Department of Homeland Security
DHS Directives System
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OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

I. Purpose

A. This Directive and accompanying Instruction establish the authorities, responsibilities, requirements, and procedures for oversight of life sciences dual use research of concern (DURC) in all activities conducted or sponsored by the Department of Homeland Security (DHS).

B. This Directive adopts the United States Government (USG) Policy for Oversight of Life Sciences Dual Use Research of Concern, issued on March 29, 2012, and the USG Policy for Institutional Oversight of Life Sciences DURC (iDURC), issued on September 24, 2014.

II. Scope

This Directive applies throughout DHS, to all life sciences research conducted, sponsored, or funded by DHS through a contract, grant, cooperative agreement, other transaction, or other arrangement. This includes all activities conducted at DHS-owned laboratories and non-DHS facilities, including activities conducted by subcontractors and sub-awardees.

III. Authorities

A. Title 6, United States Code (U.S.C.), Section 182, Chapter 1, Subchapter III, “Responsibilities and Authorities of the Under Secretary for Science and Technology”

B. United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 29, 2012), or current version of this policy and all accompanying policies, including applicable institutional oversight policies

C. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern” (September 24, 2014) or current version of this policy and all accompanying policies, including applicable institutional oversight policies

D. DHS Delegation 10001, “Delegation to the Under Secretary for Science and Technology”

IV. Responsibilities

A. The ***Under Secretary for Science and Technology (USST)***:

1. Is the DHS DURC Coordinating Official and responsible for directing, ensuring, and supporting Department-wide implementation of, and compliance with, this Directive and the accompanying Instruction;

2. Provides leadership for Department-wide implementation of this Directive and the accompanying Instruction, and ensures all DHS Components incorporate the provisions of both into their policies, procedures, and programs that involve life sciences research;

3. Delegates specific authorities to assist in ensuring (a) oversight of life sciences DURC, and (b) compliance with this Directive and the accompanying Instruction; and

4. Provides the biannual reporting response to the White House Office of Science and Technology Policy regarding the results of the DHS-wide, biannual life sciences DURC data call process.

B. The ***Compliance Assurance Program Manager (CAPM)*** serves as the head of the Compliance Assurance Program Office (CAPO), which develops and implements the Department’s DURC compliance program.

C. ***DHS Component Heads*** support Department-wide implementation of and compliance with this Directive and the accompanying Instruction.

D. The ***Institutional Contact for Dual Use Research of Concern (ICDUR)*** serves as the (1) institutional point of contact regarding compliance and implementation of DURC oversight requirements, and (2) liaison between the institution and DHS.

V. Policy and Requirements

All personnel conduct themselves in accordance with the responsibilities set forth in this Directive and the accompanying Instruction, and with any subsequently developed and approved policy, procedure, or guidance to ensure DURC compliance in all DHS activities.

A. ***Policy***:

1. DHS is committed to ensuring that DHS facilities and research institutions conducting DHS-sponsored activities meet the highest ethical standards for the management and oversight of life sciences research.

2. DHS has an ethical and moral obligation to rigorously adhere to established regulations, policies, and practices for identifying and mitigating the potential risks associated with DURC in all research sponsored by the Department.

3. In the event of any conflict between this Directive and existing federal laws and regulations pertaining to unclassified life sciences DURC, the federal laws and regulations take precedence.

B. ***Requirements***:

1. Each facility conducting DHS-sponsored life sciences activities, and activities involving one or more of the 15 DURC agents (regardless of funding source), designates an Institutional Contact for Dual Use Research of Concern (ICDUR). This person serves as the institutional point of contact regarding compliance and implementation of DURC oversight requirements.

2. Each facility conducting DHS-sponsored activities involving one or more of the 15 DURC agents establishes an Institutional Review Entity to execute the requirements of the Authorities in Section III of this Directive.

3. The Principal Investigator, designated by the relevant Research Institution, identifies life sciences research involving one or more of the 15 DURC agents. Following this, a duly appointed Institutional Review Entity conducts an institutional review process to assess whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in the USG Policy for DURC. A risk assessment should underpin the Institutional Review Entity's determination of DURC. For DHS-sponsored activities identified as DURC, each facility develops and implements a USG funding agency approved risk mitigation plan.

4. All personnel who conduct life sciences research with one or more of the 15 DURC agents are provided education and training on DURC. Education and training records are maintained for the term of the research grant or contract plus three years after its completion.

5. All incidents of noncompliance with this Directive, the accompanying Instruction, and/or the requirements established by the Authorities in Section III, involving any DHS Component, facility, or sponsored research institution, along with the associated institutional mitigation measures undertaken to prevent recurrences of similar noncompliance, are reported within 30 days to the ICDUR, Program Office, and CAPO. No action, administrative or disciplinary, may be taken against a person for the act of reporting such incidents of serious or continuing noncompliance.

VI. Questions

Please address any questions or concerns regarding this Directive to the Compliance Assurance Program Manager in the Science and Technology Directorate.

Chip Fulghum
Deputy Under Secretary for Management

NOV 27 2018
Date