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OFFICE OF SCIENCE AND TECHNOLOGY POLICY

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice; request for comment.

SUMMARY: The United States Government (USG) invites comments on the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The proposed Policy establishes institutional review and oversight requirements for certain categories of life sciences research at institutions that accept Federal funding for such research. These requirements are intended to address risks of dual use research not addressed under existing Federal regulations or guidelines. Requirement for compliance with this Policy, once finalized, will be incorporated by Federal funding agencies in accordance with their relevant statutory authorities, into the terms and conditions of awards with funded institutions that conduct research falling into the categories identified in the Policy. The public input provided through this Notice will inform future deliberations and issuance of a final Policy.

DATES: *Release date*: February 22, 2013. *Response date*: April 23, 2013

ADDRESSES: Comments may be submitted electronically to: durcpolicy@ostp.gov. Comments may also be mailed to: Dr. Franca R. Jones, Assistant Director - Chemical

and Biological Countermeasures, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, Washington, D.C. 20504. See SUPPLEMENTARY INFORMATION for specific information about submitting comments.

The proposed Policy is available on the U.S. Department of Health and Human Services Science Safety Security (S3) Website: http://www.phe.gov/s3/dualuse/Pages/default.aspx.

FOR FURTHER INFORMATION CONTACT: Dr. Franca R. Jones, Assistant Director - Chemical and Biological Countermeasures, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, Washington, D.C. 20504, durcpolicy@ostp.gov.

SUPPLEMENTARY INFORMATION:

Background

The United States Government (USG) invites comments on the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The proposed Policy establishes institutional review and oversight requirements for certain categories of life sciences research at institutions that accept Federal funding for such research. These requirements are intended to address risks of dual use research not addressed under existing Federal regulations or guidelines. Requirement for compliance with this Policy, once finalized, will be incorporated by Federal funding agencies in accordance with their relevant statutory authorities, into the terms and conditions of awards with funded institutions (see Applicability, Section 6.1)

that conduct research falling into the categories identified in the Policy (see Scope, Section 6.2). The public input provided through this Notice will inform future deliberations and issuance of a final Policy.

Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel[1], and national security. Life sciences research has and will continue to yield benefits, but no life sciences research comes without risk. Indeed, certain types of research that are conducted for legitimate purposes may also be utilized for harmful purposes. Such research is called "dual use research." Dual use research of concern (DURC) is a smaller subset of dual use research 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.

In general, there are risks associated with life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin. Many existing and synergistic statutes, regulations, and guidelines are in place to address risks associated with biosafety, physical security, and personnel reliability.[2] Some risks relate directly to the characteristics of DURC – the risk that knowledge, information, products, or

[1] Materiel includes food, water, equipment, supplies, or material of any kind.
[2] e.g. Select Agents and Toxins Program (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331); National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf); Biosafety in Microbiological and Biomedical Laboratories 5th Edition (http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)

technologies resulting from the research could be used in a manner that results in harm or threatens society. DURC should be evaluated for possible risks, as well as benefits, in all these domains to ensure that risks are appropriately managed and benefits realized. This proposed Policy addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that results in harm.

Given these dual use risks, the USG issued, on March 29, 2012, its Policy for Oversight of Life Sciences Dual Use Research of Concern (March 29 Policy). The March 29 Policy formalized a process of regular federal review of USG-funded or -conducted research with certain high-consequence pathogens and toxins to identify DURC and implement mitigation measures, where applicable. The goal of the March 29 Policy is to preserve the benefits of life sciences research while minimizing the risk that the knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm.

Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research. The proposed Policy herein, United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, addresses the institutional oversight of DURC, and will operate in tandem with the March 29 Policy that requires Federal agencies to implement similar measures for oversight of DURC. Oversight includes policies, practices, and procedures that are put in place to ensure DURC is identified and risk mitigation measures are implemented, where appropriate. Institutional oversight of DURC is a critical component

of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC. This proposed Policy delineates the procedures for the oversight of DURC and responsibilities of Principal Investigators, research institutions, and the USG. This proposed Policy, in addition to the March 29 Policy, emphasizes a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.[3] The components outlined in the March 29 Policy and in this Policy, once finalized, will be updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists.

