

April 9, 2025

Dr. Jay Bhattacharya Director National Institutes of Health 9000 Rockville Pike Bethesda, Maryland 20892

RE: Advancing the Vital Partnership Between NIH and U.S. Research Institutions: Clarifying NIH Policy Priorities

Dear Dr. Bhattacharya,

On behalf of COGR, congratulations again on your appointment as NIH Director. I write seeking clarification on NIH's policy priorities due to several recent developments that are creating confusion and uncertainty within the research community.

COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for over 228 research universities and affiliated academic medical centers and research institutes. Our member institutions perform cutting-edge research that keeps America at the forefront of scientific and technological advancement and trains the next generation of scientists and engineers. Our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge. We advocate for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.

COGR and its members value the longstanding partnership with NIH. COGR institutions have worked diligently to efficiently conduct scientific research that is vital to ensuring American's health and the country's economic success. We share your view of the vital role NIH plays in fostering "gold-standard research and innovation¹," and we appreciate efforts to align the agency's policies with evolving scientific and societal needs and priorities. We also recognize the importance of accelerating the pace of discovery and innovation, and we stand ready to work constructively with NIH to effectuate efficient and effective policies that will bolster the U.S. biomedical research enterprise.

NIH funded research conducted at U.S. research institutions is a cornerstone of U.S. public health and has contributed to groundbreaking medical advancements, economic growth,

¹ NIH News Release [April 2025] https://www.nih.gov/news-events/news-releases/jay-bhattacharya-begins-tenure-18th-director-national-institutes-health



technological innovation, and global competitiveness². This research also plays a critical role in supporting national job creation, fostering small businesses, and securing our national interests³. Recent policy changes have injected significant uncertainty into the research funding landscape. Uncertainties stemming from award terminations, funding disruptions, delays in peer review and national advisory council sessions, and inconsistencies in policy pose challenges for the ongoing and future research performed at U.S. research institutions. Resolving these issues in ways that advance science and preserve taxpayers' investment is essential to the continuity of scientific progress and maintaining American leadership in biomedical and health sciences.

We seek clarification on NIH's policy priorities and would appreciate the opportunity to discuss several recent developments that are creating confusion and uncertainty within the research community. We have outlined these issues in an addendum to this letter, highlighting areas where additional clarification and guidance would be beneficial. We welcome the opportunity to discuss effective ways to navigate and resolve these issues so that NIH extramural research continues to thrive and meet new opportunities and challenges.

We appreciate NIH's dedication to supporting the research community and welcome dialogue to ensure that policies are implemented in a manner that sustains the strength and competitiveness of the U.S. research enterprise.

We look forward to your leadership and to working together in advancing a shared mission of improving public health through scientific discovery.

Sincerely,

Matt Owens President

W.W. Owen

cc: Dr. Jon Lorsch, Acting Director, NIH Office of Extramural Research

² Advancements through NIH-supported research https://www.nih.gov/about-nih/what-we-do/impact-nih-research/improving-health

³ United for Medical Research, NIH's Role in Sustaining the U.S. Economy [March 2025] https://www.unitedformedicalresearch.org/wp-content/uploads/2025/03/UMR_NIH-Role-in-Sustaining-US-Economy-FY2024-2025-Update.pdf



ADDENDUM Requests for Clarifications

Our institutions are committed to being responsible stewards of taxpayers' funds and share NIH's dedication to advancing science in service of the public good. We highly value open communication with NIH program and grants management offices, which has been essential in helping us understand the agency's evolving scientific priorities. We hope to continue strengthening that dialogue so we can best align our research efforts with NIH's missions and goals.

Terminations: Research projects require advance planning to be scientifically meaningful. When funding is unexpectedly withdrawn, research studies, materials, and facilities may be disrupted in ways that make continuation challenging or infeasible. Without adequate time and resources for an orderly close-out, there is a risk of losing taxpayer funded research data and valuable research assets such as cell lines and animal models. In the case of clinical trials, sudden terminations may also impact participant safety and treatment continuity. More broadly, the widespread termination of research projects affects America's ability to retain scientific talent. Scientific talent that has been fostered with significant public investment through federal training grants, fellowships, and loans.

