

Congress of the United States

Washington, DC 20515

May 13, 2025

Dr. Jay Bhattacharya
Director
National Institute of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

RE: Updated NIH Policy on Foreign Subawards (NOT-OD-25-104)

Dear Dr. Bhattacharya,

We write to express our concern regarding the Updated NIH Policy on Foreign Subawards (NOT-OD-25-104) recently released by the National Institutes of Health (NIH) on May 1. We support the underlying goal of improving oversight of NIH spending, as well as strengthening the productivity and security of our international research collaborations. However, as you work to implement a new award system by September 30, we urge you to ensure there is no disruption to existing NIH grants and cooperative agreements in process and up for renewal. As written, this new policy will be highly disruptive to thousands of current NIH research projects that are already underway.

NIH foreign subgrants facilitate global research to eradicate infectious diseases, improve maternal and child health, and find cures to deadly diseases including cancer, benefiting both the U.S. and international communities. They allow U.S. researchers to access specialized resources, populations, or environmental conditions that are not readily available in the United States and to maintain U.S. leadership in biomedical research. Abruptly halting funding to foreign subawards would result in substantial destabilization to Americans who conduct global health research and to their programs and collaborations, cause significant harm to patients currently enrolled in ongoing clinical trials around the world, and deprive Americans of the important diagnostic tests and cures that these studies may have produced if they were not interrupted.

The current policy would abruptly halt numerous research studies across the world, undermining their scientific validity by preventing adequate data collection to answer their original research question and puts the health and safety of already enrolled participants at risk. As you well know, many studies and clinical trials cannot be completed in a year's time, and rather require multiple years for data to be collected and analyzed. As such, this policy will not only slow down new research studies from beginning, it will also interrupt enrollment in ongoing research studies taking place.

Even more importantly, abruptly ending clinical trials or intervention studies raises ethical concerns, because of the risk that enrolled participants will not be able to be monitored for adverse reactions or receive access to medical care or oversight. When study participants enroll in clinical trials, researchers are bound to follow the International Council for Harmonisation guidelines for Good Clinical Practice. These guidelines mandate the continued care and protection of trial participants through close clinical monitoring for adverse events and mitigation of any intervention related harms by the research team. This is not possible if foreign research funding is terminated and local country staff can not continue to follow up with participants.

Many of these studies with foreign components are answering research questions that can help save the lives of Americans with a wide variety of diseases, such as HIV, malaria or tuberculosis, but can only be conducted in foreign settings where there are enough affected patients to achieve a statistically meaningful sample size. Others will identify tests and cures for emerging infectious diseases such as Ebola virus that are not currently in

the U.S. but have the potential to reach our shores. These studies may also develop diagnostic tests and treatments for diseases that could affect service members or civil servants stationed abroad. Establishing global collaborations to support research, which has undergone competitive NIH review, requires substantial time and effort. Stopping these studies and collaborations prematurely weakens our own global health security by ensuring that we will never get the answers to these important research questions.

We urge you to ensure the continuity of lifesaving global health research while you implement a new review structure. We thank you for your consideration, and look forward to your swift response.

Sincerely,

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