Approved 9/9/2024

BOSTON UNIVERSITY
Policy on Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) in Research

1. Purpose

The purpose of this policy is to outline Boston University's (BU) plan for monitoring the care, oversight, and the review of research that may fall into the category of Dual Use Research of Concern (DURC), Pathogens with Pandemic Potential (PPP) or Pathogens with Enhanced Pandemic Potential (PEPP).

2. Covered Parties

This policy applies to all individuals engaged in potential DURC or the creation or use of PPP at or under the auspices of BU or Boston Medical Center (BMC).

3. Regulatory Background

In May 2024, the Federal government issued the "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" (*referred to as "the Policy" herein*) and an accompanying implementation guidance document, that requires funding agencies and institutional oversight of DURC and PEPP including policies, practices, and procedures to ensure this research is identified and risk mitigation measures are implemented, where applicable. This policy was enacted as a unified federal oversight framework for conducting and managing certain types of federally funded life sciences research on biological agents and toxins and now groups this type of research into two separate categories (Category 1 and Category 2). This 2024 policy supersedes previous 2012 United States Government policies and guidance on DURC, 2014 USG policy for institutional Oversight of DURC that covered research using 15 specific agents, and the 2017 Recommended Policy Guidance for Potential Pandemic Pathogen Care and Oversight (P3CO) that covered research on highly transmissible, virulent agents.

4. Scope

This policy applies to all research, regardless of funding or source of sponsorship, that involve biological agents and toxins classified as "Category 1" or "Category 2" (*See Section 6*) in accordance with the National Science and Technology Council's "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" policy.

5. Definitions

- ***Dual Use Research*** is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.
- ***Dual Use Research of Concern (DURC)*** is 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.

- ***Dual Use Research of Concern Committee (DURCCom):*** is defined as the Institutional Review Entity (IRE) at Boston University for research that may meet the criteria of Category 1 or Category 2.
- ***Pathogen with Pandemic Potential (PPP)*** is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans.
- ***Pathogen with Enhanced Pandemic Potential (PEPP)*** is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.
- ***Biological Agents*** are any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), infectious material, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious material, capable of causing:
    - Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
    - Deterioration of food, water, equipment, supplies, or material of any kind; or
    - Deleterious alteration of the environment.

6. <u>Categories of Research Subject to this Policy</u>

There are two (2) categories of research, experiments, and risk assessment that fall within the scope of this policy:

Category 1 Research

Category 1 research meets all the following three (3) criteria:

- Involves one or more of the biological agents or toxins within scope of Section 4.1.1 of the USG Policy;
- Is reasonably anticipated to result, or does result, in one or more of the experimental outcomes listed in Section 4.1.2 of the Policy; and
- Based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC, as specified in Section 4.1.3 of the Policy.

Category 1 Experiments *(Section 4.1.2 of the USG Policy):*

Research within the scope of Category 1 are those experimental outcomes with a biological agent or toxin outlined in the Policy that are reasonably anticipated to:

- Increase transmissibility of a pathogen within or between host species;
- Increase the virulence of a pathogen or convey virulence to a non-pathogen;
- Increase the toxicity of a known toxin or produce a novel toxin;
- Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin;
- Alter the host range or tropism of a pathogen or toxin;
- Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;

- Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
- Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; or
- Enhance the susceptibility of a host population to a pathogen or toxin.

Category 1 Risk assessment *(Section 4.1.3 of the Policy):*

Based on current understanding, the research can be reasonably anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to do harm with no — or only minor — modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

Category 2 Research

Category 2 research meets all the following three (3) criteria:

- Involves, or is reasonably anticipated to result in, a PPP as specified in Section 4.2.1 of the Policy;
- Is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified in Section 4.2.2 of the Policy; and
- Based on current understanding, the research institution, federal funding agency, and/or Departmental multidisciplinary review entity assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security as specified in Section 4.2.3 of the Policy.

Category 2 Experiments

Research within the scope of Category 2 are those experimental outcomes or actions with a pathogen outlined in the USG Policy that are reasonably anticipated to:

- Enhance transmissibility of the pathogen in humans;
- Enhance the virulence of the pathogen in humans;
- Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection;
- Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

Category 2 Risk assessment *(Section 4.2.3 of the Policy):*

The research can be reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security. See the Implementation Guidance for additional guidance, including illustrative examples.

