

July 5, 2023

Xanthia James, Director
Division of Grants Policy, Office of Policy for Extramural Research Admin.
National Institutes of Health (NIH), Rockledge I, Suite 350
Bethesda, MD 20817

RE: Comments in Response to NIH Updated Policy Guidance for Subaward/Consortium Written Agreements

Director James:

On behalf of more than 140 schools and programs of public health, representing over 11,000 faculty and over 81,000 students, we are pleased to provide comments on the National Institutes of Health (NIH) *Notice to Announce NIH Updated Policy Guidance for Subaward/Consortium Written Agreements, Section 15.2*. The Association of Schools and Programs of Public Health (ASPPH) appreciates the opportunity to provide insights on the updated policy.

ASPPH's commitment to global action is rooted in the belief that health knows no boundaries and that addressing global health issues requires a unified effort—as the recent COVID-19 pandemic taught us. We recognize the interconnectedness of health challenges across borders and the critical need for global collaboration, and we strive to foster international partnerships. We advocate for evidence-based policies and empower public health professionals worldwide to confront complex health challenges. We are also a founding member of The Global Network for Academic Public Health (GNAPH), which enhances academic public health worldwide through mutual learning and collaborations between academic public health institutions globally in order to improve and protect the health of people and the planet.

We are supportive of the NIH's efforts to promote greater transparency and productivity in science. However, we are deeply concerned that the updated policy for consortium/subaward agreements on NIH-funded grants will be overly burdensome for investigators and hinder advancements in global health. The new proposed requirements for foreign subrecipients will harm global public health research and training programs, impose unnecessary costs on academic institutions, and increase the regulatory burden on investigators. This blanket policy for all global health research is too broad and will negatively impact the international communities that seek research collaboration to ultimately find solutions to devastating public health crises.

Several ASPPH members have made breakthroughs in global public health research and training efforts through collaborations with foreign partners, particularly in under-resourced countries. We are particularly concerned with the provision in the updated policy which states “for foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update (no less than once every six months, or more frequently based on risks) in line with the timelines outlined in the agreement.” The updated policy will especially pose a threat to

ongoing and future work in low-and middle-income countries (LMIC), which is executed by academic institutions already made fragile by other NIH policies, such as limiting indirect costs on international partners to 8 percent. For example, the work in Uganda at one of ASPPH's member schools, NYU School of Public Health, would be profoundly impacted. Specifically, the new policy would be problematic for teams carrying out mixed-methods (controlled trials with nested qualitative studies) research in Uganda. As a result of the new burdens, research will need to become much less ambitious.

If the new policy goes into effect, we are concerned with the following negative implications for our members and the global health arena:

- **Halting and preventing critical partnerships, especially in under-resourced countries.** We are concerned that the new policy will threaten global health research, particularly in LMIC. The proposed policy will stifle current work and disincentivize ambitious research undertaken by academic public health partners. This will only exacerbate health disparities and cause major inequities across the globe. We believe that the NIH should exempt LMIC from any such regulations.

Additionally, the requirement to grant "access to financial statements", especially in partnering countries where relationships are already tenuous, could be seen as demanding access to sensitive information. This will make foreign collaborators much less likely to accept these conditions and jeopardize research partnerships with US institutions.

- **Imposing unnecessary costs on academic public health institutions.** We are concerned about the unnecessary costs the new policy will place on our member schools and programs. If put into place, prime institutions will have to shoulder additional costs for data storage, management, security, and monitoring. The new policy will also have a profound impact on mixed-methods research, where controlled trials are nested with qualitative studies. For example, audio recordings and transcripts are inherently identifiable and require multiple passes by skilled study staff. Increasing the frequency of an otherwise annual process to monthly or even quarterly will lead to increased costs and increase the risk of breaches of confidentiality.

Other areas not addressed in the proposed policy include the issue of translation for voice recording and qualitative data. There would seem to be little purpose in transferring the data if no one in the US could understand it. Translation costs would be extremely expensive. If this policy is put into place, NIH must cover the unnecessary costs inflicted on academic institutions – that are already constrained due to other NIH policies.

- **Increasing regulatory burden, which will only take away from advancements in research.** We are particularly concerned with the provision in the updated policy which states “for foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be

provided to prime recipient with each scientific update (no less than once every six months, or more frequently based on risks) in line with the timelines outlined in the agreement.” The burden placed on subrecipients will put a strain on international partnerships, while providing little benefit to U.S. researchers due to the raw format and large amount of data that must be collected.

We believe the proposed provision is extremely broad and will be too onerous both US grantees and international partners. The suggested process will likely fail to meet the intended outcome and will instead come at the expense of important global health collaborations. The required documentation and frequency of collecting and submitting data every six months will also likely be seen by other countries as an overreach by the US federal government. Further, partner subrecipients in other countries may be prohibited from releasing primary data by their governments.

The new policy is incongruous with NIH’s principles of achieving equity and enhancing collaborations. The NIH should revise the proposed process and instead leverage the 2023 NIH Final Policy for Data Management and Sharing to improve access to supporting research data. Utilizing this approach will ensure proper data access for the prime awardee and is already aligned with existing data sharing and management requirements at NIH.

ASPPH is grateful for the opportunity to provide comments on behalf of the academic public health community. We urge you to take into consideration our concerns and revise the policy to enable sound global research partnerships, rather than stifle them in regulatory burden. Please contact us if we can provide additional information.

Sincerely,



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