

Charge of the Institutional Review Entity (IRE)

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

DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

Responsibilities: The IRE will ensure that all research involving the acquisition, use, handling storage and disposal of DURC materials is reviewed for DURC potential. Furthermore, the committee is responsible for reviewing all proposed research subject to DURC conducted by faculty, staff, students and/or visiting scientists, creating draft mitigation plans when required, and submitting these plans to the United States Government (USG) agency funding the proposed research. If the research is non-Federally funded the plan is submitted to NIH for review or referral. The IRE will also annually review active mitigation plans, and report any changes in DURC or mitigations plans to the appropriate USG agency within 30 days.

Committee Composition: According to USG Policy, the committee must include persons with:

- 1) Sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at the University; and
- 2) Knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity

The IRE shall consist of at least 5 voting members appointed by the Vice President for Research (VPR). Membership will generally consist of faculty members with expertise in recombinant DNA technology, microbial pathology, virology and viral vectors, biosafety, biotoxins, transgenic plants, transgenic animals, biotechnology or knowledge of relevant DURC policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity. Non-faculty members such as administrative representatives, laboratory staff or students may also be appointed in consultation with the IRE Chairperson. Committee membership must also include a representative from the University Biosafety Office and a representative from the Center for Comparative Medicine with expertise in animal containment principles. Members are appointed for renewable three year terms.

The IRE Chairperson may establish focused subcommittees at his or her discretion, invite subject matter experts to consult, provide input or reports on a given topic, and make membership recommendations to the VPR. The IRE may also consult with the Federal department or agency that is funding the research in question for advice on matters related to DURC. Such consultations should involve the Institutional Contact for Dual Use Research (ICDUR). The ICDUR is appointed by the VPR and serves as an internal resource for issues regarding

compliance with and implementation of the requirements of DURC. The ICDUR also serves as the liaison (as necessary) between the institution and the relevant program officers at the Federal funding agencies, or for non-Federally funded research, between the institution and NIH (or the appropriate Federal funding agency to which NIH refers the institution).

Meetings: The IRE shall gather at convened meetings as necessary to conduct annual reviews of mitigation plans, all registrations from investigators working with DURC agents, and to develop mitigation plans for new registrations. The IRE Chair will ensure that any and all members recuse themselves if they are involved in the research project under review, or have a direct conflict of interest, except to provide specific information requested by the committee. At least fifty one percent of the voting membership is necessary to establish a quorum for conducting business.

Support: The VPR shall provide resources necessary to support IRE operations. This may include staffing, database services, support for member education, clerical equipment or materials, and other resources necessary to support committee operations.

The Biological Safety Officer, as a member of the Office of Environmental Health and Safety (EHS), will serve as a functional arm of the IRE and manage day-to-day operations in conjunction with the IBC Coordinator, IRE administrative staff and EHS staff. Services include providing technical expertise, and at least annual inspections to ensure that mitigation plans are rigorously followed.

Appeals: In cases of dispute with respect to procedures or decisions of the IRE, appeals should be made to the IRE in writing or in person. Appeals unresolved through IRE channels may be subsequently presented to the ICDUR and VPR for resolution.

Sanctions and Enforcement: The IRE shall investigate suspected or alleged violations of protocols, external regulations, or University policies that involve DURC. If violations are insufficiently resolved through normal channels of communications with the Principal Investigator, the Department Chairperson and ICDUR will be notified of the violation and a timeline for resolution will be established. Matters that remain unresolved will be forwarded to the relevant school dean and VPR for resolution. In matters that are deemed immediately dangerous to life and health, the IRE may immediately suspend research involving biological agents. In such extreme cases, and after consultation with the ICDUR, and VPR, the IRE may also authorize access restriction, or removal of personnel.

Reporting: The committee reports administratively to the VPR through the ICDUR. The committee is responsible for forwarding an annual written report. The report should include a roster of all IRE members, descriptions of committee decisions, and other items as appropriate.

***DURC research applies to the following agents and categories of experiments:**

Agents:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (note: there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin is included.)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus (BSL4)
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus (BSL4)
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus (BSL4)
14. Variola minor virus
15. *Yersinia pestis*

Categories of experiments:

- a) Enhance the harmful consequences of a biological agent or toxin
- b) Disrupt immunity or effectiveness of an immunization against a biological agent or toxin without clinical or agricultural justification
- c) Confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies
- d) Increase the stability, transmissibility, or the ability to disseminate the agent or toxin;
- e) Alter the host range or tropism of the agent or toxin
- f) Enhance the susceptibility of a host population to a biological agent or toxin o
- g) Generation of a novel pathogenic agent, or reconstitution of an eradicated or extinct biological agent

Approved:



25 Oct 2017

David Hudson, PhD

Date

Senior Associate VP for Research
Research Integrity Officer and
Institutional Contact for Dual Use Research (ICDUR)