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Infectious Diseases Society of America

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July 5, 2023

Lawrence A. Tabak, DDS, PhD
Acting Director
Office of the Director
National Institute of Health
Bethesda, MD 20892

Dear Dr. Tabak,

The Infectious Diseases Society of America (IDSA) is writing to share feedback on the NIH Grants Policy Statement (NIHGPS) Section 15.2 regarding foreign grant recipients. IDSA understands and shares the NIH's commitment to responsible oversight of federally funded research. However, the changes proposed are unreasonable and will have an enormous impact on the ability of the U.S. to continue its leadership role in infectious diseases (ID) research.

We are seeking clarification regarding the accountability measures outlined in the updated Grants Statement. While effective information sharing practices are important, we want to ensure that the new policy guidance does not place undue administrative burdens on the researchers, which could jeopardize essential international scientific collaboration. Global cooperation is critical to the study of infectious diseases as well as the prevention, preparedness and responses to outbreaks and pandemics. Our feedback seeks to balance the need for appropriate oversight with the need to enable international research collaboration. Specific recommendations and clarifying questions regarding the Grants Policy Statement Section 15.2 are below.

First, we seek to clarify the new reporting requirements. IDSA is concerned that the policy's call for sub awardees to turn over research documentation such as "all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report" may not be feasible in the "at least every six months" time frame outlined. This frequency of reporting is also unreasonable to request and will be difficult for researchers to implement. Many labs, especially those in smaller institutions, may not have the resources to dedicate to this level and frequency of documentation. This could delay research and disincentivize international collaboration. Additional clarification is needed to determine whether the proposed reporting requirements will be feasible. Specifically, we seek clarification on the following:

- Who will be receiving and processing these documentation sources to ensure accuracy, privacy and safety?
- Will there be additional resources dedicated for domestic and international awardees and sub awardees to implement new reporting requirements?
- Who will have access to research documentation being requested, and who will review said documentation? Recipients of the documentation should have the technical capacity and resources to accurately evaluate it.
- Could NIH offer awardees and sub awardees alternatives to the new documentation requirements, such as yearly site visits, to promote oversight without imposing restrictive administrative burdens on international collaborators? Options could provide flexibility that may make oversight more feasible.

IDSA is concerned that without clarification and flexibility, this new policy will result in reluctance in international partners to collaborate with domestic researchers and make American scientific collaborators less competitive compared to European and other international partners. Limiting US researchers' ability to form international partnerships for ID research will weaken our readiness for future public health emergencies, impede scientific advances, reduce our nation's global standing and restrict Americans' access to scientific discoveries. This will especially impact research areas like pandemic preparedness, vaccine strategies, and clinical research. Additionally, this proposal builds on historical global inequities in formerly colonized nations and could erode respect and trust for scientific expertise in countries that partner with U.S. researchers.

Once clarification is provided, IDSA urges the NIH to continue to seek stakeholder input on this important topic. Policies with such a substantial impact on the scientific community require consultation among a broad array of stakeholders and should involve sufficient time for dialogue on intended and unintended impacts. IDSA requests that the NIH provide additional opportunities for stakeholders to give input, including listening sessions, prior to finalizing this proposed policy. This will help ensure success of a new policy with minimal negative impacts.

IDSA recognizes the importance of increasing transparency and accountability in research practices. However, we believe this goal can be achieved without disincentivizing international collaboration, which is critical to many major research efforts. We welcome continued dialogue with the NIH on this important issue. We hope our comments will be useful in the NIH's efforts to advance responsible research practices, while ensuring a reasonable administrative burden on the scientific community. If you have questions about these comments or if we can help inform your efforts, please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org.

Sincerely,

A handwritten signature in purple ink, appearing to read 'C. del Rio', with a long horizontal flourish extending to the right.

Carlos del Rio, MD, FIDSA
President