DURC Stakeholder Meeting Summary: Addressing Key Issues

On September 24, 2014, the USG released the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) [FR Doc No: 2014-22770]. The Policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable.

The Policy will take effect on September 24, 2015. By that date institutions should have established the procedures necessary to comply with the Policy.

Stakeholder meeting

On July 22, 2015, the White House Office of Science and Technology Policy and the National Institutes of Health co-hosted a public workshop to discuss the DURC Institutional Policy, solicit feedback from the community, and learn the experiences of institutions as they begin to implement the Policy. The workshop included a series of panels where institutional representatives shared their experiences, challenges, and innovative practices in identifying research subject to the Policy, developing risk mitigation plans, and raising awareness about DURC.

The workshop featured:

- An interactive case study illustrating factors that investigators and institutions should consider when determining whether research is subject to the Policy.
- A series of panels composed of institutional representatives who shared their respective approaches to identifying research subject to the Policy, developing risk mitigation plans, and raising awareness and education about DURC.
- An open forum for participants to share their input on issues relating to interpretation and implementation of the Policy.

Meeting materials from the workshop, including the presentations and an archived videocast of the event, are available at http://www.phe.gov/DURCworkshop.

Major questions posed at workshop

Several important questions and issues were raised during the stakeholder workshop; the three most prevalent are addressed below.

1. In the DURC Institutional Policy, research using any amount of botulinum toxin is subject to review by an Institutional Review Entity. Much of the basic research on botulinum toxin involves the use of small quantities that have been exempted from the Select Agent Regulations. In addition, a number of clinical research projects involve the use of botulinum toxin, which would not be expected to result in any of the seven experimental effects listed in the Policy or to be classified as DURC, yet are covered under the Institutional DURC policy.

Participants noted that including such research could pose a significant burden and questioned whether an exemption could be made for clinical research or research utilizing small quantities of Botox.

The U.S. Government appreciates the concerns from the research community regarding the inclusion of any quantity of botulinum toxin in the Policy and will closely monitor the potential burden this has on institutions. For now, research involving any quantity of botulinum toxin will remain subject to the Policy. When raising awareness and training investigators on the requirements of the Policy, institutions should not only focus on infectious disease researchers but also investigators in other fields conducting life sciences research who may be using botulinum toxin, including neuroscientists, clinical researchers, and others. We also welcome continued feedback from institutions on the burden of reviewing research involving *de minimus* quantities of botulinum toxin.

2. Research with any of the 15 agents that involves any of the seven experimental effects must be reviewed by the IRE to determine if it meets the definition of DURC. Then, the institution must notify the U.S. Government funding agency of the outcome of that review (i.e. whether or not the research is determined to be DURC). Can an institution initiate research *not* identified as DURC by an IRE while the USG is reviewing the IRE's determination? How long will the U.S. Government's review of the IRE's determination take?

   If the IRE determines that research does not meet the definition of DURC, the research can begin or be continued without having to wait for concurrence from the U.S. Government. Per the Policy, the U.S. Government has 30 calendar days to respond to the institution's determination.

3. Once research is identified as DURC under the institutional policy is there a need to restrict publication?

   Very few projects are expected to meet the definition of DURC, and it is expected that, of those, the need to restrict publication of certain aspects of the research would occur only in rare cases. DURC is vitally important research that should be conducted and the results should be shared responsibly. The DURC Companion Guide (available at http://www.phe.gov/s3/dualuse) is a useful resource that describes the responsible communication of research and the development of communication strategies for DURC that minimize risk. While redacting certain experimental details or not communicating certain findings is an option, it is anticipated that most DURC findings should be communicated openly. The USG will also explore the preparation of additional guidance for institutions on the responsible communication of DURC research.

Available Resources

A number of resources related to Dual Use Research of Concern in the life sciences are available on the Science, Safety, and Security program (S3) website (http://www.phe.gov/s3/dualuse). The

website contains information on biosafety, biosecurity, biocontainment, and biorisk management. Resources include:

- The U.S. Government Policy for the Institutional Oversight of Dual Use Research of Concern
- A Companion Guide to the Policy
- FAQs on the Policy
- Case Studies on Implementation of the Policy

Other resources that institutions may find helpful for educating their researchers about the Policy include an educational brochure outlining the responsibilities of investigators, an educational poster for institutions to promote the existence of the Policy, and a training slide set providing an overview of the Policy. Copies of these materials can be obtained by emailing http://www.phe.gov/s3/dualuse. For any questions on the Policy, please contact us at DURC@OSTP.GOV