

United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern

Section I: Purpose and Principles

- 1) The purpose of this Policy is to establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. The fundamental aim of this oversight is 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.
- 2) This Policy complements existing United States Government regulations and policies governing the possession and handling of pathogens and toxins. Currently, the Select Agent Regulations ensure appropriate oversight of biosafety and biosecurity of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products. In addition, recommendations from Federal advisory bodies such as the National Science Advisory Board for Biosecurity (NSABB) have helped inform United States Government policies for identifying and managing DURC. This Policy will be updated, as needed, following domestic dialogue, engagement with our international partners, and input from interested communities including scientists, national security officials, and global health specialists.
- 3) The following principles guide implementation of this Policy:
 - a) Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel, and national security. Despite its value and benefits, some research may provide knowledge, information, products, or technologies that could be misused for harmful purposes.
 - b) Accordingly, some degree of Federal and institutional oversight of DURC is critical to reducing the risks to public health and safety, agricultural crops and other plants, animals, the environment, materiel, and national security.
 - c) Measures that mitigate the risks of DURC should be applied, where appropriate, in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.
 - d) The United States Government will facilitate the sharing of the results and products of life sciences research conducted or funded by United States Government agencies, and honor United States Government obligations within relevant international frameworks and agreements, while taking into account United States' national security interests.
 - e) In executing this Policy, the United States Government will abide by and enforce all relevant Presidential Directives and Executive Orders, all applicable laws and regulations, and support the implementation of legally binding treaties, commitments, and United Nations Security Council resolutions prohibiting the development and use of biological agents as weapons.

Section II: Definitions

- 1) For the purpose of this Policy, DURC is 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 security¹.

- 2) "Life sciences" pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules.
- 3) Extramural research is that which is funded by a department or agency under a grant, contract, cooperative agreement, or other agreement and not conducted directly by the department or agency.
- 4) Intramural research is that which is directly conducted by a department or agency.

Section III: Scope

Under this Policy, review will focus on research that involves one or more of the agents or toxins listed in Section (III.1) below, which pose the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, and produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section (III.2) below:

- 1) Agents and toxins²:
 - a) Avian influenza virus (highly pathogenic)
 - b) *Bacillus anthracis*
 - c) Botulinum neurotoxin
 - d) *Burkholderia mallei*
 - e) *Burkholderia pseudomallei*
 - f) Ebola virus
 - g) Foot-and-mouth disease virus
 - h) *Francisella tularensis*
 - i) Marburg virus
 - j) Reconstructed 1918 Influenza virus
 - k) Rinderpest virus
 - l) Toxin-producing strains of *Clostridium botulinum*
 - m) Variola major virus
 - n) Variola minor virus
 - o) *Yersinia pestis*
- 2) Categories of experiments:
 - a) Enhances the harmful consequences of the agent or toxin;
 - b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
 - c) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
 - d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
 - e) Alters the host range or tropism of the agent or toxin;

¹ This definition of DURC is derived from the NSABB definition, but is modified for purposes of this Policy.

² These agents and toxins are regulated by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73), and have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.

- f) Enhances the susceptibility of a host population to the agent or toxin; or
- g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Section IV: Department and Agency Responsibilities

- 1) Federal departments and agencies that conduct or fund life sciences research should implement the following actions:
 - a) Conduct a review to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
 - b) Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
 - c) Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
 - d) Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures. In addition:
 - i) For DURC that is proposed and not yet funded, departments and agencies will assess whether to incorporate risk mitigation measures in the grant, contract, or agreement.
 - ii) For currently funded DURC, funding departments and agencies will consider modifying the grant, contract, or agreement to incorporate risk mitigation measures. If such modifications are not possible or desirable, departments and agencies will seek voluntary implementation of mitigation measures by the institution.
 - e) A risk mitigation plan may include, but not be limited to, the following risk mitigation measures:
 - i) Modifying the design or conduct of the research.
 - ii) Applying specific or enhanced biosecurity or biosafety measures.
 - iii) Evaluating existing evidence of medical countermeasures (MCM) efficacy, or conducting experiments to determine MCM efficacy against agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications.
 - iv) Referring the institution to available DURC educational tools such as: <http://oba.od.nih.gov/biosecurity/biosecurity.html>
 - v) Regularly reviewing, at the institutional level, emerging research findings for additional DURC.
 - vi) Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.
 - vii) Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.
 - viii) Reviewing annual progress reports from Principal Investigators to determine if DURC results have been generated, and if so, flagging them for institutional attention and applying potential mitigation measures as described above, as necessary.
 - ix) If the risks posed by the research cannot be adequately mitigated with the measures above, Federal departments and agencies will determine whether it is appropriate to:
 - (a) Request voluntary redaction of the research publications or communications³;
 - (b) Classify the research:
 - (i) In accordance with National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within

³ Actions taken to restrict the publication of technology may have implications under export control laws and regulations (e.g., 15 CFR parts 730-774 and 22 CFR parts 120-130).

the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations.

- (ii) Departments and agencies may consider whether to refer classified research to another department or agency for funding.

(c) Not provide or terminate research funding.

- 2) Federal departments and agencies are requested to report the following to the Assistant to the President for Homeland Security and Counterterrorism:
 - a) Within 60 days of issuance of this Policy, the following results of the review conducted in response to Section (IV.1.a):
 - i) Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with one or more of the agents and toxins in Section (III.1).
 - ii) Aggregate number of current and proposed unclassified, intramural, and extramural research projects that include work with one or more of the agents and toxins in Section (III.1) and produces, aims to produce, or are reasonably anticipated to produce one or more of the effects listed in Section (III.2).
 - b) Within 90 days of issuance of this Policy, the following results of the review conducted in response to Sections (IV.1. b. c. and d):
 - i) Number of unclassified current and proposed DURC projects.⁴
 - ii) Number of current projects identified as DURC through initial proposals versus progress reports.⁵
 - iii) Summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.
- 3) Following completion of the reporting requirements in Section (IV.2), Federal departments and agencies are requested to submit periodic reports on items in Section (IV.2.a. and b) biannually.
- 4) Federal departments and agencies should implement Section IV in accordance with their relevant and applicable authorities, regulations, and statutes.
- 5) For additional guidance on how to conduct the risk assessment identified in Section (IV. 1.c), departments and agencies may refer to the “Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information,” which identifies useful assessment tools and is available at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html.

Section V: Consultation

As necessary and appropriate, the United States Government will continue to consult with the NSABB (in compliance with provisions of the Federal Advisory Committee Act) or convene the Countering Biological Threats Interagency Policy Committee for guidance on matters relating to the review and conduct of DURC and the mitigation of DURC risks.

^{4,5} Report the number of projects by agent and/or toxin plus the category of experiment.