Mass General Brigham

Dual Use Research of Concern (DURC)
Standard Operating Procedures (SOP)

June 2022

Overview

This Standard Operating Procedure (SOP) memorializes the process of identification, assessment, management, communicating results, and reporting Dual Use Research of Concern (DURC) conducted within Mass General Brigham (MGB) hospitals and institutions with high-consequence pathogens and toxins under the leadership of MGB Principal Investigators (PIs).

Definitions

Dual Use Research of Concern (DURC) is life sciences research that 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, materiel, or national security.

Dual Use Review Committee (DRC) is the MGB Institutional Committee formally designated to review and monitor DURC in accordance with applicable federal and non-federal laws, statutes, and regulations; sponsor policies; and institutional policies.

Institutional Contact for Dual Use Research (ICDUR) is the individual, required by federal policy, who serves as the point of contact for the hospital conducting DURC and the relevant federal funding agencies for compliance with and implementation of DURC requirements.

DURC Registration is the collection of electronic forms in the Insight Biosafety Module that comprise an Institutional Biosafety Committee (IBC) registration that describes the proposed DURC.

Risk Mitigation Plan (RMP) is a plan that mitigates concerns for DURC, outlines the required biosafety and biosecurity controls for the research, identifies potential countermeasures, and describes the responsible communication of DURC findings.

Responsible Communication is communicating the findings of DURC in a manner that allows the information to be shared to the fullest extent possible in order to realize the potential benefits of the research while simultaneously managing the risk of potential misuse of the information effectively.

Roles and Responsibilities

The Principal Investigator will:

- Notify the DRC of all research under their direction that involves DURC agents or toxins identified below in the list identifying categories of experiments.
- Work with the DRC to assess the dual use risks and benefits of the DURC.
- Develop a draft Risk Mitigation Plan (RMP) with the Institutional Biosafety Officer to guide the conduct and communication of the DURC.
- Conduct DURC in accordance with the provisions of the approved RMP.
- Communicate DURC in a responsible manner and in compliance with the approved RMP.
- Ensure DURC RMPs are kept up to date and report any proposed changes to the RMP.
- Ensure that laboratory staff (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting

biological research with at least one of the DURC agents have received adequate education and training on DURC.

- Comply with all determinations and additional requirements of the DRC and the Institutional Official.
- Report any significant problems or violations of the RMP in a timely manner.

The Institutional Biosafety Officer will:

- Review all IBC registrations and assess the proposed research to determine if it meets the definition of DURC.
- Assist the PI in developing draft RMPs to guide the DURC conduct and communication.
- Ensure that RMPs are implemented.
- Oversee and perform laboratory inspections for laboratories engaged in DURC.
- Provide advice and guidance on laboratory security.
- Immediately report any significant problems or violations of the RMP to the DRC.
- Provide education and training on DURC for individuals conducting life sciences research and maintain records of such education and training.

The MGB Sr. Director of Biosafety will:

- Act as the Institutional Contact for Dual Use Research (ICDUR) for all MGB Institutions.
- Notify the appropriate federal agency within 30 calendar days of review of any research that involves biological research that can be potentially categorized as DURC.
- Submit the approved draft RMP to the appropriate USG agency for review and approval within 90 days of the PI's submission of the research.
- Notify the appropriate federal agency within 30 calendar days of any change in the status of a DURC project at the institution or changes to the RMP.
- Comply with all determinations and additional requirements of the DRC, the DRC chairperson, and the Institutional Official.
- Develop policies and procedures related to DURC.
- Notify investigators of the results of Dual Use Review Committee reviews and providing guidance to ensure compliance.
- Serve as a resource to the regulated community (i.e., investigators, staff, biosafety officers).
- Monitor national, state, and local regulatory trends and communicate regulatory changes to institutional officials and institutional biosafety officer as necessary.
- Maintain records for the term of the research grant or contract plus three years after its completion.

The Dual Use Review Committee (DRC) will:

- Act as the Institutional Review Entity for DURC for MGB.
- Review and approve the biological DURC registration and RMP.
- Annually review RMPs and modify them as needed.
- Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC.
- Ensure that adopted policies, practices, and procedures for DURC meet applicable regulatory standards and guidelines.
- Review any findings of significant violation of RMPs, suspend or rescind registration approvals and RMPs as necessary, and recommend to the IO, limitations, or conditions on an investigators', or research study staffs', privilege to conduct DURC.

The Institutional Officials (IO) will:

- Hold investigators and study staff accountable for their DURC responsibilities.
- Ensure effective institution-wide communication and guidance on DURC.