# BOSTON UNIVERSITY Dual Use Research of Concern (DURC) Policy

#### 1. Purpose

The purpose of this policy is to outline Boston University's (BU) institutional oversight of Dual Use Research of Concern (DURC) according to the '<u>United States Government Policy for Institutional Oversight of Life Sciences Dual Use of Research Concern</u>' released on September 24<sup>th</sup>, 2014.

#### 2. Covered Parties

This policy applies to all individuals engaged in Dual Use Research at or under the auspices of BU and applies to all individuals engaged in Dual Use Research at or under the auspices of Boston Medical Center (BMC).

# 3. **Definitions**

- Dual Use Research (DUR) is defined as research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.
- 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, materiel, or national security.

## 4. Regulatory Background

On March 29, 2012, the Federal government issued the "<u>United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern</u>" that requires funding agencies to review research and research proposals to identify those that qualify as DURC, and to ensure that acceptable risk-reducing mitigation plans are in place.

On September 24, 2014, the United States Government released the <u>United States Government Policy for Institutional Oversight of Life Sciences Dual Use of Research Concern</u>" with an effective date of September 24<sup>th</sup> 2015. The policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Institutional oversight of DURC is the critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC. In 2014, the NIH developed "A Companion Guide" entitled "Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern".

References herein to the Federal government Policies and Companion Guide shall be deemed to include all revisions, updates, and successor federal policies and guidance.

**PLEASE NOTE**: On May 5<sup>th</sup>, 2025, NIH announced the implementation of <u>Improving the Safety and Security</u>

of Biological Research. Further guidance is expected in Fall 2025; BU policies will be updated accordingly.

# 5. Scope of Research Requiring Oversight Under this Policy

Research that uses one or more of the agents or toxins listed below, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in the following categories of experiments will be evaluated for DURC potential. The Institutional Contact for Dual Use Research (ICDUR) shall revise this policy to update the list of agents and toxins and the categories of experiments from time to time as updates are made in the Federal government Policies and Companion Guide.

# Agents and toxins

- 1. Avian influenza virus (highly pathogenic)
- 2. Bacillus anthracis
- Botulinum neurotoxin (For the purposes of this policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
- 4. Burkholderia mallei
- 5. Burkholderia pseudomallei
- 6. Ebola virus
- 7. Foot-and-mouth disease virus
- 8. Francisella tularensis
- 9. Marburg virus
- 10. Reconstructed 1918 Influenza virus
- 11. Rinderpest virus
- 12. Toxin-producing strains of Clostridium botulinum
- 13. Variola major virus
- 14. Variola minor virus
- 15. Yersinia pestis

## Notes:

- The agents and toxins listed in this policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products.
- Research involving use of any of the listed agents is *not* intended to include research that involves only the use of attenuated forms of these agents or the genes from these agents.
- Research that does not use any of the listed agents or toxins will also be evaluated for DURC potential if it meets other criteria for review, management and mitigation as described in this policy.

## Categories of experiments

- 1. Enhances the harmful consequences of the agent or toxin;
- 2. 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;
- 4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
- 5. Alters the host range or tropism of the agent or toxin;

- 6. Enhances the susceptibility of a host population to the agent or toxin;
- 7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

Investigators shall consider whether their research requires review under this policy throughout the lifecycle of the project. They shall initiate review of the research for DURC potential whenever any of the following criteria are met:

- The research directly involves nonattenuated forms of one or more of the listed agents or toxins; or
- The research produces, aims to produce, or can be reasonably anticipated to produce one or more of the listed experimental effects; or
- The research may meet the definition of DURC and should be considered for DURC potential.

## 6. DURC Review and Risk Mitigation

## 6.1 Institutional Contact for Dual Use Research (ICDUR)

The Institutional Contact for Dual Use Research (ICDUR) is designated by the University to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) with the relevant Federal funding agency, NIH (or the Federal agency to which NIH refers the University, for non-Federally funded research), or other outside entities. The Associate Vice President for Research Compliance (AVPRC) is designated as the ICDUR.

# 6.2 Dual Use Research of Concern Committee (DURCCom)

The Dual Use Research of Concern Committee (herein referred to as DURCCom) is established as the Institutional Review Entity (IRE) to fulfill the responsibility to conduct the DURC review. The AVPRC is responsible for appointing the chair (from among the BU faculty or staff members in scientific and technology fields) and members of the DURCCom.

