Brown University Policy: Dual Use Research of Concern (DURC)

Introduction

Certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes and is characterized by the United States Government (USG) as "dual use research" (DUR). Dual use research of concern (DURC) is a subset of dual use research defined as: "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." As a recipient of federal funds, Brown University must comply with USG policy governing DURC, which requires the designation of an institutional review entity (IRE) or a Dual Use Research Review Committee (DURRC) to identify DURC and its associated risks and devise ways to mitigate these risks.

What Is DURC?

An excellent short video discussing DURC is posted on the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) **website**. All investigators are strongly recommended to watch the video for a better understanding of the issues at hand.

Identifying Potential DURC

The process begins with the identification of research that directly involves one or more of 15 listed agents (the "DURC list"):

- Avian influenza virus (highly pathogenic)
- Bacillus anthracis
- Botulinum neurotoxin (in any quantity)
- 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

Institutional review of DURC is initiated through screening for DURC via Institutional Biosafety Committee (IBC) applications. Principal Investigators (PI) self-identification and notification of the IBC Office that he/she plans to conduct research that directly uses non-attenuated forms of any one of the listed agents.

USG policy characterizes both the PI and the IRE as responsible parties for identifying potential DURC.

Screening for DURC

The IBC has developed eight (8) screening questions that are incorporated into the IBC Biological Research Authorization (BRA) application. For those IBC applications reviewed and approved before the development of this policy, the DURC IBC Notification Form will be used to by investigators engaged in research which involves agents from the DURC list.
The formal review of potential DUR is initiated by researchers responding to the eight questions in the IBC BRA application, which is required for research involving all recombinant DNA (rDNA) and infectious materials, and continues with further review by the Dual Use Research Review Committee (DURRC) if the answer to any of the following screening questions is yes. Brown may also utilize an external DURRC if needed.

The questions ask the investigators to indicate whether the proposed research is designed to:

1. Enhance the harmful consequences of a biological agent or toxin.
2. Disrupt immunity or effectiveness of an immunization without clinical and/or agricultural justification.
3. Confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin.
4. Facilitate their ability to evade detection methodologies.
5. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
6. Alter the host range or tropism of a biological agent or toxin.
7. Enhance the susceptibility of a host population.
8. Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

Membership of the DURRC

IRE or the DURRC must consist of at least five (5) members. The DURRC must include the following members: the chair of the IBC, Director of Office of Research Integrity, and the BioSafety Officer. A subset of the Brown IBC may be used as the DURRC, depending on their expertise, as well as, other members of the Brown community designated by the Associate Vice President for Research. The DURRC could also consist of any other of the following members of the Brown community: a representative of the Risk Management Committee, the chief of Brown DPS, the Associate Provost for Research, a community member, a representative from University Communications, and representatives of the scientific community with related expertise. Scientific representatives, the chair of the IBC, and safety specialists will form the sub-committee conducting the Stage I review. The university may also utilize an outside ad-hoc DURRC depending upon the expertise needed for the review.

DURRC Meetings

The DURRC will meet when the preliminary questionnaire, from the IBC BRA, indicates that a study might be subject to DUR review, or if the IBC refers a study to be reviewed internally for DUR. The full committee will be kept abreast of the latest recommendations of National Science Advisory Board for Biosecurity (NSABB) or other advisory or regulatory bodies, and determine whether any modifications to the oversight program are required. The DURRC will maintain

minutes of its deliberations and communicate its management recommendations for oversight to the PI in writing.

Review Criteria

Each research initiative that is categorized as DUR or DURC is different and poses unique issues related to the implications of the information, materials, or technologies that may result from the research. Therefore, it is not possible to develop a single review process that can be used for all cases. However, the NSABB has developed a toolkit for such reviews that provides guidance for a comprehensive process. The Brown DURRC will perform its reviews based on these guidelines.
The framework for risk assessment and risk mitigation follows a multistep process:

- Step 1: Verify that the research directly involves non-attenuated forms of one or more of the listed agents.
- Step 2: Assess whether the research produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects.
- Step 3: Assess the risks of dual use and determine whether the research is DURC.

For research determined by the DURRC to be DURC:

- Step 4: Assess the potential benefits of the DURC.
- Step 5: Weigh the risks and benefits of the DURC.
- Step 6: Develop a draft risk mitigation plan for conducting the DURC and communicating its findings (described in detail in Section D of the Companion Guide).

DURRC Risk Mitigation Plan

Risk mitigation plans should provide sufficient details on the research in question to enable the USG funding agency to adequately assess the institution's plan for managing the risks associated with DURC identified by the DURRC. The Brown DURRC will work closely with the USG funding agency (or, for non-federally funded DURC, the NIH-designated USG agency) to develop the draft risk mitigation plan.

Risk mitigation plans should include the following:

- The name and contact information for the PI(s).
- The name and contact information for the authorized institutional official or their designee.
- The dates and details of the reviews and assessments of the research by the IRE.
- The dates and details of the PI's initial review or ongoing assessment of the research.
- Identification of whether the research has been identified as DURC under the March 2012 DURC Policy.
- Details of the risks identified by the IRE in its review of the research, and an explanation of the risk mitigation strategy or strategies that are being implemented by the institution to address those risks.
- Other materials, such as proposals and progress reports related to the research that may be requested by the USG agency.

The university must submit a copy of the draft risk mitigation plan within 90 calendar days of an DURRC's determination that the research is DURC to the USG funding agency (or, for non-federally funded DURC, the NIH-designated USG agency) for review and final approval. USG agencies are required to provide an initial response to institutions within 30 calendar days and should finalize the plan within 60 calendar days of receipt of the draft plan.