

Jayanta “Jay” Bhattacharya, M.D., Ph.D.
Director
National Institutes of Health

June 3, 2025

Dear Dr. Bhattacharya:

As organizations representing researchers, clinicians, patients and other concerned stakeholders, we write to highlight the value and importance to Americans of the National Institutes of Health’s support of collaborative international biomedical research and to express concern about the unintended consequences of the current implementation of the updated NIH policy toward foreign subawards, which risk significantly disrupting research that benefits the American public. We also urge you to work with the scientific community toward our shared goals of improving transparency at NIH while minimizing disruptions to research that Americans depend upon to deliver life-saving medical advances and would appreciate the opportunity to meet with you.

International Collaborative Research Benefits Americans

For many health conditions that are more common in other countries, international collaborations are necessary to advance our knowledge of how to diagnose, treat, or cure these diseases, and the benefits of that knowledge for Americans living with those conditions can be enormous. Increased global travel can easily increase the prevalence of many of these diseases in the US, and conducting international research now boosts our readiness. Additionally, for many conditions, limiting research to the US will add significant costs to studies, slow recruitment and significantly delay the results and innovations. Consider these examples:

- The [Pediatric MATCH](#) precision medicine trial which matched children and adolescents with advanced cancers to targeted therapies on genetic alterations. Patients were enrolled in the phase 2 trial from the U.S., Canada, Australia, New Zealand, Saudi Arabia, and other European countries.
- The HIV Prevention Trials Network ([HPTN 052](#)) study was an NIH-funded trial—conducted in 9 countries in Africa, Asia, Latin America, and North America—which proved that effective HIV antiretroviral therapy stops the sexual transmission of HIV. This finding has been foundational to public health strategies for the 1.2 million people with HIV in the U.S., informing the U=U (Undetectable=Untransmissible) campaign. More broadly, global HIV research has greatly informed chronic disease care delivery in the US, improving community-based care and retention in care for conditions including hypertension, diabetes and heart disease.
- The Tuberculosis (TB) Trials Consortium [Study 31](#) was an NIH and CDC-funded trial conducted in 13 countries, including the U.S. This study proved that a novel shorter 4-month TB treatment regimen could be as effective as the standard-of-care 6-month treatment regimen. Such research is critical, as TB affects nearly 10,000 Americans every year and TB rates have increased [every year](#) in the U.S. since 2020. [Kansas](#) is currently struggling with one of the biggest TB outbreaks in the U.S. in decades.

- A proposed histoplasmosis clinical trial that would collaborate with sites in Brazil to enroll more rapidly and cost effectively scored very well in study section such that funding would typically occur, but its current status is unclear. Histoplasmosis is a deadly fungal infection that occurs in people with transplants and autoimmune disorders as well as people with HIV. Americans will directly benefit from these results if the trial proceeds.
- Similar to the examples above, whether one considers conditions as varied as [Alzheimer's](#) disease, [cancer](#), or [stroke](#), NIH-supported international collaborations have been vital to enhancing the discovery and development of health technologies that have improved the health of millions of Americans.

Concerns with the Current Approach to the Updated Foreign Subawards Policy

While we are very supportive of the NIH's goals of improving transparency in research, we have substantial concerns about the manner in which this policy is currently being implemented. Our concerns include:

- **A funding freeze for international scientific collaborations pending the new policy:** Even though the implementation of the new award structure is pending, the NIH has stopped issuing any awards—including new, renewal, or non-competing continuation grants—that include foreign subawards. This includes new awards that have already undergone years of preparatory work, rigorous scientific review and been selected for funding. Additionally, existing multi-year awards will not be renewed if the “project is no longer viable without the foreign subaward.” Abruptly halting their funding undermines this long-term investment, wastes taxpayer dollars and jeopardizes high-impact research with direct relevance to public health in the U.S. and globally, including clinical trials. These interruptions could leave study participants in without access to life-preserving therapies and pose serious ethical concerns. Although the NIH notice indicates that steps will be taken to mitigate these impacts, emerging [reports suggest](#) that this may not be occurring consistently in practice.
- **Requiring researchers to “reapply” for awards that have already been selected for funding or that are in progress:** This requirement would apply to awards that have been selected for funding and to awards for which research activities are already underway, with significant work completed. Awards have already undergone highly competitive scientific review. Full reapplication would result in a significant loss of the taxpayer dollars already invested in the planning, launching, and partial execution of these projects. This move increases waste and jeopardizes the continuity of high-impact research critical to public health in the U.S.
- **Loss of multi-country clinical trials:** The current policy doesn't appear to include any mechanism for NIH to continue participation in multi-country clinical trials. Multi-country country collaboration opens access to more patient populations and more efficient clinical trial enrollment for diseases affecting Americans from Alzheimer's Disease, heart disease, and HIV to rare diseases with smaller patient populations.

