

Vanderbilt University Medical Center
Institutional Review Entity (IRE) for Dual Use Research of Concern (DURC)
Standard Operating Procedures

IRE Composition and Operations

1. The IRE will be comprised of 5 voting members; 3 alternate voting members; and 3 *ex officio* members representing the Institutional Biosafety Officer, Export Compliance Manager, and Institutional Contact for Dual Use Research of Concern.
2. The IRE will meet in person at least annually for general review and maintenance of any ongoing DURC projects and set standing virtual meetings to recur quarterly. Other *ad hoc* meetings may be scheduled.
3. A quorum for routine meetings will be 3 voting members. If the IRE makes a preliminary assessment that a research project could meet the definition of DURC, an *ad hoc* meeting will be called to make the DURC determination. The quorum for final determination of DURC will be all 5 voting members and 3 *ex officio* members.
4. All forms will be submitted via secure REDCap data forms.
5. Any other documents associated with DURC review will be shared via secure file transfer (e.g. Accellion).
6. All files will be assumed to include information related to DURC and maintained in a cybersecure environment until determination of DURC is completed.
 - a. Files for projects determined to be DURC will be maintained in the cybersecure environment for the stipulated data retention period.
 - b. Files for projects determined to not meet the definition of DURC may be maintained in a less stringent environment for the stipulated data retention period.

IRE Review and Risk Mitigation Process

1. The IRE review process is initiated when research is identified by a VUMC PI (either as the prime awardee or subcontractor to another institution) as utilizing any of the **15 listed agents and toxins**, typically through Institutional Biosafety Committee (IBC) registration, submission of an Initial DURC Assessment (IDA, DURC Form 1) via REDCap, or via direct contact to the Institutional Contact for Dual Use Research of Concern (ICDUR).

NOTE: Once the potential for DURC is identified by the PI, or to the PI by collaborators, the PI is should contact the ICDUR for guidance and to initiate the IDA form submission for institutional review.
2. The PI notifies the IRE as soon as any of the following apply:
 - a. The PI's research involves any of the **15 listed agents and toxins**
 - b. One or more of the **7 listed categories** of experiments can be reasonably considered applicable to the PI's research involving one or more of the **15 listed agents and toxins**
 - c. The PI's research meets criteria that may meet the definition of DURC.
3. If the IBC registration or IDA answers "not applicable" to all seven categories of experiments (see VUMC policy) AND the IRE concurs with this assessment, no further DURC review is required.

NOTE: The ICDUR will notify the PI of this decision within 5 business days.
4. If the IBC registration or IDA answers "not applicable" to all **7 listed categories** of experiments AND the IRE disagrees, the PI will be asked by the ICDUR to submit a DURC Determination Analysis (DDA, DURC Form 2) via REDCap, for assessment of potential dual use risks and benefits of the research.
5. If the IBC registration or IDA identifies any of the **15 listed agents and toxins** AND answers "yes - applicable" to any of seven categories of experiments, the PI will be asked by the ICDUR to submit a

DURC Determination Analysis (DDA, DURC Form 2) via REDCap, for assessment of potential dual use risks and benefits of the research.

6. For all cases where a DDA is submitted, the IRE will review all submitted documentation (the IBC registration or IDA, and the DDA) and conduct a meeting to determine that the research does, or does not, meet the definition of DURC. The PI may be invited to attend the IRE meeting to facilitate discussion and answer any questions.
7. Within 30 calendar days of the IRE review for potential DURC: The ICDUR will notify the appropriate funding agency that a review for potential DURC has occurred and advise the funding agency of the IRE review and determination. The ICDUR will notify the PI within the same timeframe.
 - a. If IRE determines that the work does not meet the definition of DURC, then no further review is required.
 - b. If IRE determines that the work meets the definition of DURC, the PI will be asked to submit the DURC Risk Mitigation Planning Assessment (DMPA, DURC Form 3). The IRE and the PI will use the DMPA to develop the Draft Risk Mitigation Plan.
8. The ICDUR will meet with the PI to review the Draft Risk Mitigation Plan and make recommendations to ensure the Plan is comprehensive and complies with federal requirements. The ICDUR may include representatives of other institutional offices and subject matter experts in this process.
9. Within 90 calendar days from the time that the IRE determined the research to be DURC: The ICDUR will send the Draft Risk Mitigation Plan to the appropriate funding agency for review and approval. Once submitted, the funding agency will have 60 days to finalize the Draft Mitigation Plan.
10. After a DURC Risk Mitigation Plan is developed and approved:
 - a. The PI is responsible for ensuring that the research is conducted in compliance with the DURC Risk Mitigation Plan.
 - b. The IRE is responsible for continuing annual review of the DURC. At its discretion, the IRE may require more frequent reviews to determine if modifications to the risk mitigation plan are appropriate.
 - c. The ICDUR is responsible for notifying the appropriate funding agency within 30 days of 1) any change in status of the DURC project including whether the research is determined to no longer meet the definition of DURC; and 2) details of any changes to risk mitigation plans.

NOTE: Any changes to the DURC Risk Mitigation Plan need to be approved by the appropriate funding agency.
11. The ICDUR will maintain records of the institutional DURC reviews and completed Risk Mitigation Plans for the term of the research grant/contract plus three years after its completion, but no less than eight years.

Resources:

VUMC Institutional Policy for Review of Dual Use Research of Concern (DURC)

www.vumc.org/oor/dual-use-research-concern-durc

United States Government DURC homepage:

www.phe.gov/s3/dualuse/

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern:

www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx

Points to consider when using an IBC as an IRE:
www.phe.gov/s3/dualuse/Documents/durc-ptc.pdf

DURC Companion Guide:
www.phe.gov/s3/dualuse/Pages/companion-guide.aspx

Gain-of-Function Research
www.phe.gov/s3/dualuse/Pages/GainOfFunction.aspx

Agents and toxins:

- a. Avian influenza virus (highly pathogenic)
- b. *Bacillus anthracis*
- c. Botulinum neurotoxin (any quantity, including **Botox**)
- d. *Burkholderia mallei*
- e. *Burkholderia pseudomallei*
- f. Ebola virus
- g. Foot-and-mouth disease virus
- h. *Francisella tularensis*
- i. Marburg virus
- j. Reconstructed 1918 influenza virus
- k. Rinderpest virus
- l. Toxin-producing strains of *Clostridium botulinum*
- m. Variola major virus
- n. Variola minor virus
- o. *Yersinia pestis*

Categories of experiments:

- a. Enhances the harmful consequences of the agent or toxin;
- b. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
- c. Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- d. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
- e. Alters the host range or tropism of the agent or toxin;
- f. Enhances the susceptibility of a host population to the agent or toxin; or
- g. Generates or reconstitutes an eradicated or extinct listed agent or toxin listed.