

LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service Policy

Effective Date: September 6, 2018

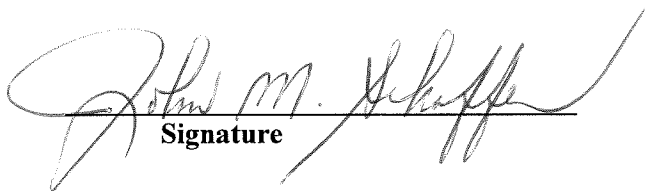
SOP Title: INSTITUTIONAL REVIEW ENTITY

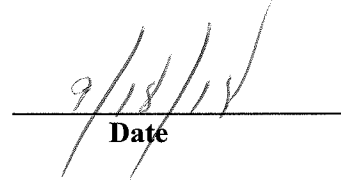
Policy: SRS--025

Policy Version: .02

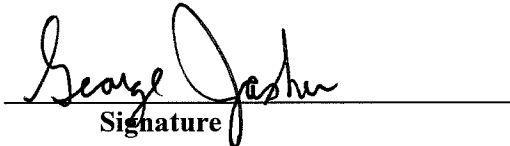
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Department: Medical Research Service


Signature


Date

Research & Development Committee Chair:


Signature


Date

Approved By:

Associate Chief of Staff/Research


Signature


Date

**LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service Safety Policy**

Effective Date: SEPTEMBER 6, 2018

SOP Title: INSTITUTIONAL REVIEW ENTITY

Policy Number: SRS--025

Policy Version: .02

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. IBC – Institutional Review Board
- d. 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 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 15 agents and toxins listed in this Policy; and

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

6. RESCISSION: Medical Research Service Policy: INSTITUTIONAL REVIEW ENTITY, SRS—025, dated September 3, 2015. The date rescission of this policy is September 2, 2021.

7. FOLLOW UP: Research Safety Coordinator.