

**VCU**

INSTITUTIONAL REVIEW ENTITY PROCEDURES FOR DUAL USE RESEARCH OF CONCERN EXPERIMENTS

I. Charge

The Institutional Review Entity (IRE) reviews any research or work conducted at, or on behalf of the University that involves one of the 15 agents/toxins designated as Dual Use Research of Concern (DURC) agents/toxins by United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

Provisions of these operating procedures shall apply to all research and production projects conducted in VCU facilities or property, including all rental or leased facilities or properties, as well as to all such projects carried out by VCU staff (temporary or full time), students or visitors in connection with VCU responsibilities.

The IRE reports to VCU's Vice President for Research and Innovation and to the Assistant Vice President for Safety and Risk Management.

II. Responsibilities

1. Ensure that all research and production projects involving the acquisition, use, storage, or disposal of DURC materials is reviewed.
2. Submit findings to the Vice President for Research and Innovation and the Assistant Vice President for Safety and Risk Management. If the research is determined to be DURC, recommendations as to a risk-based oversight plan will be developed.
3. Conduct risk-based analysis on all DURC experiments and recommend a plan of action to ensure proper oversight of all DURC experiments.
4. Develop policies and procedures to help resolve experiment specific issues involving DURC experiments.

III. MEMBERSHIP:

The VP for Research and Innovation selects the IRE Chair via a formal appointment letter and for a three-year term of service. The VP for Research and Innovation, with input from VCU's Biosafety Officer and the current IRE Chair, selects and nominates IRE members. IRE members receive a formal appointment letter from the VP for Research and Innovation for no more than three year terms of service.

1. Individuals holding the following positions or titles at VCU shall be appointed to the IRE as voting members:
 - a) Chairman

- b) Export Compliance Officer
- c) Chemical Safety Officer
- d) Biosafety Officer
- e) Practicing Scientist
- f) Practicing Scientist

2. Non Voting (Ex Officio) Members:

- a) Institutional Contact for Dual Use Research (ICDUR)

Voting Members may not participate and must recuse themselves from any vote on a research project in which he/she has been or will be participating, or in which he/she has a direct financial interest.

IV. IRE Meeting Procedures

1. The IRE shall meet as needed at the call of the Chair, but no less than once per calendar year.
2. A quorum shall consist of a simple majority of voting members. To take action, a quorum must be present in person or through telephone or video conferencing.
3. The IRE shall follow standard operating procedures throughout the review of research and production projects.
4. The Chair or designee presides over all meetings, and oversees all IRE activities.
5. Decisions and project approvals are based on a majority vote of voting members present at the time a vote is taken.
6. Voting in absentia shall take place by written formal communication.

V. AMENDMENTS AND REVIEW

1. Amendments to the operating procedures may be proposed at any meeting of the IRE.
2. The IRE operating procedures shall be reviewed by the IRE annually.

VI. EFFECTIVE DATE

These operating procedures shall take effect January 1, 2017.