#### The DURCCom must:

- Be composed of at least five (5) members;
- Execute the functions described in this policy;
- Include persons with sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at BU/BMC;
- Include persons with knowledge of relevant Federal policies and understanding of risk assessment
  and risk management considerations, including biosafety and biosecurity. The DURCCom shall also
  include, or have available as advisers, University faculty and staff knowledgeable in BU/BMC's
  pertinent commitments, policies, and standard operating procedures;
- Recuse any member who is involved in the research project and who has a directfinancial interest in the research, except to provide specific information requested by DURCCom; and
- Engage in an ongoing dialogue with the Principal Investigator (PI) of the research in question when conducting a risk assessment and developing a risk mitigation plan.

# **DURCCom Membership:**

- Chair of the DURCCom
- Director of Research Safety
- Chair of the Institutional Biosafety Committee (IBC)
- Chief Safety Officer, NEIDL

- Chief of the BU Police Department
- Export Control Officer
- One community member
- A representative from Public Relations
- · Four faculty or staff representatives in scientific and technology fields

In instances where the DURCCom does not have sufficient expertise to review a particular study, the Chair may request a consultant to provide the additional expertise needed. Consultant reviews will be included in the minutes of the meeting.

#### **DURCCom Subcommittee:**

A Subcommittee of the DURCCom has been established for purpose of determining whether research meets criteria for review by the full DURCCom. At BU, the chair of the DURCCom Subcommittee and the DURCCom full Committee will be the same individual. DURCCom Subcommittee Members include:

- · Chair of the DURCCom
- Director of Research Safety
- Chair of the IBC
- At least one faculty or staff member of the DURCCom in a scientific or technology field.

The DURCCom and the DURCCom Subcommittee will seek advice and guidance from other offices and committees at the University, including the Office of the General Counsel, as needed.

#### **DURCCom Review Process**

The DURCCom and DURCCom Subcommittee shall undertake the following steps in its review of research, which shall involve the processes described below, and in Sections 6.4 and 6.5:

- Determine whether the research utilizes nonattenuated forms of one or more of the listed agents or toxins.
- Determine whether the research produces, aims to produce, or is reasonablyanticipated to produce one or more of the listed experimental effects.
- Determine whether the research is subject to further review in accordance with this policy.
- Conduct a risk assessment and determine whether the research meets the definition of DURC.
- Assess the benefits of the DURC while considering the identified risks.
- Develop a draft risk mitigation plan for the identified DURC based on the assessment of the risks and benefits of the research. More information on drafting risk mitigation plans can be found in Section D of the Companion Guide.
- Review, at least annually, all active risk mitigation plans. If the research in question still constitutes
  DURC, the DURCCom may modify the plan as needed. More information on the annual review of active
  risk mitigation plans can be found in Section E of the Companion Guide.

#### 6.3 Education and Outreach

General DURC concepts are part of annual lab safety training which is required for all BU/BMC researchers utilizing lab space. DURC-specific training will be made available for those who engage in research that involves the use of one or more of the listed agents and toxins or research that has otherwise been determined by the DURCCom to meet the definition of DURC (See Appendix-I).

## 6.4 Screening for DURC

The DURCCom has developed screening questions that are incorporated in the IBC protocol application; these questions are based on the categories of experiments that are listed above in Section 5. When the answer to any of the screening questions is "Yes" or when the research utilizes nonattenuated forms of one or more of the listed agents or toxins, the IBC Office will forward the protocol to the DURCCom Subcommittee, which will review the application and determine whether the study may be DURC and require full DURCCom review. The IBC may also forward applications to the DURCCom Subcommittee where the PI may have replied "No" to all the screening questions if it believes the study should be reviewed by the DURCCom.

## 6.5 Two-Stage Review of DURC

## **Stage 1: DURCCom Subcommittee Review**

- If the Subcommittee determines that the research does not meet the definition of DURC, it will determine any steps necessary for ongoing monitoring of the research project. The research is not ordinarily subject to additional review or oversight; however it is expected that the PI will continue to assess their research for DURC potential (at least annually). The PI shall notify the IBC as soon as possible if there is potential for the research project to become DURC and will also communicate these changes to the IBC via any amendments and/or protocol renewals.
- If the Subcommittee determines that the research is DURC, then the study will be referred to the full DURCCom and Stage 2 will commence.

