for additional guidance, including illustrative examples.

IBC Responsibilities
The IBC reviews protocols and identifies research that may fit into Category 1 and/or Category 2 Research; this includes review of the initial protocol and any amendments that may change the category of the research in accordance with this policy. The IBC also works with the PI to ensure appropriate risk mitigation measures are in place.

Letter to PI requesting declaration of their currently approved research

To: Principal Investigator

From: Lisa Berreau, Vice President for Research
Brian Gowen, Chair USU Institutional Biosafety Committee
Ryan Jackson, Vice Chair USU Institutional Biosafety Committee

Subject: United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Compliance

I have reviewed the DURC/PEPP policy in relation to my approved research objectives for DURC/PEPP involvement and compliance:

_____ My research does not meet the requirements of Government DURC and PEPP Policy

_____ My research may meet the requirements of the Government DURC and PEPP Policy

_____ My research meets the requirements of the Government DURC and PEPP Policy

Signature	
Print Name	
Date	

Note: This completed message with be attached to you Service Now IBC protocol.

Addition of DURC and PEPP to IBC Service Now

Do your proposed research activities:

Question 2: Involve Infectious Agents?

Drop Down Box YES NO

Note for Steve: If Yes Boxes 2a-2d

Question 2a
If yes, List Infectious agents that will be used in this protocol

Fill in Box

Question 2b
Please indicate the proposed Biosafety Level

Biosafety Level	Yes/No
BSL-2	
ABSL-2	
BSL-3	
ABSL-3	

Note for Steve: This can be a drop-down menu

Question 2c
Include a select agent(s) found on the CDC/USDA list?

Fill in Box

Link: Select Agents List:

Question 2d
Will Research Require DURC and/or PEPP Approval and Oversight

Drop Down Box YES NO

Link to: Government Dual Use Research of Concern (DURC) and Pathogens with Enhance Pandemic Potential Policy

Link to: Summary of DURC Policy