Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Frequently Asked Questions

Prepared by the National Institutes of Health on behalf of the United States Government

September 2014

FAQs on the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

1. What are "dual use research" and "dual use research of concern (DURC)"?

"Dual use research" is research conducted for legitimate purposes that generates knowledge, information, products or technologies that can be utilized for benevolent and harmful purposes. Much life sciences research could be considered dual use – that is, much research yields outputs with some potential to be misused.

The *March 2012 DURC Policy* and the *Policy for Institutional Oversight of Life Sciences DURC* define "dual use research of concern," 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.*

2. Why is the Federal government issuing the *Policy for Institutional Oversight of Life Sciences DURC*?

The dual use potential of certain life sciences research has been recognized as an important biosecurity issue for a number of years. It is vitally important that researchers and their institutions are vigilant with respect to the dual use potential of life sciences research that they carry out. The *Policy for Institutional Oversight of Life Sciences DURC* articulates and formalizes the roles and responsibilities of institutions and investigators when they are conducting certain types of research supported by the Federal government. Investigators, in particular, are often best poised to understand the dual use implications of the knowledge, information, products or technologies emanating from their research and to propose and implement strategies to mitigate the possibility that the results of their research will be misused to do harm.

In short, the *Policy for Institutional Oversight of Life Sciences DURC* aims to preserve the benefits of life sciences research while minimizing the risk that the knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm.

3. How does the *Policy for Institutional Oversight of Life Sciences DURC* relate to the *March 2012 DURC Policy*?

Federal agencies and research institutions have a shared responsibility for minimizing the risks associated with the misuse of the products of their research. The *March 2012 DURC Policy* sets forth a process of regular federal review of USG-funded or -conducted research and requires federal agencies that fund or conduct life sciences research to identify DURC and evaluate this research for possible risks, as well as benefits, and to ensure that risks are appropriately managed and benefits realized. The *Policy for Institutional Oversight of Life Sciences DURC* complements the *March 2012 DURC Policy* by establishing institutional review procedures and oversight requirements that parallel those undertaken by federal funding agencies. Together, the two DURC policies work to engage life science research communities and the federal funding agencies in a shared responsibility to address the risk that knowledge, information, products, or technologies generated from life sciences research

could be used for harm. In addition, the DURC policies emphasize a culture of responsibility by reminding all involved parties of the shared interest in upholding the integrity of science and in preventing its misuse.

4. To what types of institutions does the *Policy for Institutional Oversight of Life Sciences DURC* apply?

The *Policy for Institutional Oversight of Life Sciences DURC* applies to all institutions (and their investigators) that receive Federal funding for life sciences research and that conduct research (funded by any source) involving any of 15 agents and toxins listed in the policy. The *Policy for Institutional Oversight of Life Sciences DURC* defines an institution as any government agency (federal, state, tribal, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity receiving funds for and/or conducting research.

5. What research is encompassed by the term "life sciences" in the *Policy for Institutional Oversight of Life Sciences DURC*?

The term "life sciences" pertains to the study of living organisms (e.g., microbes, human beings, animals, and plants) and their products, and includes all of the diverse sub-disciplines and methodologies of biology as well as all applications of the biological sciences. Examples of sub-disciplines include aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, and engineering of living systems. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

6. Why is the scope of the *Policy for Institutional Oversight of Life Sciences DURC* limited to research with the 15 listed agents and toxins?

Because oversight of DURC will be a new undertaking for many institutions, the USG has limited the scope of the *Policy for Institutional Oversight of Life Sciences DURC* (Section 6.2), as well as that of the *March 2012 DURC Policy* (Section III), to a 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 for Institutional Oversight of Life Sciences DURC*. The USG will assess the benefits and risks of expanding the scope of the *Policy for Institutional Oversight of Life Sciences DURC*, and will update the Policy as warranted.

7. Does the USG Policy for Institutional Oversight of Life Sciences DURC apply only to federally funded research, or does it apply more broadly?

If an institution (1) receives any federal funding for any life sciences research, and (2) is conducting work with one or more of the 15 agents and toxins listed in the policy, then any research at that institution with those 15 agents and toxins - regardless of the source of funding - must comply with the requirements articulated in the policy.