Because institutional oversight of DURC will be a new undertaking for many institutions, the USG is currently limiting the requirements in this proposed Policy, as well as the March 29 Policy, to research that meets the scope in Section 6.2, which focuses on a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The USG will solicit feedback on the experience of institutions in implementing the Policy; will evaluate the impact of DURC oversight on the life sciences research enterprise; will assess the benefits and risks of expanding the scope of the Policy to encompass additional agents and toxins and/or categories of experiments; and will update the Policy, as warranted. Research institutions are

[3] The March 29 Policy and this proposed Policy are complemented by other extant laws and treaties (e.g. 18 U.S.C. 175 and the Biological and Toxin Weapons Convention) that prohibit the development, production, acquisition, or stockpiling of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and that prohibit the use of biological agents and toxins as weapons.

encouraged to be mindful that research outside of the categories articulated in this proposed Policy may also constitute DURC. Institutions have the discretion to consider other categories of research for DURC potential and may expand their oversight to other types of life sciences research as they deem appropriate.

Finally, and importantly, research that meets the definition of DURC often increases our understanding of the biology of pathogens and makes critical contributions to the development of new treatments and diagnostics, improvements in public health surveillance, and the enhancement of emergency preparedness and response efforts. Thus, designating research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated.

Nothing in this proposed Policy supersedes the Department of Health and Human Services and the United States Department of Agriculture Select Agents and Toxins Program's (SAP) statutory authority or SAP regulations as published in 42 CFR part 73, 9 CFR part 121, and 7 CFR part 331.

Specific Questions

Public comments are sought on the entirety of the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. In addition, we are seeking input on the following specific questions:

1. For institutions conducting research that involves one or more of the 15 listed agents, please describe the feasibility and anticipated burden (administrative, resources, etc.), if any, to implement the requirements of this proposed Policy. What effect, if any, do you anticipate the proposed Policy would have on your ability to support or engage in research on any of the listed pathogens or toxins?

2. Are there alternatives to the administrative requirements of this proposed Policy that could be more easily implemented by Federally-funded research institutions and that would meet the intent of this proposed Policy or the March 29 Policy? If so, please specify.

3. How could DURC oversight be usefully integrated with other existing institutional oversight processes in order to reduce duplication and any resulting excess administrative burdens on institutions?

4. For institutions who have registered an Institutional Biosafety Committee (IBC) with the NIH Office of Biotechnology Activities in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, is it feasible for the IBC to conduct the DURC institutional review process? What are the benefits or limitations of using IBCs in this role?

5. Should research that has undergone institutional DURC review but has been determined not to be DURC be monitored for emerging DURC issues? If so, how often should such review take place?

6. Is it feasible for a single individual, the Institutional Contact for Dual Use Research (ICDUR), to be the point of contact for all dual use research-related

questions to and from the funding agency? If not, who else could help fill this role?

7. The proposed Policy calls for principal investigators (PIs) to refer any research involving one or more of the 15 listed agents to an institutional dual use research review entity (Section 7.1.A). The institutional review entity will then determine whether the research can be reasonably anticipated to produce any of the seven effects, and if so, if that research meets the definition of DURC. Is it preferable to instead require PIs to determine both whether their research involves one or more of the listed agents and also whether their research can be reasonably anticipated to produce any of the listed effects? In this scenario, the institutional dual use research review entity would then only determine whether the research meets the definition of DURC. (Note: In either scenario, the institutional dual use research review entity would also then assess the risks and benefits of the research and develop a risk management plan.)

8. Is additional guidance or explanation needed for interpreting the seven effects/categories of experiments listed in Section 6.2.2?

9. The USG is developing a document that contains the following analytic tools and guidance to assist in implementation of the Policy, once finalized:

    a. Understanding and identification of DURC
    b. Assessment of risks and benefits associated with DURC
    c. Developing a risk mitigation plan for DURC
    d. Responsibly communicating DURC
    e. Training and education on DURC

Are there any additional tools or guidance documents that would be useful in implementing and complying with this Policy, once finalized?

10. We are interested in views on the optimum relationship between the March 29 Policy and this proposed Policy. Are there any conflicts or challenges posed by implementing both policies? Should research institutions review projects for DURC issues prior to proposals being submitted to a funding agency for review? (If not, funding agencies implementing the March 29 Policy will not have the benefit of input from institutional dual use review when reviewing research proposals for DURC.) If so, should the PI and/or institution designate on the grant application that such a review has taken place and indicate its findings?

