

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN PUBLIC HEALTH
ASSOCIATION; IBIS REPRODUCTIVE
HEALTH; INTERNATIONAL UNION,
UNITED AUTOMOBILE, AEROSPACE,
AND AGRICULTURAL IMPLEMENT
WORKERS (UAW); BRITTANY
CHARLTON; KATIE EDWARDS; PETER
LURIE; and NICOLE MAPHIS,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH;
JAY BHATTACHARYA, in his official
capacity as Director of the National Institutes
of Health; UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; and ROBERT F.
KENNEDY, JR., in his official capacity as
Secretary of the United States Department of
Health and Human Services,

Defendants.

Civil Action No. 1:25-cv-10787-WGY

I, Jon Lorsch, Ph.D., hereby declare that my testimony below is true and correct to the best of my knowledge and belief and is given under penalty of perjury, pursuant to 28 U.S.C. § 1746:

1. I am the Acting Deputy Director for Extramural Research at the National Institutes of Health (NIH), an operating division of the U.S. Department of Health and Human Services (HHS). I have held this position since April 7, 2025.

2. In addition to my current role, I am the Director of the National Institute of General Medical Sciences (NIGMS), a position I have held since 2013, where I oversee NIGMS's mission-related activities, supporting basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. I am also a Senior Investigator in the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a position I have held since 2014.

3. As Acting Deputy Director for Extramural Research, I am the principal scientific advisor to the NIH Director on all matters relating to the substance, quality, and effectiveness of the NIH extramural research program. I am responsible for overseeing the Office of Extramural Research under the Office of the NIH Director. The Office of Extramural Research "provides the corporate framework for the NIH research administration and works to ensure the scientific integrity, public accountability, and effective stewardship of the NIH research grant portfolio." Office of the Director, NIH, <https://www.nih.gov/about-nih/what-we-do/nih-almanac/office-director-nih> (last visited May 12, 2025).

4. This declaration incorporates information known to me and collected through reasonable diligence from those involved in the challenged grant terminations initiated starting in late February, as well as the cancelled study section meetings in January and February.

II. NIH's Grant Terms

5. NIH does not promulgate any grant regulations itself. Rather, HHS promulgates regulations that apply to the various agencies within it, including NIH. 89 Fed. Reg. 80,055 (Oct. 2, 2024).

6. On August 13, 2020, OMB revised its Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (UAR) at 2 C.F.R. § 200 to permit termination “if an award no longer effectuates the program goals or agency priorities.” 2 C.F.R. § 200.340(a)(4); 85 Fed. Reg. 49,506. OMB’s revision was effective August 13, 2020 (85 Fed. Reg. 49,506). OMB directed agencies to “implement the language [of the revised guidance] in codified regulations...” (2 C.F.R. § 200.106); however, HHS, did not immediately adopt OMB’s revised UAR. 85 Fed. Reg. 72,899, 72,911, 72,903 (Nov. 16, 2020).

7. This caused confusion among the various entities that maintain multiple grant agreements with multiple federal agencies. Because many of those agencies adopted OMB’s 2020 revisions to the UAR, but HHS, and by extension NIH had not yet done so, these organizations found themselves subjected to grant agreements that differed on basic terms depending on the government agency.

8. As a result, repeat players in the federal grant space, specifically two professional university associations, encouraged NIH to adopt the 2020 revised UAR to align with other research agencies in an effort to reduce administrative burden on entities. In doing so, NIH understood that these stakeholders hoped to standardize the terms and conditions of the federal grants their members received. NIH acceded to their requests and

incorporated 2 C.F.R. 200 directly by reference into their grant agreements through the NIH Grant Policy Statement, a term and condition of all NIH grant awards, in 2021.

9. In addition to incorporating 2 C.F.R. § 200 directly into the NIH Grants Policy Statement, NIH announced its adoption of the 2020 updates to the UAR to the grant recipient community in 2021 (NOT-OD-21-029, available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-029.html>). Subsequently, NIH announced to the recipient community again in 2024 that NIH had adopted OMB's 2024 updates to the UAR, which retained the termination provision at 2 C.F.R. § 200.340(a)(4) without change. NOT-OD-25-059, available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-059.html#:~:text=In%20April%202024%2C%20the%20Office,implementation%20of%20the%202024%20Revisions>.

10. Before the time surrounding this and the related lawsuit, I am not aware that any NIH grant recipients objected to NIH's incorporation of 2 C.F.R. § 200 into the terms and conditions of NIH's grant awards.

III. NIH Terminates Various Grants

11. In accordance with the NIH Director's priority-setting powers, *see, e.g.*, 42 U.S.C. § 282(b)(4)-(6), various HHS and NIH officials began issuing new policy guidance to NIH personnel shortly after the inauguration of President Donald Trump on January 20, 2025.

12. Due to NIH's change in priorities, NIH issued 689 grant termination letters that are the origin of the instant action. Each grant termination letter contained an explanation as to why the grant was terminated, based on one of the six deprioritized issue

areas (COVID-19, vaccine hesitancy, China, gender issues, DEI, climate change). The letters also cited to NIH's authority pursuant to 2 C.F.R. § 200.340 to terminate the grants based on a change in agency priorities.

13. Each grant termination letter also informed the grantee of its appeal rights. Each appeal is reviewed by NIH's Deputy Director of the Office of Extramural Research to determine if the termination was done in error, or if the terminated grant does not align with agency priorities. As of May 11, 2025, NIH has received 431 appeals of grant terminations through NIH's appeals process, and appeals remain pending.

14. Between January 21, 2025, and May 12, 2025, NIH had 91,482 active grants, including Competitive and non-competitive grants.

15. Consistent with 42 U.S.C. 285t(a) and other statutes, NIH continues to support research related to "minority health conditions" and "populations with health disparities." As shown in the table of grants that NIH has prepared and attached here as **Exhibit A**, NIH has not terminated at least 25 grants related to health disparities in minority populations. Nor does NIH presently have any intent to terminate these grants.

16. To the extent permissible by law, NIH intends to re-obligate any funds it has de-obligated as a result of the various grant terminations. My understanding is that any funds that are not re-obligated will return to the Treasury at the end of the fiscal year, consistent with standard practice.

17. The Plaintiffs in this case refer to various “Directives”¹ which are documents that were created as NIH worked through the process of shifting its priorities. One document, which they refer to as the “Priorities Directive” but was in fact internal procedural guidance, ECF No. 38-11, did not result in any grant terminations, meeting delays, or meeting cancellations. Another procedural guidance document, the “Supplemental Priorities Directive,” ECF No. 38-12, is no longer in effect.

IV. NIH works to schedule meetings and to review grants

18. On January 21, 2025, the Acting Secretary of HHS, Dorothy A. Fink, issued a memorandum to the Heads of HHS’ Operating Divisions instructing them to refrain from sending any document intended for publications to the Office of the Federal Register until it had been reviewed and approved by a Presidential appointee. This pause went into effect to provide the Administration with time to “consider[] its plan for managing the federal policy and public communications processes.” The memorandum also required HHS employees to “[r]efrain from participating in any public speaking engagement until the event and material have been reviewed and approved by a Presidential appointee.”

19. Pursuant to Section 1009 of the Federal Advisory Committee Act (“FACA”), NIH must post a notice to the Federal Register each time it schedules peer review group and advisory council meetings.

20. On January 22, an HHS Department Committee Management Officer in the Office of the White House Liaison informed NIH that “all FACA activity is paused under

¹ Although “Directives” is a misleading characterization, I use Plaintiffs’ shorthand for consistency and ease of reference.

the [January 21 memorandum]” including peer review group meetings. As a result, NIH cancelled all peer review group meetings and advisory council meetings beginning on January 22, 2025.

21. The January 21 memorandum, which prohibited NIH from sending any documents to the Federal Register absent approval from a Presidential appointee, also caused NIH to not schedule any meetings beginning January 21, 2025.

22. The January 21 memorandum’s temporary pause on peer review group meetings and advisory council meetings ended before April 2, 2025. Peer review group meetings that had been previously scheduled ran from February 7 through February 18, 2025. Re-scheduled and newly scheduled peer review groups resumed on March 24, 2025. NIH resumed the process of holding advisory council meetings on or about March 18, 2025. Indeed, before April 2, 2025, NIH had resumed all reviews, meetings, and other procedural steps necessary to approve grant applications, and had resumed approving grant applications.