8. How does the *Policy for Institutional Oversight of Life Sciences DURC* relate to the Select Agent Regulations?

Select agents are those biological agents and toxins specifically identified in U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (HHS CDC) and U.S. Department of Agriculture, Animal Plant Health Inspection Services (USDA APHIS) regulations as having the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products (for further information see 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121). Each of the 15 agents and toxins listed in the Policy for Institutional Oversight of Life Sciences DURC is regulated by HHS CDC and USDA APHIS as a select agent (http://www.selectagents.gov/Regulations.html). The select agent regulations (SAR) require that individuals working with select agents undergo an FBI security risk assessment and that their institutions put into place biosafety and physical security measures to avoid accidents or thefts. These biosafety and physical security measures are critical to promoting the biosecurity of life sciences research, but do not directly address dual use issues. In particular, the SAR do not apply to research information, and hence the Policy for Institutional Oversight of Life Sciences DURC addresses another important facet of biosecurity. Thus, the oversight system for dual use research, as described in the policy, is complementary to that of select agents in that it is based on principles and practices for reducing the likelihood that knowledge, information, products, or technologies emanating from research are intentionally misused to pose a risk to public health or national security.

9. What are some of the responsibilities of research institutions under the *Policy for Institutional Oversight of Life Sciences DURC*?

Research institutions must:

- Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC;
- 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 the Policy;
- Establish an Institutional Review Entity (IRE) to execute the requirements of the Policy; a range of mechanisms for fulfilling the role of an IRE are acceptable as long as the review entity is appropriately constituted and authorized by the institution to conduct the dual use review;
- Provide education and training on DURC for individuals conducting life sciences research that involves any of the 15 agents and toxins listed in this Policy; and
- 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.

10. What are some of the responsibilities for principal investigators under the *Policy for Institutional Oversight of Life Sciences DURC*?

Principal investigators must:

- Identify research involving one or more of the agents and toxins listed in the Policy;
- Work with the IRE to assess the risks and benefits of the dual use research of concern and to develop risk mitigation measures where appropriate;
- Conduct DURC in accordance with the provisions in the risk mitigation plan;
- Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC;
- Ensure that laboratory personnel conducting life sciences research with any of the 15 agents and toxins listed in the Policy have received education and training on DURC; and
- Communicate DURC in a responsible manner.

11. Does the designation of DURC mean the research should not be communicated or conducted?

No, a determination that research is DURC, in and of itself, does not mean that the research should not be communicated or conducted. Research that is categorized as DURC is often vitally important to science, public health, and agriculture, and its findings contribute to the broader base of knowledge that advances science and public health objectives. Upon identifying research as DURC, institutions are to develop and implement appropriate measures to minimize the possibility of misuse.

12. Where can institutions and investigators find out more information about DURC and the *Policy for Institutional Oversight of Life Sciences DURC*?

For information about the requirements at your institution you may be able to consult the IRE or the ICDUR.

Information about dual use research in the life sciences in general, as well as specific details on the *Policy for Institutional Oversight of Life Sciences DURC*, including a compendium of helpful guidances - *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern – a Companion Guide to the USG Polices for Oversight of Life Sciences Dual Use Research of Concern*, can be found at the Department of Health and Human Services' Science, Safety and Security (S3) website: http://www.phe.gov/s3/dualuse

13. Is there a specific point of contact at the Federal funding agencies who can assist with questions related to the review of research and oversight of DURC?

Questions regarding whether a particular project may constitute DURC generally should first be addressed to the program officer at the funding agency supporting the project. The program officer will know who else to consult within the government for additional perspective.

In many cases, the research requiring review under the *Policy for Institutional Oversight of Life Sciences DURC* will be USG-funded and the submission of notifications and risk mitigation plans (if needed) should be made directly to the USG funding agency. When IREs are determining whether research meets the definition of DURC (see Section 7.2.B of the *Policy for Institutional Oversight of Life Sciences DURC*), they are expected to identify research that, while taking place at an institution that receives Federal funding for life sciences research, is not directly funded by a USG funding agency. For such non-USG funded research, the initial 30-day notification should be made to the National Institutes of Health (NIH; [DURC@od.nih.gov], include "DURC Notification" in the

subject line) which will in turn refer the notification to an appropriate USG funding agency, based upon the nature of the research.

14. Is there a specific point of contact within the U.S. Government (USG) for addressing questions about interpreting and implementing the policy?

Individuals with questions about interpreting or implementing the policy may send queries to DURC@ostp.gov. Questions about the possible DURC nature of particular projects of research should be addressed to the program official at the pertinent funding agency, unless the project is not Federally funded, in which case questions can be sent to DURC@od.nih.gov.

15. Are there additional guidance documents related to the oversight of DURC?

The USG has developed a *Companion Guide* to assist investigators and research institutions in the implementation of the policy and oversight of DURC. This set of 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. The *Companion Guide* is available at the Department of Health and Human Services' Science, Safety and Security (S3) website: http://www.phe.gov/s3/dualuse.