April 23, 2013

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Dear Dr. Jones:

The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Council on Governmental Relations (COGR) is an association of 190 U.S. research universities and their affiliated academic medical centers and research institutes that concerns itself with the impact of federal regulations, policies and practices on the performance of research and other sponsored activities conducted at its member institutions.

As institutions actively engaged in cutting-edge life sciences research, including work with Select Agents and Toxins, we appreciate the opportunity to provide feedback on the draft *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (DURC). AAU and COGR strongly support the Guiding Principles, outlined in Section 3 of the policy, noting only that not all life sciences research is vulnerable to misuse necessitating ongoing evaluation. We value the balance these principles aim to strike – namely, allowing critical life science research to advance while mitigating associated risks – while recognizing the proposed oversight requires careful and thoughtful handling of complex scientific challenges. Our comments below reflect an overall sense that the U.S. government needs to proceed very cautiously in its oversight of DURC, so as not to undermine the first principle that "Life science research makes possible advances in public health, agriculture, the environment, and other pertinent areas and contributes significantly to a strong economy."

Scope of oversight

AAU and COGR support limiting the scope of the policy to the 15 identified Select Agents and Toxins and seven categories of experimental outcomes. Although we note that these 15 agents are already highly regulated and strictly controlled via the Select Agents and Toxins program, we appreciate the policy's focus on the agents and toxins that present the most immediate cause for concern, allowing investigators and institutions to focus additional oversight on the results of this research and communication of those results. However, AAU and COGR strongly encourage the government not to view the current policy as a pilot project for expansion into a broader class of experiments or agents. Such an expansion could easily become too resource intensive for institutions to manage and have the result of driving researchers and institutions away from this critical area of research. It has been well documented that the implementation of the Select

Agent Rules led universities to cease work with these dangerous pathogens[1] or destroy valuable collections[2].

Responsibility of the PI in Oversight

While AAU and COGR agree that the Principal Investigator (PI) is in the best position to evaluate the DURC potential of his or her own research, working together with other involved personnel in the laboratory, the policy is unclear about how or when the PI will receive training on identifying DURC. The policy states that all research personnel working on life science research that falls within the scope of this policy must receive such training and we appreciate the flexibility afforded by this performance-based approach. We would assume, as a consequence, that, because all of the agents and toxins covered are part of the Select Agents and Toxins program, DURC training can be incorporated into the mandatory training required in the October 2012 Final Rule on Select Agent Regulations. This flexibility allows institutions to take advantage of the robust training tools for DURC developed by a number of organizations, including the Southeast Regional Center of Excellence for Emerging Infections and Biodefense and the Federation of American Scientists. Integrating the training addresses the concerns of investigators, institutions and the Federal agencies with reducing the burden of compliance as well. The recent GAO report, "Federal Inspections of Entities Registered with the Select Agent Program" (GAO-13-154, Jan 31, 2013) highlighted the overlapping and duplicative inspections conducted by the CDC, APHIS, DHS and DOD, urging them to reduce the burden of such overlap and duplication on select agent entities. Our ability to combine the training will help ensure full compliance with all the regulations governing the use of the agents and toxins.

Responsibility of Research Institutions

The review process delineated by the policy contains a number of ambiguities that we are concerned could either create onerous interpretations or leave room to question whether institutions are, in fact, compliant with the policy. For example, the policy implies, although does not specifically state, that for research undergoing Federally sponsored peer review, the identification of DURC, development of a risk mitigation plan, and implementation of the mitigation plan will occur in anticipation of a formal notice of award. Agencies must be aware that the risk mitigation plan may involve significant changes to the experimental methodology and determine under what circumstances additional review is necessary. Agencies will need to identify the individuals and/or entities within the agency for required notifications. Institutions must also "provide formal annual assurance to the Federal funding agencies that an institution is in compliance." It is not clear whether this is a project-specific assurance – to the agency directly funding the research – or a broader assurance of compliance akin to the assurance of compliance with Federal human subjects protections regulations in the Common Rule. The human subjects assurance is filed with a single office – the HHS Office of Human Research Protections – acting as agent for the Common Rule signatories. If this is intended as a broader assurance, will NIH serve as the Federal government's agent and convey the assurance to the appropriate Federal funding agencies? We would hope to avoid the need to submit multiple assurances of compliance with a streamlined process that eliminates unnecessary duplication. We assume that because the DURC policy is overlaid on the Select Agent and Toxins list it is appropriate for the Select Agent research officer (RO) to serve the DURC liaison.

Finally, the policy requires an internal appeal mechanism for PI's wishing to appeal decisions made regarding research designated as DURC by the institution. We note that previous instances of DURC and the work of the National Science Advisory Board on Biosecurity (NSABB) have made it clear that identification of DURC and appropriate mitigation of risk are topics subject to a great deal of difference of

[1] Gaudioso, J. and Salerno, R.M.. "Biosecurity and Research: Minimizing Adverse Impacts." Science. Vol. 304. 30 April 2004.

[2] Casadevall, A. and Imperiale, M. "Destruction of microbial collections in response to Select Agent and Toxins list regulations." Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. June 2010, 8(2): 151-154

opinion. For example, the decision-making process of review and re-review of the recent H5N1 avian influenza papers took nearly 5 months, an international summit of experts, and still barely reached an uneasy consensus on how to proceed. We are concerned about those occasions when institutions and investigators simply cannot agree on an appropriate plan of action. Because the policy is silent on an adjudication mechanism beyond the institution with responsibility for compliance, we assume the decision of the institution will be final.

