

Comments of The American Association of Immunologists (AAI) to the National Science Advisory Board for Biosecurity on Gain-of-Function Studies

Submitted on behalf of AAI by Lauren G. Gross, J.D., Director of Public Policy and Government Affairs The American Association of Immunologists (AAI) March 8, 2016

The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, representing more than 7,700 basic and clinical immunologists, appreciates the opportunity to provide comments to the National Science Advisory Board for Biosecurity (NSABB) Working Group on Gain-of-Function (GOF) Studies.

AAI appreciates the careful and thorough investigation of the risks, benefits, and public health considerations associated with select GOF research studies. The resulting working paper is a well-thought out document that provides an excellent foundation for the final ruling on this topic.

AAI is largely in favor of the draft recommendations that have been provided by the Working Group. There are, however, some concerns that have not yet been fully addressed. Importantly, the steps for implementation of these recommendations are not clearly laid out. AAI strongly recommends that these recommendations be implemented very cautiously to avoid potential burdens, including:

- 1) negatively affecting beneficial research perceived as GOF, but posing little real danger to public health, and
- 2) increasing the administrative burden on investigators and/or grant reviewers, taking away time and effort from important experimental research.

To avoid these unintended consequences, AAI believes that Recommendation 2 (to utilize existing policy frameworks) is the most crucial aspect of these new guidelines.

AAI believes that, very unfortunately, an individual intent on using biomedical research for nefarious purposes would not be prevented from doing so by these recommendations, and that instead, restriction of GOF research studies could actually impede advances in discovering the function and transmission of, as well as potential countermeasures against, natural and manmade biological threats. Because the risk profile of GOF studies is similar to studies using select agents, it may, in many cases, be more appropriate to apply current Dual Use Research of Concern (DURC) policies to these studies.