NIH Policy on Mitigating Risks of Life Sciences Dual Use Research of Concern

Notice Number: NOT-OD-13-107

Update: The following update relating to this announcement has been issued:

- August 30, 2013 - See Notice NOT-OD-13-110. Notice of Clarification to NIH Policy on Mitigating Risks of Life Sciences Dual Use Research of Concern.

Key Dates

Release Date: August 28, 2013

Issued by

National Institutes of Health (NIH)

Purpose

On March 29, 2012, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC). The purpose of this Guide Notice is to implement the March 2012 policy establishing federal review of United States government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to mitigate risks where appropriate and collecting information needed to inform the development of an updated policy, as needed, for the oversight of DURC.

Background

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, agricultural crops and other plants, animals, the environment, materiel, or national security. Despite its value and benefits, some research may be misused for harmful purposes. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The policy applies to research that involves one or more of 15 listed pathogens and toxins that are being used in projects with specified experimental aims that may result in research products, technology or information that could be misused to pose particular risks. The policy requires that Federal agencies continually monitor funded research for dual use research potential. When DURC is identified, Federal agencies are to work with the institutions and investigators conducting the research to develop an appropriate risk mitigation plan.

NIH Policy

If a project is determined to be DURC a risk mitigation plan will be required. In these instances, institutions, Project Directors, and Principal Investigators will develop a plan that includes mitigation measures and procedures to implement them with the aim of minimizing the risk of misuse of the knowledge, information, products, or technologies generated by the research. If during the course of the research, the research becomes DURC, the grantee is required to inform the NIH immediately of the change in DURC status and develop a risk mitigation plan as outlined above. Risk mitigation plans must be submitted to the appropriate NIH Grants Management Officer for administrative review and approval.

A copy of the full policy and other related information may be found at: http://oba.od.nih.gov/biosecurity/bio_usg_activities.html.

Implementation

NIH will conduct an administrative review of all current and future awards to determine if they involve research that could be considered DURC. If they do, a term of award will be added requiring the institution to submit a letter from the Institutional Biosafety Committee, or another appropriate review body, indicating its assessment of the DURC status of the research proposed, including the reason for its determination, and cosigned by the institutional official. If the institution determines that the research is DURC, an assessment of the risks and benefits of the research must also be included. If an institution determines that the research is not

DURC, the IC will conduct a subsequent analysis and make a final determination.

If a final determination is made that research is DURC (either during the initial institutional review or during subsequent IC review), the institution must provide a proposed Risk Mitigation Plan within a timeframe to be negotiated with the IC. The US Government Policy for Oversight of Life Sciences Dual Use Research of Concern (http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf) lists potential risk mitigation strategies. In addition, the following NIH and National Science Advisory Board for Biosecurity (NSABB) educational materials are available from the NIH Office of Biotechnology Website to assist in the development of these plans (http://oba.od.nih.gov/biosecurity/biosecurity_educational.html).

The institutional determination that research is DURC must be reassessed at least annually and the outcome included in the annual progress report. If the planned research is determined to be DURC, consistent with the U.S. Government policy and responsibility, NIH requests that grantees share with the Program Official for review any resulting manuscripts within at least 10 business days prior to planned journal submission. NIH also requests that grantees share with the Program Official any meeting Abstracts summarizing research activities supported by this grant that are intended for presentation at scientific conferences at least 10 business days prior to anticipated submission. The scope of the research and the level of support may be adjusted upon completion of all DURC assessments and the approved Risk Mitigation Plan. Failure to comply with the DURC policy and special award term and condition may result in an enforcement action as outlined in the NIH Grants Policy Statement Section 8.5, Special Award Conditions and Enforcement Actions" available at http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch8.htm#_Toc271264977.

Inquiries

General inquiries about this Guide Notice should be directed to:

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Inquiries regarding specific grant applications or projects should be directed to the assigned Program Official of the relevant NIH Institute or Center.

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