American Society for Biochemistry and Molecular Biology
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October 16, 2023

White House Office of Science and Technology Policy
1650 Pennsylvania Ave. NW
Washington D.C. 20502

RE: Request for Information on Potential Changes to the Policies for Oversight of Dual Use Research of Concern and the Potential Pandemic Pathogen Care and Oversight Policy Framework

The American Society for Biochemistry and Molecular Biology is an international nonprofit scientific and educational organization that represents more than 10,000 students, researchers, educators and industry professionals. ASBMB membership rely on funding from key federal science agencies, including but not limited to the National Institutes of Health, the National Science Foundation, and the Department of Energy.

It's through this lens the society is providing the following recommendations in response to the request for information from the White House Office of Science and Technology Policy regarding the dual use research of concern and the potential pandemic pathogen care and oversight policy framework.

Developing an integrated approach to oversight of research that raises significant biosafety and biosecurity concerns, including ePPP research and DURC.

Recommendation 1: Harmonize oversight policies for dual use research of concern and research on potential pandemic causing pathogens across federal science agencies.

The ASBMB applauds OSTP for taking steps to understand how the office can harmonize oversight policies on vital infectious disease–related research. Harmonizing policies would significantly reduce the high administrative burden many researchers and academic institutions face when conducting this type of research. High administrative burdens diminish scientific productivity and can dissuade researchers from pursuing this type of research. A unified policy would significantly ease the administrative burden and reporting requirements associated with important research.

However, the ASBMB urges OSTP to carefully analyze the potential impact of harmonizing oversight policies. Before any key policy changes are implemented, policymakers must better understand the strengths and weaknesses of current oversight policy frameworks by conducting a cross benefit analysis. A key component of conducting such an analysis must determine how much federally funded research currently falls under the DURC and P3CO framework. This analysis must also include potential challenges or barriers to implementing a harmonized framework. An analysis that addresses potential barriers can help federal agencies anticipate and/or mitigate a potential bottleneck of research study approval once policies are harmonized.

Recommendation 2: OSTP and funding agencies must clarify key definitions related to the DURC and P3CO policies and provide actionable lab guidance.

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The scientific community needs more clarity and guidance regarding the terms that are currently used in the DURC and P3CO framework that in turn would be used in a unified oversight policy framework for research of concern. For example, the term "reasonably anticipated" must be contextualized and clarified; the scientific community does not have a clear understanding of how this term can be applied to research projects. A potential solution is to clarify that the *goal* of the experiment is the criteria to use for the term "reasonably anticipated." In addition, institutions need more guidance on what research does and does not require additional scrutiny.

Scientists would also greatly benefit from clear lab guidance, rubrics and/or decision trees to better understand what research requires additional scrutiny and what research does not. The National Institutes of Health has a few tools that aid researchers in understanding if recombinant DNA work needs institutional review and, if so, at what level the work must be reviewed. The ASBMB recommends OSTP uses some of the tools the NIH has provided as examples such as the above resource and/or the NIH guidelines for working safely with potentially hazardous biological materials.

Recommendation 3: Continuously involve the scientific community throughout the process of developing a harmonized oversight policy framework.

The ASBMB applauds OSTP for requesting information and feedback from the scientific community on potential changes to the DURC and P3CO policy framework and encourages OSTP to continue to solicit feedback from the scientific community. Harmonizing this policy framework across federal agencies must be an iterative process to ensure that scientists can easily and productively comply, prevent an increase in administrative burden on federally funded scientists and their institutional biosafety committees and prepare the scientific community for upcoming policy changes.

Range of applicable pathogens and agents

Recommendation 4: Explore a flexible framework to determine which agents and/or toxins require additional review for potential DURC. This framework must include diseases of plants and animals.

The current policy outlining 15 agents/toxins of concern is constraining and yet excludes pathogens that should be of concern and subject to additional scrutiny. For example, under the current framework coronaviruses are not subject to additional scrutiny, and, as recent world events have demonstrated, they do have the ability to cause pandemics. The ASBMB recommends a flexible framework, or decision mapping tool, that would aid scientists in determining whether an agent, toxin or pathogen requires additional scrutiny. As mentioned above, this flexible framework must analyze human diseases and diseases of animals and plants. Most of the diseases of concern are of animal origin and have the potential for zoonotic spillover.

However, the recommendation to expand review to all agents that may result in one of the seven experimental effects proposes a massive increase in the scope of federal oversight of scientific research. Abundant review will significantly delay and obstruct important research and we recommend OSTP explore flexible frameworks instead of expanding review to all research that may result in one of the seven experimental effects.

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Recommendation 5: Clarify biosafety levels and how labs might need to progress to higher levels of biosafety depending on their work.

The scientific community needs more guidance on how experiences with an agent might need to change under which biosafety levels they are operating in. Often, labs will operate under biosafety level 1 or 2 but, in light of outcomes or better understandings of pathogens that are a direct result of their research, they should then be operating under higher levels of biosafety. The ASBMB recommends OSTP explore how labs can easily and quickly assess if the biosafety levels of their labs might need to change depending on their research.

Definition of potential pandemic pathogens (PPP)

Recommendation 6: The scientific community needs clearer definitions and guidance regarding potential pandemic pathogens.

The scientific community and researchers need clearer guidance on two terms in particular: "moderately virulent" and "highly virulent." To better determine virulence and potential pandemic-causing abilities of a pathogen, the ASBMB recommends a threshold using the combination of R0, morbidity and mortality measures to determine what pathogens might require additional scrutiny. It is the combination of morbidity and mortality that has implications for pandemic-causing capabilities. In addition, the ASBMB strongly urges OSTP to re-evaluate the PPP definition specifying "respiratory route." Potential pandemic pathogens are not restricted to respiratory routes of transmission, and narrowing the definition of PPP to respiratory routes of transmission has the potential to miss many PPP.

In addition, the ASBMB recommends, at the bare minimum, defining PPP should harmonize with the definitions that scientific journals follow. This will ensure uniformity of understanding across the scientific community.

Recommendation 7: An outside panel or board must define "threat to national security" instead of requiring scientists to make that determination.

The ASBMB strongly urges OSTP to create an external panel or board that can define threats to national security instead of requiring scientists to make that determination in regard to their research. Scientists do not have the appropriate information and expertise to make that determination. Appointing an external panel or board to review research that might pose a risk to national security will also give scientists some protection from undue public scrutiny.

Accountability for risk assessment

Recommendation 8: Involve the scientific community in revising the blanket exclusions for select agents and toxins in an oversight policy framework.

The ASBMB shares the concern of many scientists that the recommendation to remove blanket exclusions has the potential to impede vaccine development and place a significant burden on research activities that would now fall subject to the additional research oversight. Under 42 CFR 73.3, the HHS

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secretary has previously determined a list of biological agents and toxins that are exempt from the requirements; this includes research activities involving pathogen surveillance and vaccine development or production. If exemptions are removed, the changes in laboratory biosafety level and required equipment may create barriers for researchers and institutions in allocating the funds or resources for these requirements, making surveillance and vaccine research even more difficult. The ASBMB urges careful consideration of the impact of this recommendation on the annual updates for seasonal influenza and SARS-CoV-2 vaccines.

Exemptions and exclusions from the oversight policy framework

Recommendation 9: In silico research models should not be included in an oversight policy framework.

Another area of concern for researchers is the inclusion of *in silico* research models under the scope of research oversight policies. The ASBMB recommends that OSTP thoroughly engage with community of stakeholders and *in silico* research model experts to determine if this research poses a risk and to determine the best course of action.