# Stage 2: DURCCom Full Committee Review

- If a study is determined to be DURC, then the full DURCCom will conduct a review according to the established criteria and develop a risk mitigation plan (details described in Section 6.7).
- The DURCCom will open a dialogue with the PI to determine whether the research should proceed as planned. During this consultation, the security aspects of the research will be reviewed with the appropriate officials (e.g., Deans, Provosts, AVPRC). Internal experts (e.g., other researchers, security experts), and external experts (e.g., National Science Advisory Board for Biosecurity) may also be consulted for advice on the development of the security management which may include limiting access to the research protocol, limitation of information that will be publicly disclosed (e.g., in publications, presentations at scientific forums), and potentially curtailing certain aspects of the research. For research projects that have been determined to be DURC, the DURC component of the project must not be initiated until an approved risk mitigation plan is in place.
- Regular (at least once each calendar year) meetings will be scheduled to review all DURC studies and
  risk mitigation plans. If there are no active DURC protocols or risk mitigation plans or other business
  to discuss, the Chair may choose to cancel the annual DURCCom meeting. The Chair's decision to
  cancel the annual DURCCom meeting will be clearly communicated in writing to Research Compliance
  staff as a formal record of the cancellation.

# 6.6 Reporting to Federal Agencies (or NIH-Designated Agency for Non-Federally Funded Research)

Within thirty calendar days of the DURCCom Subcommittee review, the ICDUR will notify the Federal funding agency of any research that involves one or more of the listed agents and/or one or more of the experimental effects listed in Section 5, and whether the research meets or does not meet the definition of DURC. Per the 2014 USG DURC policy (footnote on page 10 of the policy), for non-federally funded research, notification will be made to NIH via the following email address: DURC@od.nih.gov. NIH will refer the notification to an appropriate Federal agency, based upon the nature of the research.

**Note:** Research that does not involve any of the listed agents or toxins in Section 5 does not need to be reported to the Federal agency even if it meets the definition of DURC. However, a risk mitigation plan will still be developed by the DURCCom and approved by the ICDUR if the research meets the definition of DURC. The DURCCom will implement the approved risk mitigation plan and provide ongoing oversight of the DURC.

#### **6.7 Risk Mitigation Plan**

## **Federal Policy Requirements:**

For research that involves one or more of the listed agents and toxins and one or more of the seven listed experimental effects in Section 5, and meets the definition of DURC, the ICDUR and the DURCCom shall work with both the PI and the Federal funding agency, or for non-Federally funded DURC, the NIH-designated Federal agency, to develop a risk mitigation plan. Within ninety calendar days of the DURC determination, the ICDUR shall provide the draft risk mitigation plan to the appropriate Federal agency for final review and approval. Federal agencies are required to provide an initial response within thirty calendar days and should finalize the plan within sixty calendar days of receipt of the draft plan.

Note: Notice to and approval by the relevant Federal agency is not required for research that does not involve at least one of the listed agents and toxins in Section 6.

## Developing a Draft Risk Mitigation Plan:

The DURCCom shall conclude their risk-benefit assessment of DURC by developing a draft risk mitigation plan in consultation with the ICDUR. The plan should indicate the DURC-associated risks, the specific risk mitigation measures to be employed, and how these measures address the identified risks.

The ICDUR and the DURCCom should consider the strategies outlined below to determine the most effective risk mitigation measures that are tailored specifically to the research. These strategies are not mutually exclusive and may be used alone or in combination with other strategies. Note, however, that no risk mitigation strategy (or combination thereof) can reduce risks to zero; the aim should be to adequately and appropriately manage the identified risks.

Although it is the responsibility of the ICDUR and the DURCCom to develop the draft risk mitigation plan, there may be situations that require consultation with the relevant Federal agency. Such consultations may be appropriate when, for example they require guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high, or when it considers the only viable risk mitigation measures to be not conducting the research in question or not communicating its results.

The ICDUR and the DURCCom shall work with the relevant Federal agency to finalize the risk mitigation plan. The final risk mitigation plan shall be subject to the approval of the ICDUR.

