VA NORTHEAST OHIO HEALTHCARE SYSTEM
Louis Stokes Cleveland DVAMC
Medical Research Service
Subcommittee on Research Safety Policy

Effective Date: AUGUST 11, 2021

SOP Title: INSTITUTIONAL REVIEW ENTITY

Policy Number: SRS--025

Policy Version: .03

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1. PURPOSE: Federal agencies and research institutions have a shared responsibility for minimizing the risks associated with the misuse of the products of their research.

2. POLICY: The Institutional Research Entity (IRE) is responsible for the effective oversight of Dual Use Research of Concern (DURC), which is based on identifying and managing the risks associated with the potential that the information, technology, or products generated by life sciences research could be misused to harm public health, agriculture, or national security. Risk mitigation is a process in which risks are identified and assessed, and measures are put in place to address the identified risks.

3. DEFINITIONS:

   a. IRE – Institutional Review Entity

   b. DURC - Dual Use Research of Concern

   c. SRS – Subcommittee on Research Safety

   d. IBC – Institutional Review Board

   e. CWRU – Case Western Reserve University

4. PROCEDURES:

   a. Research institutions must:

      1. Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC;

      2. Designate an Institutional Contact for Dual Use Research (ICDUR) to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of the Policy;

      3. Establish an Institutional Review Entity (IRE) to execute the requirements of the Policy; a range of mechanisms for fulfilling the role of an IRE are acceptable if the review entity is appropriately

mechanisms for fulfilling the role of an IRE are acceptable if the review entity is appropriately constituted and authorized by the institution to conduct the dual use review;

4. Provide education and training on DURC for individuals conducting life sciences research that involves any of the following 15 agents and toxins:

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

5. Report instances of noncompliance with this Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar noncompliance, within 30 calendar days.

b. The Louis Stokes Cleveland DVAMC IRE must:

Submit all studies that involve an agent of Dual Use Research of Concern to the Case Western Reserve University (CWRU) Institutional Review Entity (IRE).

**Only CWRU IRE-approved DURC submissions will be reviewed by the Louis Stokes Cleveland DVAMC IRE.*

5. MEMBERSHIP: Individuals who serve on the SRS also serve on the Institutional Review Entity in their respective roles.

6. MEETINGS: The IRE will meet when a Research Study has been submitted to the SRS that involves one or more of the fifteen agents listed in Section 4, part a, subpart 4.

7. REFERENCE: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (USG Policy), September 2015.

8. RESCISSION: Medical Research Service Policy: INSTITUTIONAL REVIEW ENTITY, SRS-025, dated August 11, 2021. The date rescission of this policy is August 14, 2024.

9. FOLLOW UP: Research Safety Coordinator.