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[By Electronic Submission to durcpolicy@ostp.gov]

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Re: OSTP-2013-041127: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. As a professional society representing more than 10,000 physicians and scientists involved in a wide range of infectious diseases (ID) research, teaching, and clinical and public health work, IDSA is uniquely positioned to bring valuable perspectives on the difficult issues involved in assessing dual use research of concern (DURC). Although risks can come from any aspect of the life sciences research enterprise, ID research is more likely than other types of life sciences research to fall into the category of research with dual use potential. At the same time, ID physicians are called upon to engage in preparedness and response activities for naturally occurring and man-made infectious diseases threats, ranging from pandemic influenza to the 2012 fungal meningitis outbreak. Thus, ID specialists are especially well-positioned to understand the risks and benefits of DURC experiments and can be valuable advisors for those who will need to undertake complicated risk-benefit analyses.

IDSA advocates balancing the public health risk of impeding the conduct of DURC against the public health risk of an accidental laboratory release or act of bioterrorism. On one hand, the institutional oversight policy must not infringe upon academic freedom or otherwise hinder free and open research to further science for the common good. Overly restrictive policies could increase the risk that scientists and institutions abandon research with Select Agents and other high-consequence pathogens. Consequently, we might not gain the knowledge needed to help identify, prevent or treat a naturally occurring, dangerous outbreak or an act of bioterrorism. Additionally, if oversight policies become extensively restrictive and research is subjected to national security classification, the practical benefits of that research will not be generally accessible to the medical and public health community. On the other hand, we recognize that there are real risks to this work that cannot be quantified, much less described with a finite list of pathogens and experiments. If we fail to put appropriate safeguards on this research, we risk an act of bioterrorism or an accidental release, with potentially catastrophic consequences.

Although the proposed policy is thoughtful and well-intentioned, we find that many aspects are vague and will be difficult to implement in current form. While we support the underlying principles outlined in the draft policy, we strongly urge the United States Government (USG) to further define the scope of oversight and to provide additional clarity and guidance for investigators and research institutions. The proposed draft serves as a good starting point, but more specificity is needed to translate policy into practice.

The Scope of the Final Policy Should Permit Flexibility Beyond a Specific List of Pathogens as Needed in the Future (Comment to Questions 11 and 12)

Appropriate consideration of DURC experiments cannot be reduced to a finite list of pathogens. We acknowledge that the current approach may be intended to allow time for institutional processes to be implemented and tested, which is a reasonable approach. However, it is important that over time, the policy not focus solely on a list of pathogens, but better reflect the broad nature of the USG-endorsed definition of DURC[1]. Our concern is highlighted by the existence of planned and ongoing gain-of-function studies with pathogens not on the current DURC review list[2]. Instead of relying on a list of pathogens, which does not accurately reflect potential risk, we recommend focusing oversight on the seven identified categories of experiments (see Section 6.2.2) and evaluating implications for human, animal, and plant death and disease, as well as environmental disturbance. Similarly, while we support limiting this initial policy framework to research using non-attenuated forms of the 15 agents and toxins listed, the final policy should account for the possibility of emerging DURC issues related to attenuated strains, such as reversion to virulence or acquisition of new traits.

Additional Guidance and Support is Needed to Assist in Implementation of this Policy (Comment to Questions 4 and 9)

Institutional Biosafety Committees (IBCs) today are not properly constituted or configured for assessments of DURC and, in many cases, they are overworked and under-resourced. At a minimum, training, guidance and additional resources should be provided to local institutions. However, even with additional resources, institutions may not have the expertise to execute DURC review policies efficiently. There is a real risk of slowing down the work of IBCs with regulatory responsibilities that they are not well-suited to handle, similar to the burdensome delays in the work of institutional review boards (IRBs) that resulted when IRBs were tasked with reviewing studies for privacy risk under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. It is also very likely that if institutions are given responsibility for DURC review without appropriate expertise and clear guidance, fear of legal liability will result in persistent, harmful delays in research review. Similar consequences currently plague IRB review, and we see clear parallels to IBCs and DURC review.

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[1] USG endorses the following definition of DURC: "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] Wain-Hobson, S. H5N1 viral-engineering dangers will not go away. Nature **2013**; 495: 411

Training, education, and financial resources for IBCs or alternative review entities should be outlined in detail and guaranteed to ensure that all institutions implementing this policy do so from a common foundation of knowledge, guiding principles, and resources[3]. Training and educational programs should include a review of potential legal liability issues, risk identification and minimization, and federal and state public disclosure regulations.

To ensure successful implementation of this policy, greater specificity and additional guidance for investigators and research institutions is needed. Because it is very difficult to undertake a rigorous quantitative risk-benefit analysis of DURC, subjective judgment guided by experience and collective expertise will inevitably be required. Although some variability should be expected between institutions due to local considerations, it is critical for the USG to limit inconsistencies by providing clear guidance and analytical tools to institutions. While the products of the National Science Advisory Board for Biosecurity (NSABB) are helpful in this regard, we believe that local institutions will need additional detail and further guidance. For example, because quantitative values cannot be assigned to risks and benefits, investigators and institutions will need alternative frameworks with which to undertake assessments of proposed research, such as an interpretation of the precautionary principle and guidance on its use.

In addition, we suggest providing hypothetical case examples for institutions to reference when engaging in DURC risk-benefit analyses. Carefully drafted hypotheticals that illustrate the key issues to be considered will provide greater clarity for both investigators and institutions. Hypotheticals would be especially helpful that illustrate common kinds of DURC and non-DURC that do not require significant forms of risk mitigation. For example, it would be reasonable to delineate specific types of experiments with public health significance that do not need to undergo DURC review, such as vaccine development studies with defined attenuated strains. These hypotheticals should initially be based on realistic but fictional scenarios, and may be supplemented by accounts of actual cases where DURC is at issue.

Thank you for the opportunity to comment on this draft policy. Should you have any questions about these comments, please contact Audrey Jackson, PhD, Senior Program Officer for Science and Research, at ajackson@idsociety.org or 703-299-1216.

Sincerely,

David A. Relman, MD, FIDSA
President

[3] In a recent study compiling data from three separate surveys of IBC members from public and private research institutions, hospitals, and clinics, over 50% of the respondents indicated that their IBC reviews research for potential dual use risks. However, only 37% of IBC members were being trained on dual use risks. *See* Hackney RW, Myatt TA, Gilbert KM, Curso RR, and Simon, SL. Current trends in Institutional Biosafety Committee practices. Applied Biosafety **2012**; 17(1): 11-18.