



Dual Use Safety Program

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1.0 Overview

The Brigham Young University Dual Use Safety Program includes the following elements:

- Designation of the Institutional Biological Safety Committee (IBC) as the required “Institutional Review Entity” (IRE), outlined in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (released September 24, 2014), to maintain overall control of the program.
- Designation of the IBC administrator as the “Institutional Contact for Dual Use Research” (ICDUR).
- Designation of a Biological Safety Officer (BSO) to conduct education and training on DURC and ensure compliance.
- Development of an effective training program.
- Development of an effective monitoring system.

2.0 Policy

All Brigham Young University employees and students working with the 15 agents and toxins listed below will comply with the conditions and procedures stipulated in the Biological Safety Program.

Avian influenza virus (highly pathogenic)
Bacillus anthracis
Botulinum neurotoxin
Burkholderia mallei
Burkholderia pseudomallei
Ebola virus
Foot-and-mouth disease virus
Francisella tularensis
Marburg virus
Reconstructed 1918 Influenza virus
Rinderpest virus
Toxin-producing strains of *Clostridium botulinum*
Variola major virus
Variola minor virus
Yersinia pestis

3.0 Requirements and Standards

Two US Government policies address the oversight of life sciences DURC.

The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012)

The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 2014)

www.phe.gov/s3/dualuse

4.0 Purpose

The Dual Use Safety Program aims to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided

by such research. The program compliments existing regulations and policies governing safe and secure use of pathogens and toxins while providing consistent oversight of DURC.

5.0 Scope

The Program applies to all Brigham Young University research and classroom instruction involving the use of the agents and toxins listed in 2.0.

6.0 Procedures

6.1 Biosafety Committee Notification and Review: The Principal Investigator (PI) or classroom instructor proposing work with a covered agent or toxin will submit the appropriate IBC form to the Office of Research and Creative Activities (ORCA). The PI will provide an initial determination that the planned research will create one or more of the effects listed below under “Categories of experiments”, which will be verified by the IBC. The IBC will determine whether the research meets the definition of DURC. The PI and IBC will weigh the risks and benefits of the research and develop a draft risk mitigation plan to be reviewed by the appropriate United States Government (USG) funding agency approval before initiating work with that agent.

Categories of experiments

- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed in 2.0, above

6.2 Approval

The USG funding agency will finalize and approve the risk mitigation plan.

The IBC will implement the approved risk mitigation plan and provide ongoing oversight.

The PI will conduct and communicate research according to the risk mitigation plan.

7.0 Responsibilities

7.1 Biological Safety Officer

- Provides training and education to students and faculty on DURC
- Ensures compliance of risk mitigation plan
- Assists in DURC review and risk assessment
- Serves on the IBC
- Offers information on program elements and federal regulations to the faculty

7.2 Institutional Biosafety Committee

- Reviews the PI's submission and determines whether the research involves any of the 7 experimental effects.
- If yes to the above determination, the IBC conducts a risk assessment to determine whether the research is DURC and if so, weighs the risks and benefits and develops a draft risk mitigation plan.
- Reviews and updates Dual Use Safety Program

7.3 Principal Investigator

- Notifies ORCA (using application form) prior to initiating work with covered agents and toxins
- Provide an initial determination whether the planned research will create one or more of the effects listed in 6.1.
- Responsible for ensuring DURC training for all people working in the laboratory
- Maintains training records

7.4 Office of Research and Creative Activities

- Provides IBC administrator
- The IBC administrator will act as the "Institutional Contact for Dual Use Research" (ICDUR) to serve as the point of contact for questions regarding compliance with and implementation of the requirements for DURC oversight policies
- Serve as the liaison between the institution and the relevant USG funding agency
- Notifies BSO and IBC of applications for use of covered material
- Maintains IBC minutes
 - Upon request, minutes are available to the public, however, proprietary or private information may be redacted; for example, trade secrets, confidential commercial information, home phone numbers and addresses, and information that may compromise BYU or national security.
- Maintains NIH IBC Registration

8.0 Training

8.1 Training: All people working on applicable research projects will receive training on DURC:

- DURC guidelines
- Specific laboratory procedures

9.0 Monitoring

9.1 Inspections: Inspections are completed by the BSO for each covered laboratory once each year. Inspection results are submitted to the IBC for review as part of the Biological Safety Program.