Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) in Research

1. Purpose

This policy aims to implement the US Government's guidelines for overseeing Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP). 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" (pdf) and an accompanying implementation guidance document (pdf). This policy requires that funding agencies and institutions oversee DURC and PEPP, including policies, practices, and procedures to ensure this research is identified and risk mitigation measures are implemented, where applicable. This policy establishes a framework for managing, overseeing, and reviewing specific types of federally funded life sciences research involving biological agents and toxins, categorizing the research into Category 1 and Category 2.

2. Applicability

This policy applies to all individuals engaged in potential DURC or the creation or use of a Pathogen with Pandemic Potential (PPP) or Pathogen with Enhanced Pandemic Potential (PEPP) at or under the auspices of the University of South Alabama that involve biological agents and toxins classified as "Category 1" or "Category 2" (*See Section 4*) per the National Science and Technology Council's "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" (pdf) policy.

The policy applies to research funded or sponsored by grants, contracts, cooperative agreements, and other agreements and transactions **issued on or after** May 6, 2025.

3. Definitions

The USA adopts the definitions provided in the US Government Policy as follows:

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 defined as 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, crops and other plants, animals, the environment, materiel, or national security.

Dual Use Research of Concern Committee (DURCCom*m*) is defined as the Institutional Review Entity (IRE) for research that may meet the criteria of Category 1 or 2.

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.

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 circulating in or recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

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.

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

4. Policy Guidelines

Categories of Research Subject to This Policy

Two (2) categories of research, experiments, and risk assessment fall within the scope of this policy:

4.1 Category 1 Research

Category 1 research meets all the following three (3) criteria:

- Involves one or more of the biological agents or toxins within the scope of Section 4.1.1 of the US Government Policy (pdf);
- Is reasonably anticipated to result, or does result, in one or more of the experimental outcomes listed in Section 4.1.2 of the US Government Policy (pdf); and
- 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 US Government Policy (pdf).

4.1.1 Category 1 Experiments (Section 4.1.2 of the US Government Policy)

Research within the scope of Category 1 is experimental outcomes with a biological agent or toxin outlined in the US Government Policy (pdf) that are reasonably anticipated to:

- 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.

4.1.2 Category 1 Risk Assessment (Section 4.1.3 of the US Government Policy)

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 harm with no — or only minor — modification to pose a significant threat with potential consequences to public health and safety, crops and other plants, animals, the environment, material, or national security.

4.2 Category 2 Research

Category 2 research meets all the following three (3) criteria:

- Involves, or is reasonably anticipated to result in a PPP as specified in Section 4.2.1 of the US Government 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 US Government 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 US Government Policy (pdf).

4.2.1 Category 2 Experiments

Research within the scope of Category 2 is experimental outcomes or actions with a pathogen outlined in the US Government 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.

4.2.2 Category 2 Risk Assessment (Section 4.2.3 of the US Government Policy)

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.

4.3 Responsibilities

4.3.1 Principal Investigator

- Be knowledgeable about and comply with all USA and US Government policies, requirements, and regulations for the oversight of biological agent and toxin research.
- Investigators proposing to work with (or generating) any replication-competent infectious agent, or proposing to work with any biologically derived toxin (in IBC oversight), must make an initial assessment of whether the research is **reasonably anticipated** to be within the scope of Category 1 or Category 2 research. This self-assessment should happen at (1) the proposal stage when seeking funding and (2) during ongoing research (continuously throughout the research lifecycle).
- Submit an IBC protocol for any research involving infectious agents, recombinant or synthetic nucleic acid molecules, select toxins (at any quantity), and/or human materials using the online IRBNet system. As part of the normal IBC registration process, all protocols are reviewed for potential Category 1 or 2 research and referred to the IRE as needed.
- If an Investigator identifies potential Category 1 or Category 2 research at the proposal stage, notify the federal funding agency and the USA Biosafety Office and be prepared to develop a risk-benefit assessment and a risk mitigation plan. If research is first identified as potentially within the scope of Category 1 or Category 2 during experimentation, halt further work and work with the Institutional Review Entity (DURCCom) to develop the risk-benefit assessments and risk mitigation plan for submission to the federal funding agency for further review and approval to continue.
- Investigators must ensure that laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting life sciences research falling under the scope of this policy have received education and training on DURC.
- If research is being proposed as part of a new funding proposal, the federal funding agency (if applicable) will require submission of the risk-benefit assessment and draft risk mitigation plan once the proposal is under consideration for funding. Agencies will give a 30-day deadline, so it is highly recommended that you submit potential Category 1 or Category 2 Research proposals to the IBC as early as possible and not wait until you are notified that the documents are needed.

