

To the attention of:

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Lyric Jorgenson Ph.D., Acting Associate Director and Director, Office of Science Policy, NIH

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Christi Grimm M.P.A, Inspector General, Office of the Inspector General, HHS

Loyce Pace M.P.H, Assistant Secretary for Global Affairs, HHS

Arati Prabhakar Ph.D., M.S., Director, Office of Science and Technology Policy, White House

We are writing today as a group of US-based coalitions — representing tens of thousands of global health researchers and advocates and hundreds of research institutions and organizations — to share feedback on the recent announcement of a new policy increasing scrutiny and reporting requirements over international recipients of National Institutes of Health (NIH) subawards.

The successful stewardship of lifesaving research conducted by the NIH is of utmost importance to our organizations and US taxpayers, as it plays a critical role in advancing the global health research and development pipeline and the work of US-based research institutions. However, we are concerned about the potential ramifications of the updated policy guidelines, as announced in the request for information (RFI) regarding "NIH Grants Policy Statement (NIHGPS), Section 15.2, which outlines the requirements for consortium/subaward agreements on NIH-funded grants."

Before this policy takes effect, we request that NIH meet with the US research community and relevant global stakeholders in a consultation process to explore strategies that meet the Inspector General's call for enhanced research oversight without jeopardizing international collaboration and engendering other adverse consequences.

Among our concerns, the decision to apply this policy exclusively to foreign research partners jeopardizes a key facet of diversity, equity, inclusion, and accessibility (DEIA), even though DEIA has been a notable priority of the Administration. In the NIH-Wide Strategic Plan for DEIA Framework, the agency makes clear its "People-Centered" framework includes foreign partners in its mission to "embrace, strengthen, and integrate diversity, equity, inclusion, and accessibility (DEIA) across all NIH activities in service of the NIH mission." Imposing these requirements could chill the environment for international research collaborations, contravening that framework and threatening efforts to engage researchers and other research stakeholders from underrepresented communities. Rather than advance DEIA and international research partnerships, the new policy could disincentivize them, by deterring US-based grantees from collaborating with international research institutions-- especially if the primary grant recipient is in charge of managing the review process.

Furthermore, we are concerned that the operationalization of the new policy may contradict existing international research and data-sharing policies such as the Nagoya Protocol. Additionally, the data collection process may run into barriers concerning privacy and what data individual countries legally allow to be collected and distributed internationally. It is a matter of both national and global health

security that the US can continue collaborating fully with international research partners. Obstacles to US engagement could compromise our access to vital information needed to respond to health threats and leave other world powers to fill the void that we have left behind.

Beyond the concerns already highlighted, the policy would impose a significant new administrative burden on grantees, which could derail or stall research progress. The policy calls for international subawardees to turn over, at least every six months, "all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report." For all labs, but particularly those that are not resourced to compile all data digitally or that do not operate in English as a primary language, these requirements could be cost-prohibitive.

Even in high-income countries, the administrative processes created by the planned policy would likely require additional resources to carry out. The timelines for releasing certain data may well leave primary grantees unable to meet the new requirements, undermining collaborations that promise significant gains in medical and public health progress. The new policy also favors tenured professors and larger institutions, who have a greater capacity to absorb this administrative burden, running counter to NIH's goal to better support early-stage researchers. We believe the increased administrative costs associated with this policy would be higher than necessary to meet the worthy transparency and oversight goals which we agree are critically important.

Ultimately, we are concerned this policy and its known (and yet unknown) ramifications have not been sufficiently vetted by the research community. With these considerations, our ask of the NIH and the Administration is to extend the timeline for vetting and implementing the policy until the aforementioned issues are resolved so that the spirit of the new directive is not overshadowed. While we welcome the chance to comment via the RFI, we feel further interactive dialogue with the research community is warranted. We are cognizant of the need to take definitive action and know members of the research community stand ready to work with the Institutes to identify strategies that advance research oversight without compromising fruitful international research collaborations.

We see this policy as one that has been proffered in good faith to assuage the fears and doubts that closed-door science can inadvertently cause. However, as highly invested stakeholders of domestic and global research, we want to ensure the policy is not simply reactionary, but rather one that strengthens science and international collaborations and further solidifies scientific advancement as a cornerstone of the US's global influence.

Thank you for your attention to this matter, and we look forward to engaging in future dialogue to discuss our concerns in greater detail.

Signed:



American Society for Microbiology



American Society of Tropical Medicine and Hygiene



Bay Area Global Health Alliance



Center for Global Health Innovation



Global Health Technologies Coalition



Federal AIDS Policy Partnership Research Working Group



Infectious Disease Society of America



North Carolina Global Health Alliance



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