

**Statement of the National Science Advisory Board for Biosecurity Regarding the USG  
Deliberative Process and Research Funding Pause on Selected  
Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses**

**November 25, 2014**

Since 2005 the National Science Advisory Board for Biosecurity (NSABB) has provided advice and guidance to the U.S. government on the issue of dual use research in the life sciences. This has included consideration of so-called “gain-of-function” studies that generated highly pathogenic avian influenza viruses that were transmissible between mammals by respiratory droplets. Such gain-of-function studies raised biosafety and biosecurity concerns, dividing the scientific community and the public at large over whether and how scientists should conduct these studies. We commend the White House Office of Science and Technology Policy for embarking on a deliberative process aimed at considering the risks and benefits associated with certain gain-of-function studies. The NSABB is proud to be asked to take on an important role in this process and looks forward to deliberating the issue. However, due to questions raised regarding the funding pause for certain gain-of-function studies, we recommend prompt clarification of what studies are affected by this pause and what studies are not. This is important to avoid unnecessary adverse impacts to the research community that may impair public health efforts such as disease surveillance and progress in understanding MERS and SARS.

At the NSABB meeting on October 22, 2014, we heard concerns from leading influenza researchers that the funding pause might adversely affect critical research that they view as necessary for the preparation of influenza vaccines, possibly including some surveillance studies. We also heard concerns from some researchers studying the MERS and SARS coronaviruses that the funding pause may prevent them from developing mammalian models for studying infections by these viruses. If so, we fear that preventing or delaying the development of such animal models could have significant consequences, particularly at a time when MERS, for example, continues to present an ongoing public health concern. It should be noted that details of the above-referenced experiments were not provided, and we recognize that projects will need to be evaluated on a case-by-case basis to determine if they are subject to the funding pause. Nevertheless, the examples and concerns cited at the NSABB meeting underscore the point that great care should be taken to not apply the funding pause to specific studies that inform surveillance and other activities critical to public health.

U.S. government officials at our October 22 meeting clarified that the pause was anticipated to affect only a few dozen projects, was not intended to apply to characterization studies, and was not intended to impact surveillance efforts. They also noted that there is a process for exempting certain gain-of-function studies from being covered under the funding pause “if the head of the USG funding agency determines that the research is urgently necessary to protect public health or national security.” Additional clarifications were made and updates were provided by government officials during the NSABB meeting held in November. Nevertheless, there appears to be confusion among the research community about which projects are affected and how exemptions can be sought. We urge the U.S. government to: immediately review the pause; clarify language that may be capturing research that was not intended to be restricted (such as surveillance); educate program officers in the agencies about what research is subject to the pause; and ensure that there is an expedited and clearly articulated process for granting exemptions so that work that is vital to public health or national security can proceed without further delay.

Finally, we would note that while the funding pause is intended to directly impact only a small number of laboratories, we heard concern on October 22 that it could cast a broader shadow over infectious disease research, discouraging young researchers from entering this critical discipline. With this in mind, we encourage the U.S. government to ensure that the deliberative process and final policy decisions regarding certain gain-of-function studies are completed in a timely manner.