Recently, institutions have received NIH terminations citing 2 C.F.R. § 200.340, stating that the award "no longer effectuates program goals or agency priorities." In many cases, however, institutions lack visibility into how priorities are being determined or communicated. We note here Congress' statutory directive to NIH that the director "assemble accurate data to be used to assess research priorities" including "information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities" [42 U.S.C. §282(b)(4)(A)]). We respectfully request greater clarification on how termination decisions are made and how scientific priorities are identified. Clarity on these points will help research institutions and their faculty to better contribute to and align with NIH's scientific priorities to advance impactful research.

Appeals of Terminations: The Uniform Guidance requires federal agencies to provide a written notice of termination that includes the reasons for termination, effective date, and the portion of the federal award to be terminated [2 C.F.R. § 200.341]. Further, federal agencies are required to maintain written procedures for "processing objections, hearings, and appeals," and in the case of termination for noncompliance, "provide the recipient with an opportunity to object and provide information challenging the action" [2 C.F.R. § 200.342]. In fulfillment of these and other regulatory obligations and to ensure that awardees fully understand their rights and responsibilities in the event of a termination, we welcome additional information. Can NIH clarify the process for institutions to file an appeal? Will NIH consider issuing community guidance or FAQs on filing an appeal? Who should grant and contract recipients contact if they have questions? Is there a defined time period for NIH to make decisions about appeals, and how long will it take for institutions to receive a decision?

<u>Orderly Closeout</u>: In instances of terminations, facilitating an orderly closeout is not only consistent with federal regulations but also essential to preserving the value of taxpayer



investment in the research. It is our understanding that publication costs incurred during the closeout period are allowed without NIH prior approval, as outlined in 2 C.F.R. § 200.461 and clarified in NIH Guide Notice NOT-OD-25-059, including in cases where an award is terminated.

We also understand that orderly closeout requests may be submitted to the Program Officer and Grants Management Specialist for costs incurred within the approved pre-termination budget period—or within the 120-day closeout window [2 C.F.R. § 200.343]. These costs may fall outside the scope of standard closeout expenses, as defined in 2 C.F.R. § 200.472 or identified in the NIH Grants Policy Statement. However, they still provide a clear benefit to the government and the public by helping to avoid unnecessary waste of taxpayer-funded research resources.

Additionally, some termination notices include language stating that the recipient institution may request funds to support "patient safety and orderly closeout of the project." While we understand that such costs are necessary and appropriate for orderly closeout, we believe that an orderly closeout option should not be inherently limited to that single cost category.

As stewards of taxpayer funds committed to advancing scientific discovery in the public interest, we remain committed that project closeouts are handled in full compliance with federal requirements. We also seek to maximize the impact and transparency of research investments. To help institutions navigate these situations consistently and appropriately, we respectfully request that NIH consider issuing an FAQ that supports the above points to provide clarification for the research community. Additionally, we would appreciate your confirmation that a request for orderly closeout may include other types of costs as noted above, with the understanding that full or partial approval remains at NIH's discretion.

<u>Funding Disruptions</u>: Reports from our member institutions indicate ongoing delays in the issuance of new and non-competing continuation awards. This negatively impacts research activities, including retention of talented research professionals. Additionally, the suspension of peer review meetings under the Federal Advisory Committee Act has introduced uncertainty into the grant review process. Given the importance of timely funding for maintaining research momentum and ensuring the investment of the research, we ask that NIH share what steps it is taking to address these delays. How does NIH intend to rectify the backlog of reviews? Are there specific programs that no longer meet the agency's priorities? How will this be communicated to the research community?

Centralized Peer Review: Each of NIH's 27 Institutes and Centers, (ICs) is supported and managed by highly trained scientific subject matter experts who work closely with IC Advisory Councils made up of external scientific experts to identify research needs and opportunities within their mission to support the most urgent discoveries and interventions needed that will impact human health and well-being as soon as possible. The funding mechanisms utilized are highly specialized, such as those that support Centers, program projects, training grants, and career development awards. According to the March 6, 2025, NIH Press Release, the Center for Scientific Review (CSR) manages 78% of NIH initial peer reviews, which are primarily investigator initiated R01s, and the ICs manage 22% of the remaining more complex



and discipline specific projects⁴. The financial comparisons in the NIH press release fail to fully represent the vast differences in the funding mechanisms being reviewed by CSR compared to the ICs and the IC specific expertise available to ensure proper review. **Given that ICs have subject-specific expertise and advisory councils tailored to their respective missions, can NIH share how it will ensure complex funding mechanisms, such as centers, program projects, cooperative agreements, training grants, and career development awards, continue to receive expert review? What considerations are being made to maintain the effectiveness of IC-specific funding strategies?**

