

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

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Section 1. Introduction

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, materiel¹, and national security. Despite its value and benefits, however, certain types of research conducted for legitimate purposes can be utilized for benevolent or harmful purposes. Such research is called “dual use research.” 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.

In general, there are risks associated with life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin. Many existing and synergistic statutes, regulations, and guidelines are in place to address risks associated with biosafety, physical security, and personnel reliability.² Some risks relate directly to the characteristics of DURC – the risk that knowledge, information, products, or technologies resulting from the research could be used in a manner that results in harm or threatens society. DURC should be evaluated for possible risks, as well as benefits, in all these domains, to ensure that risks are appropriately managed and benefits realized. This Policy addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that results in harm.

Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research. A comprehensive oversight system must include both Federal and institutional oversight processes. The goal of oversight is to preserve the benefits of life sciences research while minimizing the risk that knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm. On March 29, 2012, the U.S. Government (USG) issued its “Policy for Oversight of Life Sciences Dual Use Research of Concern” (*March 29 Policy*). That policy formalized a process of regular Federal review of USG-funded or -conducted research with certain high-consequence pathogens and toxins to identify DURC and implement mitigation measures, where applicable.

The Policy herein, “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” addresses institutional oversight of DURC. Oversight includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures

¹ Materiel includes food, water, equipment, supplies, or material of any kind.

² e.g. Select Agents and Toxins Program (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331); National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf); Biosafety in Microbiological and Biomedical Laboratories 5th Edition (<http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>)

are implemented, where applicable. Institutional oversight of DURC is a 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. This Policy, in addition to the *March 29 Policy*, emphasizes a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.³ The components outlined in the *March 29 Policy* and in this Policy will be updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists.

Because institutional oversight of DURC will be a new undertaking for many institutions, the USG is currently limiting the requirements in this Policy, as well as the *March 29 Policy*, to research that meets the scope in Section 6.2, which focuses on a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The USG will solicit feedback on the experience of institutions in implementing the Policy; will evaluate the impact of DURC oversight on the life sciences research enterprise; will assess the benefits and risks of expanding the scope of the Policy to encompass additional agents and toxins and/or categories of experiments; and will update the Policy, as warranted. Research institutions are encouraged to be mindful that research outside of the categories articulated in this Policy may also constitute DURC. Institutions have the discretion to consider other categories of research for DURC potential and may expand their oversight to other types of life sciences research as they deem appropriate.

It is important to note that research that meets the definition of DURC often increases our understanding of the biology of pathogens and makes critical contributions to the development of new diagnostic, prevention, and treatment measures, improvements in public, animal, and plant health surveillance, and the enhancement of emergency preparedness and response efforts. Thus, designating research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated.

Nothing in this Policy supersedes the Department of Health and Human Services and the United States Department of Agriculture Select Agents and Toxins Program's (SAP) statutory authority or SAP regulations as published in 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

³ The *March 29 Policy* and this Policy are complemented by other extant laws and treaties (e.g. United States Code Title 18 Section 175 part a, 175 part b, and 175b and Biological and Toxin Weapons Convention) that prohibit the development, production, acquisition, or stockpiling of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and that prohibit the use of biological agents and toxins as weapons.

Section 2. Purpose

The purpose of this Policy is to strengthen regular institutional review and oversight of certain life sciences research with high-consequence pathogens and toxins in order to identify potential DURC and mitigate risks where appropriate. This Policy delineates the roles and responsibilities of Federal funding agencies, research institutions, and life scientists, and establishes requirements and performance standards for review of research, identification of potential DURC, and development and implementation of risk mitigation measures for DURC, where applicable. In so doing, the Policy seeks to preserve the benefits of DURC while minimizing the risk that the knowledge, information, products, or technologies generated from such research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Section 3. Guiding Principles for Oversight of Life Sciences Dual Use Research

The following principles serve as a guide for oversight of life sciences dual use research generally:

- A. Life sciences research makes possible advances in public health, agriculture, the environment, and other pertinent areas and contributes significantly to a strong national security and economy.
- B. Life sciences research has the potential to produce beneficial knowledge, information, technology, or products that can also be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, or the environment. Therefore, it is appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.
- C. Life sciences research is by nature dynamic and can produce unanticipated results, and therefore must be evaluated on an ongoing basis for dual use potential.
- D. Oversight of DURC must recognize both the need for security and the need for research progress; as such, the degree of oversight should be consistent with the possible consequences of misuse.
- E. Effective oversight helps maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of DURC and is acting responsibly to protect public welfare and security.
- F. Federal agencies that fund DURC, the recipients of those public funds, and individuals who conduct this research share the oversight responsibility.
- G. It is essential to have a consistent approach to the oversight of DURC.
- H. Any oversight process for DURC should be periodically evaluated both for effectiveness and impact on the research enterprise.