# Strategies for Mitigating DURC-Associated Risks:

For details about each strategy, please refer to Section D of the Companion Guide.

- Determine whether existing biosafety and biosecurity measures are adequate;
- Evaluate applicability of existing countermeasures;
- Develop a plan for responsibly communicating the findings of DURC;
- Educate and train research staff using available DURC educational tools;
- Develop a plan for monitoring the DURC;

• Do not conduct certain aspects of the DURC.

# **Elements of a Draft Risk Mitigation Plan:**

Risk mitigation plans shall provide sufficient details on the research to enable the relevant Federal agency to adequately assess the University's plan for managing the risks and should include the following:

- The name and contact information for the PI(s);
- The name and contact information for the authorized institutional official;
- The name of the ICDUR (if different from the authorized institutional official);
- The dates and details of the reviews and assessments of the research by the DURCCom;
- 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 federal Policy;
- Details of the risks identified by the DURCCom and an explanation of the risk mitigation strategy or strategies;
- Other materials, such as proposals and progress reports related to the research that may be requested by the relevant Federal agency.

## 6.8 Implementation of the Risk Mitigation Plan

After a risk mitigation plan is developed and is approved by the relevant Federal agency, the DURC must be conducted in accordance with that plan. The DURCCom shall review all risk mitigation plans at least annually and modify the plans as needed. Plans that need modification require approval by the ICDUR and relevant federal agency prior to implementation.

#### 6.9 Monitoring of DURC

It is possible that research that originally met the definition of DURC may progress in such a manner that it is no longer DURC. Therefore, it is critical that the PI and the DURCCom maintain active communication and continuously review the progress of the research. This review may take the form of quarterly reassessment of the research by the PI by assessing the work against the specific screening questions in the IBC application to see if any changes have occurred and reporting the findings to the IBC and the DURCCom. The success of this continued monitoring is based on a culture of responsibility where all participants accept the importance of their role in ensuring that scientific progress is achieved with adequate and appropriate management of the security risks associated with DURC. PIs must report any noncompliance with this policy promptly to the DURCCom and IBC. The DURCCom shall review all reports of noncompliance and recommend an appropriate risk mitigation plan or change to a plan, including mitigation measures to prevent recurrences of similar noncompliance, for approval by the ICDUR and the relevant Federal agency.

The ICDUR shall also provide notification within thirty days of the following to the relevant federal agency:

- Noncompliance with this policy, as well as mitigation measures undertaken by the University to prevent recurrences of similar noncompliance.
- Any change in the status of a DURC project (including whether the research is determined by the DURCCom to no longer meet the definition of DURC), and
- Detailed recommendations for, or changes to, risk mitigation plans.

#### 6.10 Appeals by PIs

PIs shall have ten days from receipt of institutional decisions regarding research that is determined by the DURCCom to meet the definition of DURC to submit an appeal in writing to the ICDUR. The appeal shall

include the reason for the appeal and justification for the requested change to the decision. The ICDUR may conduct an inquiry and may solicit internal or external consultation during the inquiry, including consultation with the DURCCom and the relevant Federal agency. After completing the inquiry, the ICDUR shall issue a final determination and shall report the determination to the PI and the DURCCom.

#### 6.11 DURC Carried Out at Multiple Sites

There may be situations where elements of a potential DURC project are being carried out at multiple institutions, for example, through a subaward with a primary institution which directly receives the grant or contract from a Federal funding agency. In cases of such collaborations involving multiple institutions via a subaward, the prime awardee institution is ordinarily responsible for notifying the relevant Federal agency of research that is determined to be DURC (unless otherwise determined in the subaward) and providing copies of each institution's risk mitigation plan. Furthermore, the prime awardee institution should ensure that DURC oversight is consistently applied by all institutions participating in the collaboration.

#### 6.12 Transfer of Data and Materials

#### **Transfers Sent to External Institutions:**

For the limited number of studies that are categorized as DURC, it is important to conduct appropriate due diligence prior to sharing data, materials, or technology with external institutions. The PI, with help from Research Compliance, should obtain some basic information from the requestor. This should include answers to the following questions:

- Is the requestor from a legitimate institution and is he or she engaged in the type of research for which the information is being requested?
- Is the requestor familiar with the concept of DURC and its requirements?
- What specific data, materials, or technologies are being requested and for what purpose?
- Will the requestor agree to certain limitations or restrictions regarding access to the data, materials, or technology?
- Will the requestor's institution agree to such limitations or restrictions?