No-Cost Extensions (NCEs) and Expanded Authority: In February, the NCE module in eRA Commons was deactivated for approximately ten days. During this time, recipients were unable to submit NCE requests as afforded by NIH Standard Terms of Award. The ability to implement the first no-cost extension under expanded authority is a fundamental tool for project continuity, especially for early career investigators and newly established research programs. It provides additional time to establish research programs, hire specialized research personnel and complete project objectives. Research projects often experience unavoidable delays in the first year due to establishing the research program, or the "shortcycling" of awards by the NIH. This NIH procedure provides 12 months of funding over a shorter period of time in the initial award year in order to distribute the workload for the agency for non-competing renewals thus requiring scientists to request no-cost extensions. Challenges may include hiring talented personnel, acquiring necessary equipment, and setting up experimental protocols. NCEs ensure that these logistical hurdles do not compromise the ability of researchers to complete their scientific projects. Importantly, NCEs do not increase the total funding of a project but instead allow for the efficient use of existing funds to achieve the project's goals, ultimately maximizing the impact of federal research investments. Given that research often faces early-stage logistical delays, will NIH maintain expanded authorities for NCEs?

Temporary Restraining Orders (TROs) and Preliminary Injunctions: We recognize there are legal proceedings that impact specific NIH grants and policies, including those related to the funding freeze, indirect cost rates (IDC), and diversity, equity, and inclusion (DEI) initiatives. Court proceedings often include injunctive relief that impacts the enforceability of NIH policies in certain jurisdictions or nationwide, and it can be difficult for institutions to navigate this rapidly changing environment. We appreciate NIH's new webpage, Implementation of New Initiatives and Policies, and we believe that adding to this page a section on NIH's implementation of court directives impacting research funding and associated policies would be extremely beneficial for awardees. Further, publicizing this information would clearly demonstrate how NIH is ensuring consistency in funding policies subject to court orders and/or identifying when policies are inconsistent in the cases of orders with a narrower jurisdictional scope.

Award Terms and Stakeholder Engagement: Consistency in federal grant terms and conditions is essential for institutions managing multi-year research projects. Retroactive or mid-cycle changes to award terms create significant financial challenges, disrupting research progress and the investment of taxpayers. At the same time, the recent elimination of the

⁴NIH News Release [March 2025] https://www.nih.gov/news-events/news-releases/nih-centralizes-peer-review-improve-efficiency-strengthen-integrity



Richardson Waiver⁵ raises concerns about the ability of stakeholders to provide input on policy changes that impact federally funded research. Engaging with stakeholders through a structured public comment process to gather input ensures that policy changes reflect the realities of the research environment and facilitate policy implementation. Additionally, the public comment process affords taxpayers an opportunity for input on the policies and programs funded by their tax dollars. Can NIH clarify its current position on obtaining input from stakeholders and taxpayers? How does NIH plan to ensure this critical feedback is solicited and considered moving forward? At a minimum, will NIH retain notice and comment periods for substantive changes to NIH awardees policies, terms, and conditions?

Payment Management System (PMS) Draw Requirement: Recent changes to PMS have raised efficiency concerns. While strong internal controls are crucial for preventing improper payments and ensuring the responsible use of taxpayer funds, the additional documentation requirements in PMS have varying impacts. For some entities drawing funds, these measures may serve as useful controls. However, research institutions are already subject to audits and control-based reviews of their federal activity, along with the requirement to attest, under penalty of civil and criminal sanctions, to the allowability of the funding draws. Given these existing safeguards, it does not appear that the new requirement provides additional value or that research institutions should be expected to provide detailed information. We ask that NIH share how it evaluates the impact of these changes on administrative burden. Are steps being taken to ensure that payment processing remains efficient while maintaining appropriate oversight?

⁵ HHS Rule [March 2025] https://www.federalregister.gov/documents/2025/03/03/2025-03300/policy-on-adhering-to-the-text-of-the-administrative-procedure-act