NIH's Implementation of the U.S. Government Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

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On January 10, 2025, NIH published Guide Notice NOT-OD-25-061 (2025 [hereinafter cited as *"New Policy"*]) to detail its implementation of the Office of Science and Technology Policy's *U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)* (Executive Office of the President, 2024b) and the companion *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, May 2024* (Executive Office of the President, 2024a, [hereinafter cited as *"Implementation Guidance"*]). The New Policy sets forth processes for institutions and funding agencies to identify, assess, and mitigate risks associated with research that involves certain pathogens that, through misuse, could cause significant societal harm.

The New Policy (effective May 6, 2025) vastly expands the number of biological agents, toxins, and experimental categories that require institutional and agency review ("Covered Research") and places substantial new burdens on researchers, institutional biosafety review entities (IREs), and research administrators to ensure appropriate review, risk/benefit assessment, risk mitigation plan development, and communication with federal funding agencies.

Since the *New Policy's* initial publication, the American Biological Safety Association (ABSA) and the Council on Governmental Relations (COGR) have been working together to analyze its requirements and communicate with NIH and the Office of Science and Technology Policy to learn more and to alert them to questions and concerns.

Although the *New Policy* applies to all federal agencies that conduct or fund Covered Research, institutions have been especially eager to see NIH's implementation plan because it funds the bulk of Covered Research. This article focuses on NIH's implementation by discussing the *New Policy's* expanded scope and requirements and proposing a possible team approach to implementation.

The New Policy's Expanded Scope

The *New Policy* and *Implementation Guidance* supersede the "Federal DURC Policy" (Executive Office of the President of the United States, 2012), the "Institutional DURC Policy" (Executive Office of the President of the United States, 2014), and the "P3CO Framework" (Executive Office of the President, 2017). It combines the current U.S. government DURC and potential pandemic pathogens policies and establishes two categories of regulated research: Category 1 (DURC) research and Category 2 (PEPP) research. It prohibits federal funding for Category 1 or 2 research in the following countries of concern: North Korea, Iran, Russia, China (including Hong Kong and Macau), Cuba, Syria, and Venezuela.

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Category 1 research encompasses a vastly expanded number of biological agents and toxins and additional categories of experimental outcomes. Significantly, the *New Policy* requires institutional review of research that uses Select Toxins in amounts below certain thresholds which current DURC policies exclude from review (see, e.g., Possession, Use, and Transfer of Select Agents and Toxins [2005a]; Possession, Use, and Transfer of Select Agents and Toxins, [2005b]; Select Agents and Toxins, [2005]; HHS Select agents and Toxins [2005]). Similarly, Category 2 research covers more broadly defined categories of biological agents/toxins and experimental outcomes. Accordingly, institutional IREs can expect a substantial increase in the protocols for which they are required to perform at least an initial evaluation. The *New Policy* details review processes, roles and responsibilities; risk-benefit assessment; and mitigation requirements and requires institutions to make their review processes publicly available. It continues the current requirement that institutions establish an IRE (which may be the Institutional Biosafety Committee) and name an Institutional Contact for Dual Use Research (ICDUR) – an individual designated to serve as the institution's internal resource and funding agency liaison regarding DURC/PEPP. However, the IRE and ICDUR have increased responsibility under the *New Policy*.

NIH Notice Requirements

NIH will apply the *New Policy* to all new and existing NIH-funded research. It also 'strongly encourages' but does not require institutions "to implement oversight of non-federally funded Category 1 or Category 2 research conducted in their institutions in accordance with the DURC/PEPP Policy" (NIH, 2025). Institutions must ensure investigators work with IREs to assess research projects at proposal and throughout the research to determine if they potentially involve Category 1 or 2 research. For new research proposals, institutions must provide this assessment to NIH at Just-in-Time. For research projects active on or after May 6, 2025, institutions must provide the assessment to NIH at the time of the next Research Performance Progress Report (RPPR) or other non-competing application.

The institution, through an Authorized Organizational Representative, must provide NIH with the following documentation as part of the assessment:

- Confirmation that the IRE reviewed the research project.
- Category determination (including any determination that the project is neither Category 1 or 2 research).
- Risk-benefit assessment of the research.
- Risk mitigation plan for Category 1 or Category 2 research.

NIH will review this documentation and refer any questions or requests for additional information to the institution's ICDUR. NIH must verify the institution's categorization and approve any risk mitigation plan before the research can proceed. Category 2 research must also be reviewed and approved by a Department of Health and Human Services departmental-level committee. After reviews are complete, the funding institute or center makes funding decisions and incorporates necessary terms and conditions in the award notice or contract. Institutions must ensure that Category 1 or 2 research is conducted in accordance with these terms and conditions and the risk mitigation plan. NIH will require funding recipients to report compliance issues and to provide annual reports for Category 1 research, semiannual reports for Category 2 research, and an annual policy compliance assurance.

A Team Approach to Institutional Implementation

The *New Policy* directs funding applicants and recipients to "develop the necessary infrastructure and personnel" to comply with the *New Policy* and begin training relevant staff its requirements. Implementation and compliance will require close cooperation and solid lines of communication between researchers, biosafety officers, IREs and research administrators.

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Given the May 6, 2025 effective date, institutions must act quickly to identify all active and upcoming federally-funded research subject to review under the *New Policy*. This includes research that was previously exempt from review under current requirements because of the small amounts of Select Toxins involved. Questions remain as to whether the NIH Notice falls under the Trump Administration's January 20, 2025 Executive Order (Executive Office of the President, 2025) which states that agencies should consider postponing until March 21, 2025, the effective date for any rules issued in order to review any questions of fact, law and policy that the rules raise. "Appendix C" of the Implementation Guidance includes a list of all regulated

biological agents and toxins. Institutional biosafety, research administration, and departmental personnel should consider working together to develop a survey to identify researchers using items on this list. Biosafety personnel can work with identified researchers to determine if their research involves covered experimental outcomes and thus requires IRE review, and survey data can be used to estimate review burden and associated personnel need and costs. IREs should consider developing requirements for expected risk-benefit assessments and risk mitigation plans.

Research, compliance, biosafety, and IRE personnel also should consider forming a team to review the *New Policy* and determine what modifications are needed for existing policies and procedures, roles and responsibilities, forms, and associated electronic systems. Institutions should consider the ICDUR's new, more detailed responsibilities and determine the appropriate administrative level for the individual filling this position.

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COGR and ABSA plan to continue their joint efforts to gather additional information about NIH and other agencies' implementation of the *New Policy* and educate their members on the policy's requirements and strategies for successful implementation.

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