Temple University
Guidance on Institutional Oversight of Life Sciences Dual Use Research of Concern.

I. Purpose of this Guidance

This Temple University Dual Use Research of Concern (DURC) Guidance (hereinafter, this "Guidance") complies with the NIH Guidance: NIH Implementation of US Government on Institutional Oversight of Life Sciences Dual Use Research of Concern (Notice Number: NOT-OD-15-017, release date November 21, 2014). This Guidance ensures that Temple University identifies Dual Use Research of Concern (DURC) and implements risk mitigation measures, as applicable. This Guidance sets the rules for the individuals and committees at Temple University who are responsible for the implementation of the University's requirements with respect to DURC.

II. Definitions

Dual Use Research of Concern (DURC): Broadly speaking, DURC is research conducted for legitimate purposes that can be utilized for both benevolent and harmful purposes. It is more readily 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 products of research may be misused for harmful purposes. The fundamental aim of this oversight Guidance 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.

DURC Agents: the following 15 agents and toxins referred to in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (the "2014 Policy"):

1. Avian influenza virus (highly pathogenic)
2. Bacillus anthracis
3. Botulinum neurotoxin (For purposes of this Guidance, there are no exempt quantities of botulinum
4. neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for
5. DURC potential.)
6. Burkholderia mallei
7. Burkholderia pesudomallei
8. Ebola virus
9. Foot-and-mouth disease virus
10. Francisella tularensis
11. Marburg virus
12. Reconstructed 1918 Influenza virus
13. Rinderpest virus
14. Toxin-producing strains of Clostridium botulinum
15. Variola major virus
16. Variola minor virus
17. 15. Yersinia pestis

Experimental Effects of Concern: the following 7 categories of experiments referred to in the 2014 Policy:

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
4. Increases the stability, transmissibility or the ability to disseminate the agent or toxin.
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed in the definition of DURC Agents above.

Institutional Biosafety Committee (IBC): The IBC is the institutional committee responsible for the review and oversight of recombinant DNA research and Temple University

Institutional Contact for Dual Use Research (ICDUR): The ICDUR is the individual designated by the University to be the institutional point of contact for questions relating to compliance with this Guidance and the liaison with the relevant US Government funding agencies. Mary B. Pultro, IBC Coordinator, for Temple University, has been designated as the ICDUR for purposes of this Guidance.

Institutional Review Entity (IRE): A Dual-Use Research of Concern (DURC) Subcommittee will serve as the IRE and consist of five Institutional Biosafety committee (IBC) members and/or appointed consultants, who have been fully trained to serve on the IBC and have signed an applicable confidentiality agreement. With members appointed by Temple University's Vice President for Research, the IRE is charged with identifying DURC as described by the scope of this Guidance and assess such research for the benefits and risks associated with its conduct and communication. This assessment must be performed when research (regardless of the source of funding) is identified that involves one or more of the agents and toxins listed as DURC Agents in this Guidance and such research is conducted at Temple University or its affiliate institutions.

III. Research Projects and Agents Covered by this Guidance:

This Guidance applies to all research projects, regardless of the funding source, that involve one or more of 15 listed agents or seven categories of experiments listed above. and those research projects that are conducted at Temple University or one of its affiliated subcontracting institutions. This Guidance requires that Temple University review research involving these agents to determine whether it can be anticipated to result in specified experimental effects, and if so, whether these projects constitute DURC. This Guidance specifies the responsibilities of Principal Investigators, the Institutional Contact for Dual Use Research of Concern, the Institutional Review Entity, and the grantee institution with respect to research subject to this Guidance.

This Guidance applies to all New and Renewal awards issued on applications submitted on or after January 25, 2015, and to all non-competing continuation awards issued on or after January 25, 2015. Temple University investigators conducting life sciences research subject to this Guidance have a number of responsibilities that they must fulfill, described in more detail in the context of the full NIH Policy (http://www.phe.gov/s3/dualuse, for a comprehensive listing of those requirements).

IV. Requirements for Principal Investigators

A Principal Investigator ("PI") must submit for institutional review any of his/her research that meets any of the following criteria:

- The research directly involves non-attenuated forms of one or more of the listed DURC Agents (see above);

- The research with non-attenuated forms of one of more of the listed DURC Agents that also produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern (see above); or

- The PI concludes that his/her research may meet the definition of DURC.

If a PI's research meets (or future research during the grant writing phase) any of the foregoing criteria, he/she will also assess whether the research produces, aims to produce or is reasonably anticipated to produce one of more of the Experimental Effects of Concern. Upon completion of such assessment, he/she will promptly notify the IBC by contacting the Institutional Contact for Dual Use Research (the "ICDUR") and provide the ICDUR with documentation indicating the reasons for the PI's conclusion that his/her research involves 4 potential DURC and sufficient data to permit the IBC/IRE to complete the review required by Section V below.

V. DURC Review and Reporting

The IRE, with members appointed by Temple University's Vice President for Research, is charged with identifying DURC as described by the scope of this Guidance and assess such research for the benefits and risks associated with its conduct and communication. This assessment must be performed when research (regardless of the source of funding) is identified that involves one or more of the agents and toxins listed in this Guidance and are conducted at Temple University.

DURC Evaluation, Assessment, and Reporting:

Research projects may be recommended for assessments by any regulatory committee at Temple University, including Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Institutional Review Board, Environmental Health and Safety, committee members, university faculty, and employees, If research funded by NIH is assessed by the IRE for DURC potential, the institution will be required to notify the Grants Management Official listed on the Notice of Award of the results of the IRE review process within 30 days. In instances when the research is determined to be DURC, NIH will work with the institutions and investigators conducting the research to develop an appropriate risk mitigation plan to minimize the risk of misuse of the knowledge, information, products, or technologies generated by the research. This may be implemented through a term of award. If, during the course of conducting research, the research becomes DURC, the grantee will be required to inform NIH immediately of the change in DURC status and to develop a risk mitigation plan as outlined above. The institution will be responsible for ensuring that DURC is conducted in accordance with the approved risk mitigation plan. Within 30 calendar days of identifying non-compliance, the institution will have to report to NIH any instances of noncompliance with this Guidance, as well as measures undertaken by the institution to prevent recurrences of similar situations of noncompliance.

If any non-US Government (USG) funded research is identified as DURC, notification should be made within 30 days to the NIH Program on Biosecurity and Biosafety Policy (See contact details listed below). Failure of NIH grantees to comply with this Guidance and any special award terms and conditions 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/policy.htm#gps.

Resources

To assist institutions in implementing this Guidance, the USG has developed "A Companion Guide to the USG Policies for Oversight of Life Sciences Dual Use Research of Concern" (Companion Guide). The Companion Guide offers tools that promote the understanding and identification of DURC, risk assessment and development of risk mitigation plans and risk management processes, the responsible communication of DURC, and training and education on the DURC issue.

Additional educational tools and resources can be found on the U.S. Government Science, Safety, Security (S3) website: http://www.phe.gov/s3/dualuse.

Inquiries:

Inquires about this guidance should be directed to:

Program on Biosecurity and Biosafety Policy
Office of the Director
National Institute of Health
Telephone: 301-496-9838
Email: DURC@od.nih.gov

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

General inquiries about this Guidance should be directed to:
White House Office of Science and Technology
Email: DURC@ostp.gov

- See more at: NOT-OD-15-017: NIH Implementation of the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern