Threatening the Future of Global Health — NIH Policy Changes on International Research Collaborations

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The U.S. National Institutes of Health (NIH), responding to audits conducted by the Office of Inspector General of the Department of Health and Human Services (HHS) and the Government Accountability Office, recently announced a new policy for foreign subrecipients of NIH funding that departs sharply from decades of NIH efforts to promote research integrity and build research capacity globally.[1] Beginning October 1, 2023, foreign subaward recipients will be required to provide the U.S. prime grantee "copies of all lab notebooks, all data and all documentation that support the research outcomes… no less than every six months, or more frequently based on risks"; the NIH reserves the right to examine these documents as part of its oversight responsibilities.

The new policy responds in particular to an audit that criticized the NIH's inability to secure laboratory notebooks and raw data from the Wuhan Institute of Virology in China[2] (a subrecipient of an NIH grant to one of us [P.D.]), as well as to congressional pressure to enhance oversight.[3] But the policy's broad and often vague language is subject to interpretation, which will complicate implementation. The mandate represents a shift from previous requirements for sharing scientific data of "sufficient quality to validate and replicate research findings," which specifically excluded laboratory notebooks, preliminary analyses, completed case-report forms, drafts of scientific papers, and communications between colleagues.[4] We believe that imposing these new requirements on all foreign subrecipients of NIH funding, without adequate input from U.S. grantees and their international collaborators, sends the message that the NIH doesn't trust scientists in other countries to meet the highest standards of ethical and responsible research practice.

The NIH — the largest funder of health research worldwide, with an annual budget of more than $40 billion — plays a key role in promoting and defending the integrity of research and exerts substantial influence in advancing best practices for the responsible conduct of research and fiscal accountability. Promoting equitable partnerships focused on problems of mutual importance to the United States and partner countries generates research benefiting U.S. and global populations. NIH-funded international research has led to the discovery of oral rehydra-

tion for cholera and other enteric infections, treatment and management of HIV, and vaccines for polio, Ebola, dengue fever, and Covid-19.

We believe the new requirements will have wide-ranging negative consequences and be seen as an overreaction to the risk of inadequate oversight. Although it may be reasonable to have foreign subrecipients provide certain documents, such as clarifications of conflicts of interest or authorship, at the proposed frequency, the policy's broad nature will undermine its intended oversight purpose by eroding the trust of the global scientific community, creating inequities between partners, and erecting barriers to the effective conduct of research. It is particularly troublesome in the aftermath of the Covid-19 pandemic, which crystallized the importance of international cooperation in identifying, preventing, and mitigating pandemic threats and rapidly evaluating vaccines and therapeutics. By applying requirements to all grants with foreign subrecipients, the NIH risks imposing policies that are unfeasible, run counter to the principles of fairness and collaboration, disrespect the scientific autonomy of international partners, and may lead to politicization of international collaborations that are currently working well.

Objectivity, honesty, openness, accountability, fairness, and stewardship are core values of research integrity. Especially given the long history of colonial inequity and power asymmetry in international research, successful programs rely on mutual trust and respect to achieve accountability and oversight. At best, the unnecessarily bureaucratic NIH policy document demonstrates insensitivity to foreign researchers; at worst, it represents an arrogant assertion of U.S. primacy. The requirements threaten the mutually respectful relationships that are essential for productive collaboration by imposing intrusive managerial control. The international scientific community may see them as evidence that the NIH and, by proxy, U.S. institutions more broadly are extracting data from foreign researchers because they don't trust those researchers to safeguard information and make it available when requested.

Moreover, laws in many countries state that data generated by their citizens' efforts belong to the country, not a foreign funder; mandated transfer of all research data to U.S. institutions may be unacceptable under such regulations. And documents transferred from foreign subaward recipients to U.S. institutions and the NIH may be subject to the Freedom of Information Act, which requires disclosure of U.S. agency records, including documents from federally funded research, upon citizen request. Foreign collaborators may perceive this possibility as an additional infringement on country-specific regulations that govern the data and intellectual property they create.

Obligatory unidirectional transfer of documents undermines the principles of fairness, mutual accountability, and research equity that the global health community endorses.[5] A policy that presumes that U.S. researchers adhere to higher standards for research integrity than foreign collaborators is not grounded in evidence. If the aim is to improve overall transparency and accountability, why does the policy target only foreign subrecipients, refraining from addressing document transfer from U.S. institutions to domestic or foreign partner institutions?

The administrative burden on foreign collaborators of frequent transfer of research documents will be substantial. Foreign subrecipients are already overburdened by NIH-specific regulations exceeding their national and institutional requirements, such as preaward vetting, documentation of ethics-committee compliance with HHS regulations for the protection of human subjects, financial conflict-of-interest reporting, and auditing to demonstrate compliance with NIH financial and internal control requirements. The NIH caps facility and administrative reimbursement for foreign subrecipients at 8% of allowable direct costs, well below the real cost, whereas rates for U.S. institutions are typically above 40% — a disparity suggesting that foreign institutions are in effect subsidizing NIH-sponsored research.[5] The administrative demands created by the new policy will exacerbate these inequities.

International clinical trials, which are pivotal to the NIH's mission, are especially vulnerable because they often take place at multiple sites in a partner country and can generate hundreds of data pages and spreadsheets daily. Requiring frequent transfer of these data, often including protected health information that must be deidentified and processed, is another unfunded mandate. Moreover, it's unclear whether the NIH has sufficient capacity to review all these data or whether the policy will simply generate a mountain of rarely examined documents.

The new policy is surprising in light of existing alternative approaches to accountability. For example, the NIH could impose these rules only on research that

warrants exceptional biosafety oversight, such as work deemed by the HHS P3CO committee to involve enhanced pathogens of pandemic potential. This approach would satisfy the presumed motivation for these rules[2] and would probably be supported by the international scientific community and the public.

Other approaches are grounded in the NIH's extensive history of strengthening research capacity globally. Thanks to Fogarty International Center research-training programs and NIH international collaborations, there are cohorts of competent and accomplished researchers from low- and middle-income countries who could have provided insights to shape better solutions. Using contracted in-country auditors who respect foreign researchers' autonomy, understand local laws, and implement audits that also inform capacity-building efforts could mitigate the punitive aspects of the demands. The NIH has been a leader in introducing new technology such as REDCap (Research Electronic Data Capture) databases, electronic data collection and entry, mHealth, cloud-based storage, sample identification protocols, and biosafety oversight harmonization. Capacity strengthening aimed at wide dissemination of new technologies could be more effective than heavy-handed requirements as an incentive for strengthening accountability and oversight. Though some institutions will be willing to comply with the changes, we would expect them to be the exception rather than the norm.

For a policy to be adhered to, it must be tailored to the capacity, needs, and local regulations of foreign institutions. The premise behind the new NIH policy, the lack of advance consultation, its excessive demands, and its overly broad reach threaten to reverse progress in international collaboration with U.S. scientists and damage the NIH's reputation as a global health leader. If countries find the policy too onerous, they may resist the agency's vision of accountability, cease collaborating with U.S. scientists, and seek other partners. If the NIH changes course now, it may be able to build on its historical successes and address oversight concerns with trust and respect, negotiation, and consensus building. We urge NIH leaders to reconsider, consult widely, adopt more equitable and transparent approaches to enhancing and funding appropriate oversight, and continue to support international researchers' shared goal of improving global health.

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