11. This proposed Policy is intended to apply to projects that directly use non-attenuated forms of the 15 agents or toxins listed in Section 6.2.1 and/or use botulinum toxin at any quantity. Should the scope also include (please provide information to support your answer):

    a. The use of any of the listed 15 agents or toxins in attenuated forms;

    b. The use of the genes from any of the listed 15 agents or toxins (all genes? Only certain types of genetic information? If the latter, how could this be specified?);

    c. *In silico* experiments (e.g. modeling experiments, bioinformatics approaches) involving the biology of the listed 15 agents or toxins;

    d. Research related to the public, animal, and agricultural health impact of any of the 15 listed agents or toxins (e.g. modeling the effects of a toxin,

developing new methods to deliver a vaccine, developing surveillance mechanisms for a listed agent)?

12. Is the scope of the proposed Policy appropriate? If not, why not? Should the scope be expanded to all select agents, microbes, or all life sciences? If so, why? What factors should be considered in determining the final scope of oversight? What criteria might be used to determine what research should/should not be subject to oversight? If the Policy, once finalized, were expanded to cover other types of life sciences research (i.e. beyond the 15 listed agents), what effect, if any, would it have on your ability to conduct that research?

13. The USG recognizes that there may be some institutions that choose to expand their oversight beyond the 15 agents listed in Section 6.2.1 and/or beyond the seven categories listed in Section 6.2.2 or currently have a DURC oversight process in place that is beyond the scope of this proposed Policy. For those institutions, what additional agents or toxins, other categories of experiments, and/or other domains within the life sciences were considered for potential oversight? What impact has the expanded oversight had on the conduct and administration of the institution's life sciences research?

14. The USG recognizes that there will be situations where a PI is conducting potential DURC at multiple institutions. Should each institution have oversight of these projects and if DURC is being conducted at their institution, develop and implement risk mitigation plans? Or should the PI's primary institution have this responsibility? (Refer to "Note" following Section 7.2.K)

15. The proposed Policy requires institutions that would be subject to the proposed Policy by virtue of Federal funding, to apply the proposed Policy to non-Federally funded research. Under the proposal, institutions would submit information about DURC reviews and risk mitigation plans on non-Federally funded projects to the National Institutes of Health (which may in turn refer the results and plans to the appropriate Federal agency based upon the nature of the research). Applying the DURC policy to Federally and non-Federally funded research promotes more meaningful oversight of DURC at the institutional level and fosters uniform approaches to the responsible conduct and communication of all research that may raise DURC concerns at an institution. Is this approach feasible? If not, what is the best mechanism for structuring oversight for non-Federally funded research?
16. The proposed Policy requires institutions to maintain records of DURC reviews, risk mitigation plans, and personnel training for three years. However, grant cycles are often longer than three years and DURC communications may arise even after funding has ended. This could result in situations where important records (e.g., the risk mitigation plan) are not available at the institution for certain DURC projects. Should the record-keeping requirements for this proposed Policy be longer to allow access to records over (and beyond) the lifetime of a DURC project? What is an appropriate amount of time that institutions should be required to retain such records?

Availability of the Proposed Policy

The proposed Policy is available on the U.S. Department of Health and Human Services Science Safety Security (S3) Website: http://www.phe.gov/s3/dualuse/Pages/default.aspx.

Comment Submission

Comments may be submitted electronically to: durcpolicy@ostp.gov. Comments may also be mailed to: Dr. Franca R. Jones, Assistant Director - Chemical and Biological Countermeasures, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, Washington, D.C. 20504. In your response, please provide the following information:

Date

Name/Email/Phone Number

Affiliation/Organization

City, State

General Comments:

Comments to Specific Questions (1-16) Listed in Supplementary Information as Follows:

Comment to Question 1

Comment to Question 2

Comment to Question 3

Comment to Question 4

Comment to Question 5

Comment to Question 6

Comment to Question 7

Comment to Question 8

Comment to Questions 9

Comment to Question 10

Comment to Question 11

Comment to Question 12

Comment to Question 13

Comment to Question 14

Comment to Question 15

Comment to Question 16

You will receive an electronic confirmation acknowledging receipt of your response, but will not receive individualized feedback on any suggestions. No basis for claims against the U.S. Government shall arise as a result of a response to this request for comment or from the Government's use of such information.

Ted Wackler

Deputy Chief of Staff

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