7. Responsibilities

Institutional Contact for Dual Use Research (ICDUR)

The Institutional Contact for Dual Use Research (ICDUR) is designated by the University for questions regarding compliance with and implementation of the requirements for oversight of research meeting Category 1 or Category 2, 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 ICDUR is responsible for appointing members to the DURRCom. The Associate Vice President for Research Compliance (AVPRC) is designated as the BU ICDUR.

Principal Investigator (PI)

PIs will work with the DURCCom to assess whether their research meets criteria for Category 1 or Category 2, risk-benefit assessments for the research, research staff training and education, communication plans, and risk mitigation plans, as appropriate, to submit to the federal agency considering funding the research.

Institutional Biosafety Committee (IBC)

The IBC reviews protocols and identifies research that may fit into Category 1 or Category 2; this includes review of the initial protocol and any amendments that may change the category of the research in accordance with this policy. Research that falls within Category 1 or 2 is forwarded by the IBC to the DURCCom for their review.

Dual Use Research of Concern Committee (DURCCom)

The DURCCom is the Institutional Review Entity (IRE) at Boston University that confirms when research meets the criteria of Category 1 or Category 2 and develops the associated Risk Mitigation Plans. Further information on the DURCCom and its subcommittee is in the following sections of this policy document.

8. DURCCom Membership

Criteria for the DURCCom includes the following:

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 potential of the range of relevant life sciences research conducted at BU/BMC;
- Include persons with sufficient breadth of expertise to assess whether the research meets Criteria 1 or Criteria 2, and assess its risk and mitigation efforts;
- Include persons with knowledge of relevant Federal policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity.
- 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 conflict of interest in the research (financial or otherwise, serving as PI or research personnel), and may not be

present for the vote on protocols in which they have such conflicts except to provide specific information requested by DURCCom; and
- Engage in dialogue with the Principal Investigator (PI) of the research when conducting a risk assessment and developing a risk mitigation plan.

DURCCom Membership:
- DURCCom Chair
- Chair of the Institutional Biosafety Committee (IBC)
- Director of Research Safety
- Chief Safety Officer, NEIDL
- Chief of the BU Police Department
- Export Control Officer
- One (1) community member
- A representative from Public Relations
- Two (2) faculty representatives in scientific and technology fields (these faculty are not otherwise represented above, e.g. IBC or DURCCom Chair).

DURCCom Chair
The Chair of the DURCCom shall be appointed by the AVPRC from among the faculty 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. The chair of the DURCCom Subcommittee and the DURCCom full Committee will be the same individual.

DURCCom Subcommittee
A Subcommittee of the DURCCom has been established for the purpose of determining whether research meets Criteria 1 or 2 and if so, referral to full DURCCom for further review. DURC/P3CO Subcommittee Members include:
- DURRCom Chair
- Chair of the IBC;
- Director of Research Safety;
- At least one faculty member of the DURCCom

Meeting Schedule
- Subcommittee meetings are scheduled as needed to review research that may meet criteria for Category 1 or 2.
- Full committee meetings will be scheduled to review research that the subcommittee recommends as meeting criteria for Category 1 or 2, along with their corresponding risk mitigation plans. If there are no active protocols, 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 by the Research Compliance staff as a formal record of the cancellation.

9. DURCCom Review Process

Screening for Category 1 or 2 Research
The DURCCom has developed specific 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 6. The IBC office is responsible for initial screening of IBC protocol applications to identify whether the PI has marked "Yes" to any of the screening questions or whether the research may meet criteria of Categories 1 or 2. 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 meet criteria for Categories 1 or 2 and require full DURCCom review. The IBC may also forward applications to the DURCCom subcommittee where the PI may have replied 'no' to all questions if the IBC believes the study meets criteria for Categories 1 or 2 and should be reviewed by the DURCCom.