AAU and COGR appreciate that the policy provides flexibility to the institution as to the institutional entity involved in DURC review, including the possibility of referral to an external review body. Given that the necessary expertise for this type of review may be lacking on the Institutional Biosafety Committee or at the institution, it is critical that institutions are provided the flexibility to enable them to meet the criteria for the review body, as detailed in Section 7.2-E of the policy. However, the requirement for a mechanism for review on demand (Section 7.2-C) at any time a PI identifies DURC potential, is not in keeping with this flexibility. Institutional review bodies often meet on a regular schedule, and if an institution is using an external entity for review, the university may have little control over when the review body is available. While we recognize that DURC may arise mid-stream through the research process, we question the feasibility of a system dynamic enough to allow review and development of a risk mitigation plan at any time, without significant disruption to the research.

AAU and COGR are also concerned about the record keeping requirements associated with DURC. By its very nature, information related to DURC is sensitive, were it not, there would be no need for any policy for oversight of its communication. We believe it is important for the federal government to note that institutions, particularly public universities, are subject to state open records laws that limit the institution's ability to control information held by the institution. We do not support the retroactive use of classification or ambiguous systems related to sensitive-but-unclassified information. However, the federal government may wish to provide guidance on the type of information it is appropriate to include in DURC review records and mitigation plans to avoid release of sensitive information.

Responsibilities of Federal Entities

The institutional policy fails to answer questions raised by publication of the March 29th policy explaining the federal role in the oversight process. Institutions are directed to make their procedures for reviewing DURC accessible to the public. We believe the public – particularly the regulated entities – would benefit from access the Federal agencies procedures as well. We assume such procedures describe the process for conducting reviews of current or proposed research for DURC potential and the timeline for reporting to the researcher and institution, so they might move to the next step, to "in collaboration with the institution or researcher, develop a risk mitigation plan."

It is not entirely clear what role NIH or any Federal agency plays in the management of non-Federally funded research. Throughout the proposed policy, institutions report non-Federally funded research reviews and determinations, mitigation plans, instances of non-compliance to NIH who may, or may not, "notify the appropriate Federal funding agency." If the research is not funded by a Federal agency, we are confused about what agency would be given information and – we are presuming – some level of jurisdiction over the research activity. Giving the Federal government a substantive role in research activities in which it has no financial interest must be carefully weighed and appropriately assigned. We think the question of relinquishing a measure of control over the dissemination of research results in which the Federal government has no role or interest deserves further discussion and deliberation. In the short term, this policy should focus on the research funded by the Federal government.

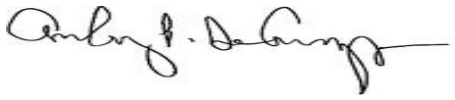
In addition, the new policy requires federal agencies to notify institutions when the agency disagrees with an institution's decisions regarding identification of DURC or the development or implementation of the

risk mitigation plan, and goes on to say that they will work with institutions to try to address the disagreements. We are concerned about how this process will work including who at the agency will be involved and over what time period. As mentioned above, the subjective nature of evaluating DURC seems to breed non-consensus: what happens when institutions and agencies simply cannot agree? What person or entity makes the final determination and is that determination subject to appeal? As an example, if a federal agency makes a determination that part of a research study should not be published or communicated – as the NSABB's original determination stated in the case of the H5N1 avian influenza studies – this could pose significant issues for the institutions, including, but not limited to trigger of export control requirements, threats to ongoing collaboration, professional damage to the careers of faculty, students, or other research personnel, or violation of an institution's own policies on the acceptance of restrictive research clauses. We recognize and share the Federal agencies interest in mitigating real risks of misuse but we are deeply concerned with abrogating the control of our research activities to the Federal government without a clear path for debate and discussion. What courses of action are available to an institution in such an event, beyond the "consultation with the Federal funding agency" suggested in the policy? Would the NSABB or another scientific body with appropriate expertise be convened to assist in such a discussion?

Context of Research Regulations

As a final point, AAU and COGR believe that DURC oversight, particularly in going forward with consideration of the efficacy of the new policy, needs to be considered in the broader context of the myriad regulations governing life sciences research. Compliance with new regulations is not without cost, and regulations are often generated, as was this policy, in hasty reaction to an adverse event, rather than through a deliberative considered process. As a recent report on dual use review and institutional oversight prepared by the Association for the Advancement of Science, AAU, the Association of Public and Land-grant Universities and the Federal Bureau of Investigation noted, "Adding another federal requirement to the current list of unfunded mandates with which research institutions must comply would increase the financial, administrative, and regulatory burden at already-stressed research institutions."[3] Discouraging researchers or institutions from federally funded research with Select Agents or delaying research with additional layers of review can only hurt national security, the antithesis of the intent of the DURC policy. Again, we would encourage the U.S. government to carefully evaluate the impact of the new policy on life sciences research when making decisions to renew or expand its implementation.

Sincerely,



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[3] http://cstsp.aaas.org/files/AAAS-APLU-AAU-FBI%20report%20Final.pdf