Once the information is gathered, the ICDUR and DURCCom will review the findings and, after consultation with the relevant Federal agency, if necessary, will determine whether approval should be granted. Once the due diligence is completed, the material transfer agreement will be handled by the Office of Technology Development, after consultation with the Export Control Officer, according to existing policies and procedures.

# Transfers Received from External Institutions:

The transfer of data, materials, or technology from an external institution may trigger evaluation of the research for DURC potential or, for research that has been categorized as DURC, may involve special consideration in light of the risk mitigation plan. For BU researchers, the Office of Industry Engagement shall consult the ICDUR, DURCCom, IBC staff, and/or the Export Control Officer prior to executing a material transfer agreement, as needed. For BMC researchers, the ICDUR and DURCCom shall be available for consultation with the appropriate BMC office(s).

## 6.13 Export Controls and DURC

Export Controls are Federal government regulations that govern the transfer of controlled materials, items, software or technologies abroad or to non-U.S. Persons in the United States. They are largely

outlined in three sets of regulations: the Export Administration Regulations (EAR) administered by the Bureau of Industry and Security, Department of Commerce, the International Traffic in Arms Regulations (ITAR) administered by the Directorate of Defense Trade Controls, Department of State, economic and trade sanctions administered by the Office of Foreign Assets Controls and the Treasury Department.

In conjunction with this policy, Principal Investigators shall review BU's Export Control <u>website</u> and its policy and procedures outlined in the <u>Export Control Manual</u> to ensure compliance with U.S. export controls.

The listed agents in Section 5 of this policy are controlled under the Export Administration Regulations, <u>Category 1</u> of the Commerce Control List. There are two types of transactions: 1) export of controlled material/technology or software; and 2) transfer of technology or software to non-U.S. Persons in the Unites States or abroad. Export licenses may be required in both circumstances. As a result, the Office of Technology Development shall consult with the Export Control Officer prior to the execution of Material Transfer Agreements. Pls shall consult with the Export Control Officer prior to the transfer of controlled technology or software to non-U.S. Persons.

To foster scientific advances, certain information is exempt from the EAR including information that is publicly available, information resulting from fundamental research, and educational information. A vast majority of research is considered fundamental research, which means basic and applied research in science and engineering where the resulting information is ordinarily published, shared broadly with the scientific community, and the techniques used during the research are publicly available or part of the published information.

Fundamental research is exempt from the Export Administration Regulations unless the researcher: a) accepts restriction on publication of the research results; b) accepts restriction on foreign national participation; c) uses techniques/data that are not publicly available; or d) participates in proprietary/industrial development without the intent to publish the research results. PIs shall consult with the Export Control Officer on the application of export controls to the research prior to accepting restrictions from a sponsor.

Under certain circumstances, DURC research may involve items, materials, data or services developed for military use and controlled under the ITAR. ALL research with materials, items or data enumerated on the U.S. Munitions List (USML) requires technology control plan and license authorization for non-U.S. Persons. Therefore, PIs shall consult the Export Control Officer prior to conducting research with materials that could have been developed for military use.

Note: Identification of research as DURC has no direct bearing on whether an export license is required. However, certain risk mitigation measures (e.g., the imposition or acceptance of restrictions on publication) MAY affect whether the research is subject to export authorization requirements. Please contact the Export Control Officer for more information.

#### 6.14 Publication and Dissemination of Information to the Public

The DURCCom will consider the following modes of communicating its findings to the public, based on the <a href="Companion Guide">Companion Guide</a>:

- 1. Communicate or publish as is.
- 2. Communicate or publish with addition of appropriate contextual information. For example, it may be important to address:

• The significance of the research findings for public health and/or public safety, agriculture, the environment, or material;