- I. The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise and will continue to be the goal of the USG. It also should continue to be the goal of institutions engaged in life sciences research.
- J. Educating the scientific community about the dual use potential of life sciences research and cultivating a sense of responsibility for dual use research among life scientists is essential for promoting responsible research behavior.
- K. No policy or set of guidelines can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key considerations in the responsible evaluation of research for dual use potential. It is incumbent on those engaged in life sciences research to adhere to the intent of this Policy as well as to the performance standards described herein.

Section 4. Definitions

For the purpose of this Policy the following terms are defined:

- A. “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.
- B. “Dual use research of concern,” or “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 security.
- C. “Institution” is any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity involved in funding, conducting, or sponsoring research.
- D. “Institutional Contact for Dual Use Research,” or “ICDUR,” is designated by the institution to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant Federal funding agency.
- E. “Institutional review entity” is established by the institution to execute the requirements in Section 7.2.B.i-7.2.B.v below and has the attributes described in Section 7.2.E below.
- F. “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 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 to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

- G. “National Science Advisory Board for Biosecurity” (NSABB) is a Federal advisory committee established to advise the USG on dual use research issues.

Section 5. Policy Statement

It is the policy of the USG that:

- A. Life sciences research that meets the scope specified in Section 6.2 of this Policy is subject to Federal as well as institutional oversight. The purpose of this oversight is to preserve the benefits of such research while minimizing the risk that the knowledge, information, products, or technologies generated by DURC could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security; and
- B. Oversight includes the identification of life sciences research that raises dual use concerns as well as the implementation of measures to mitigate the risk that DURC is used in a manner that results in harm. Measures that mitigate the risks of DURC should be applied in a manner that minimizes, to the maximum 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.

Section 6. Applicability of this Policy and Scope of Oversight of DURC

6.1. Applicability

This Policy and its oversight requirements apply to:

- A. Federal departments and agencies that fund or conduct life sciences research.
- B. Institutions within the United States that receive Federal funds to conduct or sponsor life sciences research, and conduct or sponsor research that is within the scope identified in Section 6.2, regardless of source of funding.
- C. Institutions outside of the United States that receive Federal funds to conduct or sponsor research that is within the scope identified in Section 6.2.

Non-compliance with this Policy may result in suspension, limitation, or termination of Federal funding, or loss of future Federal funding opportunities for the non-compliant Federally-funded research project and of Federal funds for other life sciences research at the institution. While each Federal funding agency is responsible, in accordance with their

relevant statutory authorities, for determining how best to ensure compliance with the oversight requirements set forth in this Policy for research it funds, the USG, to the maximum degree possible, will develop and promulgate consistent processes for this purpose.

Institutions that do not receive any Federal funds for life sciences research, but that nevertheless conduct life sciences research that has the potential to generate knowledge, information, products, or technologies that could be used in a manner that results in harm, are strongly encouraged to implement similar oversight procedures consistent with the culture of shared responsibility underpinning this Policy.

6.2. Scope of Oversight Required Under this Policy

Consistent with the *March 29 Policy*, under this Policy, life sciences research that uses one or more of the agents or toxins listed in Section 6.2.1, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 will be evaluated for DURC potential.

6.2.1. Agents and toxins⁴

- a) Avian influenza virus (highly pathogenic)
- b) *Bacillus anthracis*
- c) Botulinum neurotoxin⁵
- 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*

6.2.2. 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 and/or agricultural justification

⁴ 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, 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.

⁵ For the purposes of this Policy, there are no exempt quantities of toxin. Research involving any quantity of Botulinum neurotoxin should be evaluated for DURC potential.