4.3.2 Institutional Biosafety Committee (IBC)

- The IBC reviews protocols and identifies research that could be classified under Category 1 or Category 2. This includes reviewing the initial protocol and any amendments that may alter the research category according to the established policy. The IBC forwards research within Category 1 or 2 to DURCCom for their review.

4.3.3 Dual Use Research of Concern Committee (DURCCom)

DURCCom is the Institutional Review Entity (IRE) that confirms when research meets the criteria of Category 1 or Category 2 and develops the associated Risk Mitigation Plans. Criteria for the DURCCom include the following:

- Be composed of at least five (5) members;
- Execute the functions described in this policy;
- Include persons with sufficient expertise to assess the potential of the range of relevant life sciences research;
- Include persons with sufficient expertise to assess whether the research meets Category 1 or Category 2, and evaluate its risk and mitigation efforts;
- Recuse any member who is involved in the research and who has a conflict of interest; and

- Engage in dialogue with the Principal Investigator of the research when conducting a risk assessment and developing a risk mitigation plan.

4.3.3.1 DURCCom Membership

A Subcommittee of the IBC has been established to determine whether the research meets Criteria 1 or 2 and to review and approve such research.

- IBC Chair
- LID Director
- Two (2) faculty representatives in scientific and technology fields (these faculty are not otherwise represented above, e.g., IBC Chair or LID Director).
- Export Control Officer (Office of Research Compliance)
- IACUC/IBC Administrator

5. Procedures

5.1 Meeting Schedule

Subcommittee meetings are scheduled as needed to review research that may meet Category 1 or 2 criteria and their corresponding risk mitigation plans.

5.2 DURCCom Review Process

5.2.1 Screening for Categories 1 or 2 Research

DURCCom has developed specific screening questions incorporated in the IBC protocol application; these questions are based on the categories of experiments listed above in Section 6. The IBC office is responsible for initial screening of IBC protocol applications to identify whether the PI has marked "Yes" to any of the screening questions or whether the research may meet the criteria of Categories 1 or 2. When the answer to any of the screening questions is "Yes" or when the research utilizes nonattenuated forms of one or more of the listed agents or toxins, the IBC Office will forward the protocol to the DURCCom subcommittee, which will review the application and determine whether the study may meet criteria for Categories 1 or 2 and require full DURCCom review. The IBC may also forward applications to the DURCCom subcommittee, where the PI may have replied 'no' to all questions, if the IBC believes the study meets Categories 1 or 2 definitions and should be reviewed by DURCCom.

5.2.2 Review of Criteria 1 and 2

Stage 1: The DURCCom subcommittee will determine whether the research falls under Category 1 or Category 2 and requires a full DURCCom review, following the process outlined below:

- If the subcommittee determines that the research does not meet the criteria of Category 1 or 2, the IBC staff will communicate this determination to the PI in writing, ordinarily within 5 business days of the meeting. The IBC staff will notify the PIs that they are expected to continue to assess their research for any changes that may alter this status at least annually. The PI shall notify the IBC immediately if there is a potential for the research project to change in any way that may affect the research category. The PI may also communicate these changes to the IBC via amendments and/or protocol renewals. If the subcommittee

determines that the research meets the criteria of Category 1 or 2, it will be referred to the DURCCom full committee.

Stage 2: When the subcommittee determines that the research meets Category 1 or 2 definition, the full DURCCom will review according to the established criteria and develop a risk mitigation plan.

When DURCCom determines that Criteria 1 or 2 are met, the IBC staff will arrange a meeting between the DURCCom Chair and other designated DURCCom members, the PI, and appropriate University officials (e.g., Deans, Provosts, AVPRC) to discuss the research in more detail, including the security aspects. Internal experts (e.g., other researchers, security experts), and external experts (e.g., National Science Advisory Board for Biosecurity) may also be consulted for advice on the development of the security management which may include limiting access to the research protocol, limitation of information that will be publicly disclosed (e.g., in publications, presentations at scientific forums), and potentially curtailing certain aspects of the research. For research projects that meet the criteria of Category 1 or Category 2, these components must not be initiated until an approved risk mitigation plan is in place.

5.3 Education and Outreach

Specific training and oversight will be made available for those who engage in research using one or more of the listed agents and toxins or research that the DURCCom has otherwise determined to meet the criteria of Category 1 or Category 2. Depending on the research, additional training may be required, as determined by the DURCCom.

5.4 Report to Federal Funding Agency (or NIH- Designated Agency for Non-Federally Funded Research)

Within thirty (30) calendar days of the DURCCom review, the XXXXX will notify the Federal funding agency of any research that involves one or more of the listed agents, one or more of the listed experimental effects, and whether the research meets or does not meet the criteria of Category 1 or Category 2. For non-Federally funded research, notification will be made to NIH, which may refer the notification to an appropriate Federal or local agency, based upon the nature of the research.