- How the new information or technology will be useful to the scientific community;
- The biosafety and biosecurity measures in place as the research was conducted; and
- The careful consideration that was given to the concerns about dual use in the decision to publish (e.g., a formal biosecurity review).
- 3. Communicate or publish openly but withhold specific information that is of concern. For example, "decouple" the material that poses security concerns from some or all the potentially useful scientific information, or remove information (e.g., technical details about an enabling technology). For example, it may be important to address:
  - Deleting certain information and then communicating or publish openly;
  - Communicating information "of concern" through nonpublication/non-presentation channels;
  - Identifying what parties should be given the restricted information and how it should be distributed.
- 4. Communicate only to selected parties (not openly communicate). For example, it may be important to address:
  - Communication to selected parties—need to specify who they are and the mechanisms of communication;
  - Communication of selected information to selected parties, but the rest of the information is not communicated at all, to anyone.
- 5. Do not communicate at all.

## Timing of communication, based on considerations set forth above:

- 1. Communicate immediately, to the extent decided above;
- 2. Defer communication (to the extent decided above) until a clearly defined and agreed-upon endpoint is reached (e.g., a condition is met such that communication no longer poses the same degree of risk).

## Final consideration of the agreed-upon course for going forward:

- 1. Does the proposed course of action mitigate, to an acceptable level, the risks that were identified in the risk-benefit analysis?
- 2. Are new risks introduced because of changes/modifications? Are there new concerns or unintended consequences regarding the proposed communication? If so, what are they and can they be mitigated?
- 3. Is it likely that the proposed course of action will be challenging to implement or enforce? Is a contingency plan necessary? Would additional resources be required?

## Criteria for Consulting the U.S. Government

It is expected that the ICDUR and the DURCCom can develop plans for the responsible communication of DURC findings in most cases. However, there may be some rare situations in which consultation with the relevant Federal agency may be helpful. The Federal agency may be consulted by the ICDUR or the DURCCom (not by individual researchers) for cases where:

- Unique expertise (e.g., on national security) is needed to assess the potential risks associated with communicating the research;
- The DURCCom requires guidance on developing an adequate risk mitigation strategy for communication in cases where the potential risks of communication are perceived as particularly high:
- The DURCCom considers the only viable risk mitigation strategy to be not conducting the research in question or not communicating its findings;

• The PI whose research has been reviewed does not agree with the DURCCom's findings, and the institution would like to request outside advice; or

• The research in question represents a particularly complex case or appears to fall outside the definition of DURC but still seems to present significant concerns.

# 7. Recordkeeping

For each research project that is categorized as DURC under this policy, the DURCCom shall maintain records of the DURC review(s) and completed risk mitigation plan(s) for the term of the research grant or contract plus three (3) years after its completion, but no less than eight (8) years, unless a shorter period is required by law or regulations. The DURCCom shall also maintain records of the researchers' education and training for the term of the research grant or contract plus three (3) years after its completion. Research Compliance staff will maintain records of DURCCom and DURCCom subcommittee meetings and findings.

## 8. References

- HHS and USDA Select Agents and Toxins
- Administration for Strategic Preparedness and Response ASPR
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- Improving the Safety and Security of Biological Research

# 9. Policy History:

Original Date Approved: December 16, 2014

Revised: June 13, 2022, May 13, 2025

Next Review Date: May 2028

# **Appendix I: Enhanced Dual Use Research Training**

Boston University's Dual Use Research of Concern (DURC) education and training program for faculty and staff is focused on providing a general framework for:

- Recognizing and understanding what types of research could be considered DURC.
- A discussion of the seven (7) types of "experiments of concern" that are described in the "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern" released September 24, 2014.
- Issues pertaining to potential limitation of such research or publication of data, materials, or technology produced from such research.

Additional training will be required for researchers who engage in research that involves the use of one or more of the listed agents and toxins or research that has otherwise been determined by the DURCCom to meet the definition of DURC. These individuals will be provided with additional training to enhance their understanding of the issues related to the conduct of such research. The training will be customized for the targeted audience and will cover the following general topics:

- What is Dual Use Research (DUR)?
- What is DURC?
- Need for continued monitoring of DUR and recognizing when it might become DURC
- What is biosecurity?
- What is the *culture of responsibility*?
- What is "due diligence"?
- Communications (what to say, when, and to whom)?
- Introduction to relevant documents and references from the NSABB.
- The role of the Dual Use Research of Concern Committee (DURCCom)
- The roles and responsibilities of PIs and researchers