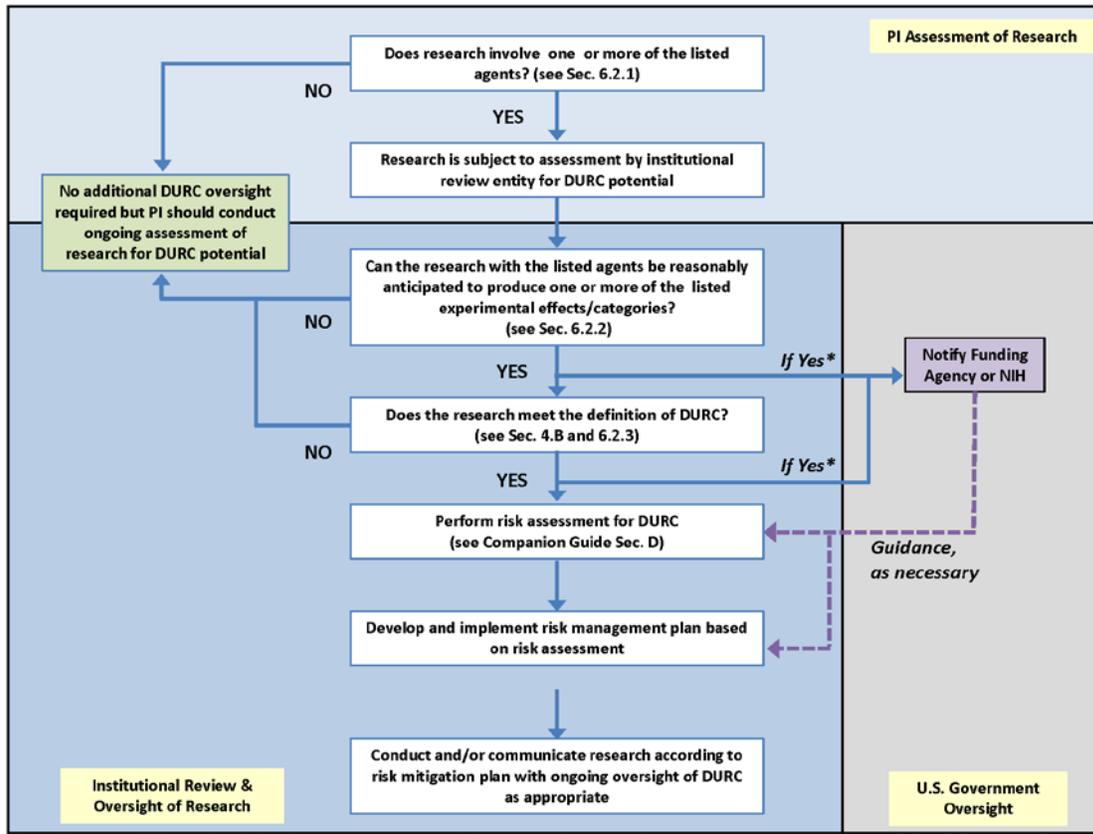
- c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- e) Alters the host range or tropism of the agent or toxin
- f) Enhances the susceptibility of a host population to the agent or toxin
- g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in 6.2.1, above.

Section 7. Organizational Framework for Oversight of DURC

This Section describes the organizational framework for the oversight of DURC and articulates the roles and responsibilities of PIs, institutions, Federal funding agencies, and the USG under this Policy. Generally, components of the oversight system for DURC include:

- A. Identification, by the PI, of life sciences research that falls within the scope of Section 6.2.1 (described in Section 7.1 below);
- B. An institutional review process for assessing whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2, and if so, determining whether the research meets the definition of DURC in Section 4.B. This includes assessing the benefits and risks associated with its conduct and communication, developing a plan for mitigating identified risks, and ensuring that research is conducted in accordance with the risk mitigation plan (described in Section 7.2 below);
- C. Notification of the results of this review process and provision of the risk mitigation plan by the institution to the Federal funding agency or for non-Federally funded research, to the National Institutes of Health (NIH) (which will receive for administrative purposes on behalf of all of the institution's Federal funders) and annual assurance of compliance with the Policy described in Section 7.2 below; and
- D. Oversight by Federal funding agencies and the USG as articulated in the *March 29 Policy* with additional responsibilities with respect to this Policy described in Section 7.3 and 7.4 below.

Figure 1 provides an overview of the institutional oversight process.



*Notification of the Federal funding agency or NIH if the research meets the criteria in Section 6.2.2 and the definition of DURC in Section 4.B can be concurrent.

7.1. Responsibilities of Principal Investigators of Research that is Subject to Institutional DURC Oversight

In accordance with this Policy, PIs are to:

- A. Identify his or her research involving one or more of the agents or toxins listed in Section 6.2.1 and refer that research to an appropriate institutional review entity to be reviewed for its DURC potential. If a PI determines that his or her research does not utilize any of the agents or toxins listed in Section 6.2.1, no further action by the PI is needed in terms of DURC oversight (Figure 1).
- B. Work with the institutional review entity to develop risk mitigation measures where appropriate.
- C. Conduct DURC in accordance with the provisions in the risk mitigation plan.
- D. Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC.
- E. Ensure that laboratory personnel conducting life sciences research that falls within the scope of this Policy (i.e., those under the supervision of laboratory leadership,

including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) have received education and training on DURC.

