April 12, 2013

Franca R. Jones, PhD  
Assistant Director - Chemical and Biological Countermeasures  
Office of Science & Technology Policy  
Eisenhower Executive Office Building  
1650 Pennsylvania Avenue  
Washington, D.C. 20504

Comments submitted electronically to: durcpolicy@ostp.gov

Dear Dr. Jones:

The Federation of American Societies for Experimental Biology (FASEB) is composed of 26 scientific societies collectively representing over 100,000 biomedical researchers. FASEB expresses its support for the proposed US Government (USG) Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) and thanks the USG for this opportunity to provide comments on the proposed policy.

While FASEB greatly appreciates the flexibility provided to universities and research centers in this proposed policy, we also recognize that this flexibility could lead to confusion. To mitigate this, FASEB encourages the USG to develop case studies to supplement the training materials. Case studies should, at a minimum, address the following areas: (1) examples of how to incorporate DURC review into existing institutional processes, such as Institutional Biosafety Committees (IBCs) and institutional administration of the Select Agent Program; (2) examples of how the DURC review committees would determine whether a line of inquiry is DURC; and (3) examples of how to develop and implement a risk mitigation plan, especially in regard to informational risk. One scenario that FASEB strongly recommends to be included as a case study is the redaction of a portion of a scientific manuscript, which has significant implications under US export control laws.

It is critically important that training materials provided by federal departments and agencies be made available with reasonable lead time prior to the implementation of the policy so that institutions have sufficient time to plan and communicate any concerns. Therefore, FASEB recommends that the final version of the policy be delayed until such materials have been published.

In this era of budgetary constraint, it is essential that this policy be developed in a cost-efficient manner, both for institutions and federal departments and agencies, while still achieving the goal of minimizing
risk related to DURC. Therefore, FASEB recommends that federal departments and agencies collaborate to create a single set of training materials including premade presentations for institutional use and perhaps a standardized online training module for investigators. Educational materials and training programs have already been created under the October 2012 Select Agent program final rule and by organizations including the Federation of American Scientists and the Center for Arms Control and Non-Proliferation. FASEB encourages the USG to adapt these materials and/or collaborate with the Select Agent program to meet the proposed policy’s training requirements.

As the USG moves forward with this policy, FASEB encourages continued evaluation of the regulatory and financial burden of this policy, especially in the context of other regulatory policies. We recommend that the USG regularly review the policy and its potential burden in this context and seek expertise from the National Science Advisory Board for Biosecurity (NSABB), institutions, and professional organizations for how best to minimize these burdens.

Finally, FASEB notes that not all institutions will have internal expertise for every research project brought to them for review. The policy should ensure federal departments and agencies will provide prompt consultative support to institutional DURC review bodies and create a defined mechanism for this assistance.

FASEB appreciates your consideration of our comments and looks forward to working with the USG on these issues. Please let us know if we can be of further assistance.

Sincerely,

Judith S. Bond, PhD
FASEB President