5.5 Risk Mitigation Plan

For research that involves one or more of the listed agents and toxins and one or more of the listed experimental effects and meets the criteria for Category 1 or Category 2, the DURCCom shall work with both the PI and the Federal funding agency, or for non-Federally funded research the NIH-designated Federal agency, to develop a risk mitigation plan. Within ninety (90) calendar days of the DURCCom's determination that the research meets the criteria of Category 1 or Category 2, the PI shall provide the draft risk mitigation plan to the appropriate federal agency for final review and approval. Federal agencies must provide an initial response within thirty (30) calendar days and should finalize the plan within sixty (60) calendar days of receipt of the draft plan.

5.5.1 Developing a Draft Risk Mitigation Plan

DURCCom shall conclude its risk-benefit assessment of the research in Category 1 or 2 by developing a draft risk mitigation plan in consultation with the PI. The plan should indicate the associated risks identified by DURCCom, the specific risk mitigation measures to be employed, and how these measures address the identified risks.

The DURCCom should consider the strategies outlined below in Section XXX in development of the most effective risk mitigation measures.

- Determine whether existing biosafety and biosecurity measures are adequate.
- Evaluate the applicability of existing countermeasures.
- Develop a plan for responsible communication of the findings of the relevant research category.
- Educate, develop, and train research staff using available educational tools, including seeking specific expertise in creating training.
- Develop a plan for monitoring the research.
- Do not conduct certain aspects of the research.

For details about each strategy, please refer to Section F on Guidance for Institutional Review Entities: Drafting Risk Mitigation Plans of the US Government Policy (pdf).

5.5.2 Implementation and Monitoring of the Risk Mitigation Plan

After a risk mitigation plan is developed and approved by the relevant Federal agency, the research must be conducted according to that plan. DURCCom shall review all risk mitigation plans at least annually and modify them as needed. Plans that need modification require approval by the relevant federal agency before implementation.

Research that initially met the definition of Category 1 or 2 may progress so that it no longer meets these criteria. Therefore, it is critical that the PI and the DURCCom maintain active communication and continuously review the research progress.

5.6 Export Controls and DURC

Export Controls are Federal government regulations on the transfer of controlled materials, items, software, or technologies abroad or to non-U.S. Persons in the United States. They are outlined mainly in three sets of regulations: the Export Administration Regulations (EAR) administered by the Bureau of Industry and Security, Department of Commerce, the International Traffic in Arms Regulations (ITAR) administered by the Directorate of Defense Trade Controls, Department of State, economic and trade sanctions administered by the Office of Foreign Assets Controls and the Treasury Department. PIs shall review USA's Export Control Compliance Policy in conjunction with this policy.

Under certain circumstances, Category 1 or 2 may involve items, materials, data, or services developed for military use and controlled under the International Traffic in Arms Regulations (ITAR). ALL research with materials, items, or data enumerated on the U.S. Munitions List (USML) requires a Technology Control Plan and license authorization for non-U.S. Persons. Therefore, PIs shall consult the Export Control Officer before researching materials that could have been developed for military use.

Note: Identification of Category 1 or Category 2 research has no direct bearing on whether or not an export license is required. However, specific risk mitigation measures (e.g., the imposition or acceptance of restrictions on publication) MAY affect whether the research is subject to export authorization requirements.

5.7 Recordkeeping

For each research project that is categorized meeting the criteria of Category 1 or 2 under this policy, the DURCCom shall maintain records of the review(s) and approved risk mitigation plan(s) for the term of the research grant or contract plus three (3) years after its completion, but no less than seven (7) years, unless a shorter period is required by law, regulation or sponsor requirement. DURCCom shall also maintain records of the researchers' education and training for the term of the research grant or contract, plus three (3) years after its completion. The IACUC/IBC Administrator will maintain records of DURCCom subcommittee meetings and findings.

5.8 Enforcement

Principal Investigators must promptly report any noncompliance with this policy to the IBC. DURCCom shall review all reports of noncompliance and recommend appropriate corrective actions or modifications to existing Risk Mitigation Plans, including preventative measures to avoid recurrence. Any non-compliance determinations and risk mitigation plan changes must be reviewed and approved by the relevant federal agency.

6.0 Related Documents

NOT-OD-25-061, January, 10, 2025 - NIH Implementation of the US Govt Policy for Oversight of Use of Concern and Pathogens with Enhanced Pandemic Potential

United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Implementation Guidance for the United States Government Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

HHS and USDA Select Agents and Toxins

Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research Of Concern