- F. Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not simply at the point of publication. When researchers are planning to communicate DURC, it is their duty to ensure that it is done in a responsible manner, and in compliance with any risk mitigation plan stipulated by the institutional review entity.

7.2. Responsibilities of Research Institutions that Conduct Research that is Subject to Institutional DURC Oversight

In accordance with this Policy, research institutions are to:

- A. Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC.
- B. When research is identified by a PI as utilizing one of the agents or toxins listed in Section 6.2.1, initiate an institutional oversight process that includes (Figure 1):
 - i. Verification that research utilizes one or more of the agents or toxins listed in Section 6.2.1;
 - ii. Determination of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2;
 - iii. Determination of whether the research meets the DURC definition (Section 4.B) and is therefore DURC. If the institutional review determines that the research in question does not fall within the scope of Section 6.2.2 or does not meet the definition of DURC, the research can continue without additional DURC oversight;
 - iv. Assessment of the dual use risks and the benefits of the research;
 - v. Development of a risk mitigation plan for DURC, as necessary;
 - vi. Implementation of the risk mitigation plan. After a risk mitigation plan is developed, the research must be conducted in accordance with that plan and must be periodically reviewed by the institution to determine if additional modifications to the risk mitigation plan are appropriate. For research that has been proposed but not yet initiated, the DURC component of the project should not be initiated until a risk mitigation plan is implemented;
 - vii. Within 30 calendar days of the institutional review of the research for DURC potential, notification of the Federal funding agency of any research that falls within the scope of 6.2, including whether it meets or does not meet the definition of DURC. For non-Federally funded research, notification may be made to NIH (who may in turn notify the appropriate Federal funding agency, based upon the nature of the research); and

- viii. Within 90 calendar days from the time that the institution determined the research to be DURC, provision of a copy of the risk mitigation plan to the funding agency for review – or for non-Federally funded research, provision of the plan to NIH for review (or referral to the appropriate funding agency).
- C. Ensure that internal policies establish a mechanism for the PI to refer a project to the institutional review entity if, at any time, his or her work with one or more of the agents or toxins listed in Section 6.2.1 also produces or can be reasonably anticipated to produce one or more of the 7 effects listed in Section 6.2.2, or may meet the definition of DURC.
- D. Designate an Institutional Contact for Dual Use Research (ICDUR) to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section 6.2 and/or meets the definition of DURC. If questions arise regarding compliance, implementation of this Policy, or the *March 29 Policy*, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the institution and the relevant program officers at the Federal funding agencies, or for non-Federally funded research, between the institution and NIH (or the appropriate Federal funding agency to which NIH refers the institution).
- E. Establish an institutional review entity to execute the requirements in Section 7.2.B.i-7.2.B.v above. A range of mechanisms for fulfilling the role of an institutional review entity are acceptable as long as the review entity is appropriately constituted and authorized by the institution to conduct the dual use review. Options include: (1) a committee established for dual use review; (2) an extant committee (such as an Institutional Biosafety Committee[IBC]) whose constitution meets or could meet, with the addition of ad hoc members, the requirements outlined below; or (3) an externally administered committee (e.g., an IBC or review entity at a neighboring or regional institution or a commercial entity).

Regardless of the mechanism selected to fulfill the institutional responsibility of reviewing research that falls within the scope of Section 6.2.1, the review entity must:

- i. Be sufficiently empowered by the institution to ensure compliance with the institution's dual use research policies.
- ii. Have sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility.
- iii. Have knowledge of dual use issues, concerns, and related institutional and Federal policies and understand risk assessment and risk management considerations. The review entity should be aware that a variety of risk mitigation measures are available and that designating research as DURC does

not necessarily mean that the research should not be conducted or communicated.

- iv. Make its procedures for reviewing life sciences research for dual use potential accessible to the public. The posted policies of the institution should include an overview of the institution's procedures or review process, but should not include details of particular cases or the minutes of the DURC review entity's proceedings.
 - v. On a case by case basis, recuse any member of an institutional review entity who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity.
 - vi. Engage in an ongoing dialogue with the PI of the research in question when developing appropriate risk mitigation plans.
 - vii. Maintain records of institutional DURC reviews and completed risk mitigation plans for three years.
- F. Provide education and training on DURC for individuals conducting life sciences research that falls within the scope of this Policy. Institutions may also wish to address dual use topics in existing courses on research ethics or the responsible conduct of research.
- G. Maintain records of personnel training on dual use research for three years.
- H. Report instances of noncompliance with this Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar noncompliance, within 30 calendar days to the Federal funding agency or, for non-Federally funded research, to NIH (which will receive for administrative purposes on behalf of all of the institution's Federal funders).
- I. As necessary, assist the PIs of life sciences research when questions arise about whether their research may require further review or oversight.
- J. Establish an internal mechanism for PIs to appeal institutional decisions regarding research that is determined by the institutional review entity to meet the definition of DURC.
- K. On an annual basis, provide a formal assurance to the Federal funding agencies that the institution is in compliance with all aspects of this Policy.

