



## PRESS RELEASE

### **THE CONSORTIUM OF UNIVERSITIES FOR GLOBAL HEALTH CALLS FOR BALANCED REGULATIONS TO SAFEGUARD TRANSPARENCY IN RESEARCH – Modification to the NIH Grants Policy (GPS), Section 15.2, which outlines the requirements for consortium/subaward agreements on NIH-funded grants.**

The Washington, DC-based Consortium of Universities for Global Health ([www.cugh.org](http://www.cugh.org)), is one of the world's largest academic-based, global health organizations. We work across research, education, advocacy, and service to improve the health of people and the health of our planet. Although our nearly 180 institutional members and 38,000 global health practitioners span the globe, the majority of our members are American, many of whom conduct research with overseas partners.

New regulations just released by the U.S. National Institutes of Health (NIH), <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html>, that will come into effect on Oct 1, 2023, introduce increased oversight on subrecipients working with primary researcher grantees funded by the NIH. These new regulations will compel sub-awardees to provide copies of all relevant lab notebooks, data, and documentation to the primary grantee every few months and give the NIH the right to request access to any supporting documentation from the subprime. We are concerned that these new regulations will impede international research collaborations and will not have the positive effects envisioned by the NIH. Rather they may threaten ongoing research and global health collaborations that are important for the security of the US and the world.

Our concerns are as follows:

- Global health research notebooks, lab notes, and data are often in forms that would have to be deidentified, translated, labeled, and formatted before anyone, including PIs, could utilize the data for any reason.
- NIH needs to think through how research partners in other countries can release primary data when their governments may not allow them to do so.
- The changes place a huge administrative burden on international partners who are currently grossly under-supported for admin activities w/ indirect costs capped at 8%.
- It places a large, new, administrative burdens on US grantees.

- Existing data sharing agreements between US and international partners (which have been complicated and time consuming to establish) will have to be renegotiated and rewritten.
- This policy may result in violations of human subjects' protections by providing data with personal identifiers to people who should not have access to such information. In some countries, this may have serious ripple effects (eg: in countries where LGBTQ activities are a crime that may carry a death penalty)
- This type of unilateral requirement for foreign partners violates principles of equity and destroys the trust that is foundational for research collaborations. How would each of us feel if we had to provide this kind of material with this kind of frequency to a research funder in the UK, Germany, China, or any other country?
- This policy is likely to diminish US leadership and competitiveness in global health research.
- The regulations are unlikely to strengthen the quality or safety of collaborative research with partners in LMICs.

Oversight is necessary to ensure that research reports and data meet US expectations and standards. Reasonable regulations can strengthen the primary recipient's confidence that the data and reports they are receiving from sub-awardees have not been altered by a third party. The US government and the researchers they fund have a common interest in ensuring transparency and accuracy regarding US taxpayer-funded research.

To achieve this, CUGH calls on the NIH to:

- delay the date new regulations will come into force.
- listen to the feedback they are receiving from US scientists, their partners, and that which is included in this brief, and modify the regulations accordingly.
- streamline the new regulations so they will not impose onerous reporting requirements but will increase research transparency over reports and data from sub-recipients.
- include funding in the grant that will cover the costs of any additional reporting.

CUGH also acts as a forum where scientists can provide solutions to improve research in an equitable, impactful and transparent manner that respects human rights for all. This includes developing constructive ways that will improve the proposed regulations in a manner that addresses the concerns of the NIH and the research community.

**For additional information contact** Dr. Keith Martin, Executive Director, Consortium of Universities for Global Health, 202-974 6363, [executivedirector@cugh.org](mailto:executivedirector@cugh.org)