

July 13, 2023

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Performing the Duties of the Director  
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Re: Follow-up to Comments on the NIH Updated Policy Guidance for  
Subaward/Consortium Written Agreements

Dear Dr. Tabak,

Thank you for your service to our nation. Your leadership at the National Institutes of Health (NIH) has fostered profoundly important contributions to scientific, medical, and public health progress benefiting us all.

In that context, we request that you convene stakeholders in an interactive process that grounds the Institutes' "Guidance for Subaward/Consortium Written Agreements" in the principles of effectiveness, cost-efficiency, practicality, and fairness. We appreciated your willingness to accept public comments on the updated guidance; however, to achieve the Institute's objectives and avoid the unintended consequences of the current policy, it is essential to engage subawardees and primary awardees working on-the-ground in an interactive problem-solving process.

The stakes are high for research transparency and accountability, for patients, and for the best interests of our nation. The challenges with the update that is to go into effect on October 1, 2023, include:

- 1) **Ineffectiveness** The sheer volume of notes and data engendered by this policy update would overwhelm any workable monitoring system, contravening transparency and accountability;
- 1) **Costly Duplication and Waste** The policy update would swell taxpayer-borne administrative costs, reducing the funding and time devoted to research itself;
- 2) **Reduced U.S. Influence** The policy update would disincentivize research partnerships with the U.S., even as China and other economic competitors aggressively seek those partnerships out;
- 3) **Slower Medical Progress** The policy update would undercut global research inclusiveness (research institutions in under-resourced nations are also more

likely to lack the resources and infrastructure needed to meet the new reporting requirements), despite the proven role of inclusiveness in accelerating progress against both infectious and non-infectious diseases that rob Americans of hope, health, and time; and

4) **Compromised Biosecurity** The policy update would have a counter-strategic impact on our nation's biodefense capabilities, which necessarily include on-the-ground research and surveillance partnerships in regions of the world where biodefense threats will – not could – emerge.

We understand that it is important to avoid unnecessary delays and are confident that an interactive process can be accomplished on an expedited basis.

Thank you for considering this request. We look forward to your response and stand ready to assist your efforts.

Sincerely,

A handwritten signature in cursive script that reads "Mary Woolley".

Mary Woolley  
President and CEO  
Research!America