December 3, 2014

Andrew M. Hebbeler, PhD
Assistant Director, Biological and Chemical Threats
National Security and International Affairs Division
Office of Science and Technology Policy
Executive Office of the President

Dear Dr. Hebbeler:

Research on dangerous substances must be carefully conducted. Dual use research of concern (DURC) is research that poses a heightened risk for misuse and “The U.S. Government Policy for Institutional Oversight of Life Sciences DURC” serves to identify and to mitigate such risks. DURC, however, represents a very small segment of the biological research that produces many benefits for our nation and the world. Historically, many of these advances have resulted from the free scientific exploration of fundamental biological mechanisms, and it is important that this be preserved to the greatest extent possible.

The regulation of DURC must serve two goals: (1) protect the public from harmful misuse of biological research; and (2) enable scientists to safely conduct the studies that will help them better understand the effects of pathogens and toxins and reduce their threat to public health. The Federation of American Societies for Experimental Biology (FASEB) believes that the current policy could be strengthened by ensuring consistency of oversight, enhancing coordination with related rules and regulations, and instituting a robust plan for policy evaluation. We thank the U.S. government for providing institutions with a full year to establish compliance, and urge that the recommendations below be implemented prior to final implementation of the policy.

**Consistent oversight**

The policy affirms that “[i]t is essential to have a consistent approach to the oversight of DURC.” However, we are concerned that the diffuse oversight structure, with each institution and agency operating separately, could lead to discordant interpretations and inefficiencies. Case studies are a valuable resource for benchmarking existing practices and guiding decision-making, and FASEB requests that additional case studies be developed.

As noted in FASEB’s [prior comments](#), institutions with smaller research programs may not have sufficient scientific expertise or financial resources to conduct proper DURC review. This could result in inaccurate assessment, particularly if this policy is broadened to cover more agents in the future and more institutions are called upon to review research for dual use implications. Therefore, **FASEB recommends that the U.S. Government permit the formation and utilization of regional or national Institutional**
Review Entities (IREs) to carry out institutional DURC review and the development of risk mitigation plans. Regional IREs could be coordinated by a major research institution or a state health department.

The two-tier process of DURC review, in which the institutional review is confirmed by the federal agency sponsoring the research, raises concerns regarding the absence of a formal mechanism to ensure uniform interpretation and implementation of the policy by different agencies. For example, on November 21, 2014, the National Institutes of Health issued a notice (NOT-OD-15-017) describing its implementation of the policy, applicable to all new and renewal awards issued on applications submitted after January 25, 2015. While NIH-funded investigators and institutions will have until September 25, 2015 to fulfill the requirements of the DURC policy, such variance between agencies can lead to confusion and additional regulatory burden. To assure consistency, FASEB encourages the U.S. Government to establish a single federal board to review institutional DURC determinations and risk mitigation plans. If it is not possible to establish such a board, FASEB recommends that, at a minimum, the U.S. Government revise the policy and create a formal mechanism to facilitate uniform coordination and cooperation among the agencies in their oversight of DURC.

Greater integration or coordination with the Select Agent program

Separate implementation of the U.S. Government DURC policies and the Select Agent Program could lead to confusing redundancies in oversight and training. Therefore, FASEB recommends that the U.S. Government DURC policies be functionally integrated with the existing and well-established Select Agent Program, and all of the relevant regulations, polices, and resources be made accessible through a central website. Guidance documents should also describe how compliance activities for all of these rules can be streamlined at the laboratory and institutional levels.

Policy evaluation and metrics

FASEB is pleased that the policy states that “[a]ny oversight process for DURC should be periodically evaluated both for effectiveness and impact on the research enterprise.” However, the policy does not provide a timeframe or propose a mechanism through which such review would occur. Therefore, FASEB encourages the U.S. Government to establish a mechanism to evaluate the implementation and efficacy of this policy annually and make the findings public to ensure that issues are rapidly addressed. At some point, biennial review may be more appropriate.

Well-characterized metrics and well-defined goals are critical for evaluating the effects of new policies. FASEB recommends that the following metrics be included when evaluating the implementation of the DURC policy: (1) number of projects reviewed and number determined to be DURC by IREs; (2) number of IRE decisions overturned by the funding agency; (3) number and percentage of risk mitigation plans substantially revised by the agencies; (4) financial cost of IRE oversight and DURC training among institutions; (5) number of staff and faculty hours dedicated to IRE review and oversight; (6) average and median time elapsed between investigator submission and first IRE review; and (7) number of projects
identified as DURC by an IRE that were discontinued shortly thereafter, along with an assessment of the potential impact on scientific progress. We also encourage the U.S. Government to examine a random sample of DURC oversight documents from institutions and agencies to assess consistency with the policy mission and efficacy of implementation.

On behalf of the over 120,000 scientists represented by FASEB’s 27 scientific societies, I urge the U.S. Government to strengthen the institutional DURC policy to ensure consistency of oversight, enhance coordination with related rules and regulations, and institute robust and transparent policy evaluation. We thank the U.S. Government for its continued leadership and outreach to the scientific community on this issue, and we look forward to ongoing collaboration.

Sincerely,

Joseph R. Haywood, PhD
FASEB President