Two-Stage Review for Criteria 1 and 2

Stage 1: The DURCCom subcommittee will determine if the research meets the criteria for Category 1 or Category 2 and requires full DURCCom review, following the below process:

- If the subcommittee determines that the research *does not meet* the criteria of Category 1 or Category 2, the IBC staff will communicate this determination to the PI in writing, ordinarily within 5 business days of the meeting. The IBC staff will notify the PIs that they are expected to continue to assess their research for any changes that may alter this status at least annually. The PI shall notify the IBC immediately if there is a potential for the research project to change in any way that may affect the category of research. The PI may also communicate these changes to the IBC via amendments and/or protocol renewals.

- If the subcommittee determines that the research meets the criteria of Category 1 or Category 2, it will be referred to the DURCCom full committee.

Stage 2: When the subcommittee determines that the research meets the criteria of Category 1 or 2, the full DURCCom will conduct a review according to the established criteria and develop a risk mitigation plan (details described in Section 12)

When the DURCCom determine that Criteria 1 or 2 are met, the IBC staff will arrange a meeting between the DURCCom Chair and other designated DURCCom members, the PI and appropriate University officials (e.g., Deans, Provosts, AVPRC) to discuss the research in more detail, including the security aspects. 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 meet the criteria of Category 1 or Category 2, these components of the project must not be initiated until an approved risk mitigation plan is in place.

10. Education and Outreach

General DURC and PPP concepts are part of annual lab safety training which is required for all BU/BMC researchers utilizing lab space. Specific training and oversight 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 criteria of Category 1 or Category 2, and additional training may be required, depending on the research, as determined by the DURCCom. Additional information is available on the BU website dedicated to DURC.

11. Report to Federal Funding Agency (or NIH-Designated Agency for Non-Federally Funded Research)

Within thirty (30) calendar days of the DURCCom review, the ICDUR will notify the Federal funding agency of any research that involves one or more of the listed agents, one or more of the listed experimental effects, and whether the research meets or does not meet the criteria of Category 1 or Category 2. For non-Federally funded research, notification will be made to NIH, which may in turn refer the notification to an appropriate Federal or local agency, based upon the nature of the research.

12. Risk Mitigation Plan

12.1 Federal Policy Requirements:

For research that involves one or more of the listed agents and toxins and one or more of the listed experimental effects and meets the criteria for Category 1 or Category 2, the ICDUR and the DURCCom shall work with both the PI and the Federal funding agency, or for non-Federally funded research the NIH-designated Federal agency, to develop a risk mitigation plan. Within ninety (90) calendar days of the DURCCom's determination that the research meets the criteria of Category 1 or Category 2, 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 (30) calendar days and should finalize the plan within sixty (60) calendar days of receipt of the draft plan.

12.2 Developing a Draft Risk Mitigation Plan:

The DURCCom shall conclude their risk-benefit assessment of the research in Category 1 or 2 by developing a draft risk mitigation plan in consultation with the ICDUR. The plan should indicate the associated risks identified by the DURCCom, 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 in 12.3 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:

- The DURCCom requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
- The DURCCom 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.

12.3 Strategies for Mitigating DURC/PPP Associated Risks:

- Determine whether existing biosafety and biosecurity measures are adequate;
- Evaluate applicability of existing countermeasures;
- Develop a plan for responsibly communicating the findings of the relevant category of research;
- Educate, develop, and train research staff using available educational tools, including seeking out specific expertise in the creation of the training;
- Develop a plan for monitoring the research;
- Do not conduct certain aspects of the research.

For details about each strategy, please refer to Section F of the USG Policy. .

12.4 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 Category 1 or Category 2 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.

12.5 Implementation of the Risk Mitigation Plan

After a risk mitigation plan is developed and is approved by the relevant Federal agency, the research 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.

13. Monitoring of DURC

It is possible that research that originally met the definition of Category 1 or Category 2 may progress in such a manner that it no longer meets these criteria. Therefore, it is critical that the PI and the DURCCom maintain active communication and continuously review the progress of the research (e.g. quarterly/regular updates or progress reports from PI, as stipulated in the risk mitigation plan) with the initial screening questions, reported findings, etc. 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 this research.

Non-compliance: 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 corrective action plan, or modification to an existing Risk Mitigation Plan, including measures to prevent recurrence. Determinations of non-compliance and changes to risk mitigation plans must be reviewed and approved by the ICDUR and the relevant Federal agency. The ICDUR shall report instances of noncompliance with this policy, as well as mitigation measures undertaken by the University to prevent recurrences, within thirty (30) calendar days to the Federal funding agency or, for non-Federally funded research, to the Federal agency designated by NIH.