- **Loss of US scientific workforce:** Abrupt losses or unplanned delays or interruptions in funding can leave many researchers, particularly early-career researchers, unable to sustain their careers. Because so much US research includes an international component, a high number of researchers are at risk of leaving the field entirely, which would leave the US without the workforce we need to deliver needed breakthroughs.
- **Broader Implications for U.S. Public Health and Scientific Leadership:** Beyond the direct impact on specific research projects, the current implementation of this policy may weaken the United States' ability to prepare for and respond to global health threats. International collaborations enhance our early warning systems, accelerate the development of vaccines, treatments, and diagnostics for emerging diseases, and are often more cost-effective than domestic-only studies. Stepping back from these partnerships could erode U.S. leadership in biomedical research.

Recommendations

Facilitate rapid restructuring of awards or streamlined reapplications with no termination or minimal interruption of research: We do not support termination of any research grants under the new policy but recognize that some grants have already been terminated and others may be terminated. Given this, and the fact that different foreign collaborations may have different needs based upon the type of research being conducted, structure of the project and specific partners involved, we recommend that NIH work with currently-funded researchers to develop and offer multiple options that provide sufficient transition time to allow researchers to meet the new financial reporting requirements with no or minimal disruption or delays to research. These options include:

- Restructure awards in a manner that rapidly transitions foreign subawards to the linked foreign awards system, with no or minimal interruption of ongoing research and no or minimal delay for projects already selected for funding.
- Enable researchers to maintain foreign partners in existing grants through consultancy and fee-for-service arrangements.
- Provide a highly streamlined reapplication process for researchers to transition to the new linked grants system with strong assurances of funding for researchers whose grants had already scored well or been approved.

Technical assistance: While we recognize the goal of improved transparency and tracking of funds, we are concerned that some important foreign research partners who provide significant benefits to Americans may not currently have the capacity to directly implement the upcoming NIH policy for linked awards. We request that NIH provide technical assistance to foreign research partners to help ensure successful implementation.

Limited exemptions: We recommend NIH consider granting foreign subawards that meet certain thresholds. For example, if a US prime grantee affirms they cannot identify a different partner that could provide the same benefit as this foreign partner, and the foreign partner's budget or staff size is below a certain threshold, such that it may be unable to comply with the foreign prime requirements or the new linked grants requirements, it could be considered for a foreign subaward.

In addition, we recommend that multi-country clinical trials be exempt or otherwise permitted under the new policy. In these instances, we believe the benefits of enabling foreign collaborative research far outweigh the risks.

The above requests are consistent with the NIH goal of improving transparency. Implementation of these recommendations will help ensure that innovative scientific research that benefits Americans can proceed and that critical international collaborations developed in good faith following prior NIH guidance are not arbitrarily harmed. Without changes such as these, the updated NIH policy is likely to undermine U.S. taxpayer investments and harm the health of Americans.

Thank you for your consideration of our perspectives and recommendations. We share your commitment to accountability and strong stewardship of federal research funds and stand ready to work together to ensure international research continues to deliver for the American people. We would welcome the opportunity for dialogue with you to help ensure sufficient policies, processes and resources that will enable international research collaboration that provides significant health benefits to Americans.

Sincerely,

American Society for Microbiology
American Society of Tropical Medicine and Hygiene
DNDi North America
Global Health Technologies Coalition
HIV Medicine Association
Infectious Diseases Society of America