Note: The USG recognizes that there will be situations where a PI is conducting potential DURC at multiple institutions. It is under the purview of each institution to review these projects and if DURC is being conducted at their institution, develop and implement risk mitigation plans as appropriate.

7.3. Responsibilities of Federal Departments and Agencies that Fund Research that is Subject to DURC Oversight

The oversight process and the roles and responsibilities of the Federal departments and agencies that fund life sciences research are delineated in the complementary *March 29 Policy*. In accordance with this Policy aimed at institutions, Federal departments and agencies that fund DURC are to:

- A. Require all institutions they fund that meet the applicability criteria in Section 6.1 to implement this Policy. One mechanism for implementing the Policy is through a term and condition of award.
- B. Respond to questions from institutions regarding the oversight of DURC and provide guidance to institutions regarding compliance with this Policy.
- C. For department- or agency-funded and proposed life sciences research that meets the criteria listed in Section 6.2.1, assess the applicability of the criteria listed in Section 6.2.2, and for such research that also meets the definition of DURC, complete a risk assessment prior to the funding decision and when progress reports are submitted by PIs. Federal departments and agencies will review projects on an ongoing basis for DURC and are to:
 - i. For research that meets the criteria in Section 6.2.1, notify an institution when the department or agency assesses that the research meets the criteria listed in Section 6.2.2 and meets the definition of DURC;
 - ii. Notify an institution when the department or agency does not agree with an institution's assessment of the applicability of the criteria listed in Section 6.2.2 or with an institution's determination of the DURC status of such research;
 - iii. Review institutional risk mitigation plans and notify an institution of any concerns or disagreements with a risk mitigation plan; and
 - iv. Prior to reaching its final determination, the funding agency will consult with institutions to address any disagreements identified in accordance with sections 7.3.D.i, ii, and iii above.
- D. Respond to reports of non-compliance with this Policy and work with institutions to address such non-compliance.
- E. For research institutions in low-resource environments outside of the United States that receive USG funds, the funding department or agency may elect to serve as the implementing institutional review entity if appropriate.

7.4. Responsibilities of the USG

In accordance with this Policy, the USG is to:

- A. Develop training tools and materials for use by the USG agencies and by institutions implementing this Policy.

- B. Provide education and outreach to affected stakeholders about dual use policies and issues.
- C. Provide guidance to institutions on the distribution of DURC research products and on the communication of DURC.
- D. Convene advisory bodies such as NSABB, as necessary, to develop recommendations on particularly complex cases of DURC.
- E. Periodically assess the impact of this Policy on life sciences research programs and institutions, and update the Federal and institutional dual use research oversight policies as appropriate. This should be informed by national and international dialogue with interested communities, including scientists, research administrators, security experts, and public health officials.

Section 8. Resources for Institutional Oversight of DURC

It is the expectation of the USG that PIs and institutions will be able to identify, assess, and appropriately manage DURC. To assist in these processes, the following resources are available for optional use:

- A. **Guidance Documents for DURC Oversight.** The USG has developed a compendium of tools to assist investigators and research institutions in the implementation of DURC oversight outlined in this Policy and the *March 29 Policy*. These tools will aid in the understanding and identification of DURC, the risk assessment and development of risk mitigation plans and risk management processes, the responsible communication of DURC, and training and education on DURC.
- B. **Consultation with the Federal Funding Agency.** Institutions may consult with the Federal department or agency that is funding the research in question for advice on matters related to DURC. Such consultations should involve the ICDUR. The funding agency program officers can provide guidance on DURC issues. Questions regarding non-Federally funded research can be directed to the NIH or to the Federal funding agency to which NIH refers the institution based on the nature of the research in question. Consultation with the funding agency is not mandatory or intended as a substitute for institutional dual use review or the reporting requirement (see Section 7.2.B above). Such consultations may be appropriate when:
 - i. The institutional review entity requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
 - ii. The institutional review entity considers the only viable risk mitigation measure to be not conducting or not communicating the research in question;

- iii. The PI does not agree with the finding of the institutional review entity and so the institution would like to request outside advice;
- iv. The research in question represents a particularly complex case or appears to fall outside the current definition of DURC, but still seems to present significant concerns; or
- v. Guidance is required to ensure a clear understanding of how the Federal government interprets the definition of DURC and related terms.