Change in Category Status or Risk Mitigation Plans

The ICDUR shall provide notification to appropriate federal agencies within thirty (30) days of the following:

- Any change in the status of this project (including whether the research is determined by the DURCCom to no longer meet the criteria of Category 1 or Category 2), and;
- Details of any changes to risk mitigation plans (such changes to be approved by the relevant Federal agency).

14. Appeals by PIs

PIs shall have ten (10) days from receipt of institutional decisions to submit a written appeal to the ICDUR regarding research that is determined to meet the criteria of Category 1 or Category 2.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.

15. Category 1 or Category 2 Research Carried Out at Multiple Sites

There may be situations where elements of a project are being carried out at multiple institutions, for example, through a subaward from a primary/awardee institution which directly receives the grant or contract from the Federal funding agency. In cases of such collaborations, the primary/awardee institution is responsible for coordinating institutional review decisions with the sub awardee institution, notifying the relevant Federal agency of research that is determined to meet the criteria of Category 1 or Category 2, and providing copies of each institution's risk mitigation plan. Furthermore, the primary institution should ensure that oversight is consistently applied by all institutions participating in the collaboration.

16. Transfer of Data and Materials

Transfers Sent to External Institutions:

For the limited number of studies that meet the criteria of Category 1 or Category 2, it is important to conduct 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 are they engaged in the type of research for

which the information is being requested?
- Is the requestor familiar with the concept of this work 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 Industry Engagement after consultation with the Export Control Officer, according to existing policies and procedures.

Transfers Received from External Institutions:
When data, materials, or technology are transferred from an external institution to an investigator at BU, the Office of Industry Engagement will contact the IBC office to confirm that the research has appropriate approval in place. Depending on what is being transferred and how it will be used, an evaluation may be required to assess the potential for the research to meet Criteria 1 or 2. 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).

17. Export Controls and DURC

Export Controls are Federal government regulations on 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, PI's shall review BU's Export Control Policies and Procedures as outlined in the Export Control Manual to ensure compliance with BU and U.S. export controls.

The listed agents in Section 6 of this policy are controlled under the Export Administration Regulations, Category 1 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 Industry Engagement shall consult with the Export Control Officer prior to the execution of Material Transfer Agreements. Principal Investigators 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 Export Administration Regulations 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 and shared broadly with the scientific community. The techniques used during the research are publically 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 publically available; or d) participates in proprietary/industrial development without the intent to publish the research results. Principal Investigators 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, Category 1 or 2 may involve items, materials, data or services developed for military use and controlled under the International Traffic in Arms Regulations (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, PI's shall consult the Export Control Officer prior to conducting research with materials that could have been developed for military use.

Note: Identification of Category 1 or Category 2 research has no direct bearing on whether or not 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 Office for more information.

18 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 Companion Guide:

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 materiel;
    - 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 of 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 communicate 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:

- Communicate immediately, to the extent decided above;
- 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:

- Does the proposed course of action mitigate, to an acceptable level, the risks that were identified in the risk-benefit analysis?
- Are new risks introduced as a result of changes/modifications? Are there new concerns or unintended consequences regarding the proposed communication? If so, what are they and can they be mitigated?
- 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 on Communicating Criteria 1 or 2 Research Findings

It is expected that the ICDUR and the DURCCom can develop plans for the responsible communication of DURC findings in the majority of 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 DURCComs 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 criteria of Category 1 or Category 2, but still seems to present significant concerns.

19 Recordkeeping

For each research project that is categorized meeting the criteria of Category 1 or Category 2 under this policy, the DURCCom shall maintain records of the review(s) and approved risk mitigation plan(s) for the term of the research grant or contract plus three (3) years after its completion, but no less than seven (7) years, unless a shorter period is required by law, regulation or sponsor requirement. 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.

References

United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with

Enhanced Pandemic Potential

Implementation Guidance for the United States Government Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

HHS and USDA Select Agents and Toxins

Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research Of Concern

8. History:

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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 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 fifteen (15) 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 Review Committee (DURCCOM).
- The roles and responsibilities of participants.