23. NIH’s efforts to reschedule these meetings are complicated by two issues. First, in rescheduling meetings, NIH must ensure compliance with the procedural requirements of 41 C.F.R. Part 102-3. Compliance with these requirements necessarily slows down the rate at which NIH can schedule meetings. These requirements include filing a public notice with the Federal Register at least 15 days before each peer review group meeting and advisory council meeting, except in “exceptional circumstances, such as a national emergency or natural disaster,” which are not applicable here. 41 C.F.R. Part 102-3.150. Second, NIH’s peer review groups are composed of peers and experts in the scientific community. The vast majority of these peer review group participants juggle

attending the meetings with teaching and managing their own research. As such, NIH's ability to reschedule these meetings depends on the schedules of thousands of individuals external to NIH.

24. Despite these challenges, NIH has been moving rapidly to reschedule and hold meetings impacted by the short pause, and to process grant applications. Since March 4, 2025, NIH has published over 150 notices to the Federal Register for upcoming peer review group meetings. Many of these notices announce multiple meetings. It has also published notices for numerous advisory council meetings. NIH intends to schedule all statutorily required advisory council meetings. To account for the brief pause in scheduling and holding meetings, NIH has scheduled more meetings than usual for this time period. For example, in 2023, 83 peer review group meetings managed by NIH's Center for Scientific Review (CSR) were held between March 24 and May 31. In 2024, CSR managed 104 meetings in that time period. This year, as currently reflected in publicly available information at <https://www.csr.nih.gov/RevPanelsAndDates/RevDates.aspx>, NIH will hold 306 CSR-managed peer review group meetings for that same time period. Adding meetings managed across NIH's Institutes and Centers to the total managed by CSR, there are 578 NIH peer review group meetings scheduled between March 24 and May 31, 2025. This is 245 more NIH peer review group meetings for this same time period last year.

25. Despite the short delay in scheduling and holding peer review and advisory council meetings to allow for the administration transition, NIH has been on pace with its reviewing grant applications and holding meetings and has caught up from the pause when compared to prior years. NIH anticipates that by the end of May 2025, NIH will have completed 100% of its Cycle III peer review meetings. By that same time, NIH also

anticipates that it will have reviewed 100% of Cycle III grant applications, for a total of 32,819 Cycle III applications reviewed.

26. The NIH Institutes and Centers (ICs) have also held or scheduled advisory council meetings that were delayed as a result of the pause. NIH and all of its ICs will hold advisory council meetings at least three times this fiscal year.

27. From the date of the temporary pause through May 12, 2025, NIH issued 11,362 new non-competitive grants. NIH has also issued 1,971 new competitive grants in that same time frame.

28. At the same time, due to the barrage of litigation and TROs currently active against NIH, NIH's internal procedures have necessarily needed to proceed with caution to assure compliance with all applicable laws and court rulings.

V. Kirschstein National Research Service Awards were not terminated.

29. NIH awards Kirschstein National Research Service Awards ("NRSA"), pursuant to 42 U.S.C. § 288(a)(1).

30. NIH awards various grants to individuals for career development and training. These grants provide researchers at various stages of their careers development and training opportunities, including by covering tuitions and costs, and funding research programs. The parent programs for these funding opportunities are research training grants (T-series grants), fellowship grants (F-series grants) and career development grants (K-series grants).

31. Although some of the specific, non-Congressionally mandated NRSA programs have ended, the parent programs remain active, and NRSA Notices of Awards continue to be made.

32. Pursuant to NIH's authority, and subject to its discretion, NIH terminated some NRSA funding opportunities, but did not terminate many others. NIH continues to issue and publicly post Notice of Funding Opportunities for NRSA grants. *See* <https://grants.nih.gov/funding/nih-guide-for-grants-and-contracts/parent-announcements> (last accessed May 12, 2025).

33. In addition, NIH is in the process of reissuing Notice of Funding Opportunities for additional NRSA programs.

34. As of the date of the information contained in **Exhibit B**, NIH continues to fund more than 5,172 NRSA grants around the country. None of these grants were terminated. The funding of these grants meets any NIH statutory obligations. Attached as **Exhibit B** is a true and accurate table, created by NIH, of NRSA grants that were not terminated.

I HEREBY DECLARE TO THE BEST OF MY KNOWLEDGE AND BELIEF,
UNDER PENALTY OF PERJURY under the laws of the United States of America, that
the foregoing is true and correct.

EXECUTED this 12th day of May, 2025 at Washington, DC.

Jon R. Lorsch
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Digitally signed by Jon R. Lorsch -S
Date: 2025.05.12 17:23:49 -04'00'

JON LORSCH, Ph. D.