IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAI'I; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; and STATE OF WISCONSIN,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAYANTA BHATTACHARYA, in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART, LUNG, AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE

No. 1:25-cv-10814-BEM

ON DEAFNESS AND OTHER COMMUNICATION DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; and CENTER FOR SCIENTIFIC REVIEW,

Defendants.

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs the Commonwealth of Massachusetts, the State of California, the State of Maryland, the State of Washington, the State of Arizona; the State of Colorado; the State of Delaware; the State of Hawai‘i, the State of Minnesota; the State of Nevada; the State of New Jersey; the State of New Mexico; the State of New York; the State of Oregon; the State of Rhode Island; and the State of Wisconsin allege as follows:

INTRODUCTION

1. The National Institutes of Health (NIH) is a federal agency responsible for conducting and supporting biomedical research. Widely acknowledged as a "crown jewel" of America's scientific institutions—a characterization the agency's director recently reiterated[1]—NIH is the largest public funder of medical research in the world.

2. NIH has "a long and illustrious history [of] supporting breakthroughs in biology and medicine."[2] NIH scientists pioneered the rubella vaccine, eradicating a disease that, in the 1960s, killed thousands of babies and left thousands more with lifelong disabilities.[3] NIH studies led to the discovery of the BRCA mutation, helping countless Americans reduce their risk of breast and ovarian cancer.[4] And NIH research fueled the development of treatments for HIV and AIDS, transforming what was once a fatal disease into one with a nearly normal life expectancy.[5] These are just a few of many, many examples: over the years, NIH-supported research has had a profound impact on Americans' health and wellbeing. Indeed, it is hard to find a medical breakthrough in recent years that has *not* been assisted—whether directly or indirectly—by NIH.[6]

3. NIH's activities have also contributed to our Nation's economic security and prosperity. Today, the United States is a global leader in the health and life sciences—thanks, in

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[1] Opening Statement of Dr. J. Bhattacharya, S. Comm. on Health, Educ., Lab. & Pensions (March 5, 2025), https://bit.ly/Bhattacharya-Statement.

[2] *Id*.

[3] Lyons M., *IRP Vaccine Research Stretches Back to the NIH's Birth*, NIH Intramural Rsch. Prog. (May 18, 2020), https://irp.nih.gov/blog/post/2020/05/a-long-tradition-of-vaccine-breakthroughs.

[4] *Enhancing Breast and Ovarian Cancer Care: The Discovery of BRCA1 and BRCA2*, Nat'l Cancer Inst. (March 7, 2014), https://www.cancer.gov/research/progress/discovery/brca.

[5] *HIV/AIDS Treatment*, Nat'l Inst. of Allergy & Infectious Disease (Jun. 16, 2020), https://www.niaid.nih.gov/diseases-conditions/hiv-treatment.

[6] *See, e.g.*, Cleary E.G. *et al.*, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum, no. 4 (2023) (showing NIH funding contributing to 99.4% of FDA-approved drugs from 2010 to 2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC10148199.

no small part, to NIH. The agency's grants have allowed America to train the next generation of doctors, researchers, and biomedical entrepreneurs. And they have ensured that crucial innovations take place in American institutions—allowing the United States to reap the economic benefits of those discoveries. The numbers speak for themselves: in Fiscal Year 2024 alone, NIH's more than $36 billion in awards spurred more than $94 billion in new economic activity—a return of $2.56 for every $1 invested. These investments supported more than 407,000 jobs across every State and the District of Columbia.

4. That critical work is now in jeopardy. By law, NIH provides much of its support for scientific research and training in the form of grants to outside institutions. Since his inauguration, however, the President has issued a barrage of executive orders prohibiting federal agencies from supporting any initiatives with a perceived nexus to certain subjects he opposes, such as "DEI" and "gender ideology." Taking its cue from the executive orders, defendants have adopted a series of directives that curtail NIH's support for previously advertised funding opportunities and previously awarded grants relating to these and other blacklisted topics.

5. These directives are unlawful—as are defendants' actions in developing, implementing, and enforcing them. Plaintiffs bring this action to seek relief for the immediate harms that defendants and their directives are causing to state research institutions.[7]

6. First, defendants' recent policies and actions violate the Administrative Procedure Act (APA). In promulgating directives that prohibit research into certain politically disfavored subjects, defendants have flouted express statutory and regulatory provisions, including statutory

[7] In recent months, a number of the plaintiff states have brought lawsuits challenging other unlawful policies and decisions that affect NIH grants. *See* Complaint, *Massachusetts v. NIH*, No. 1:25-cv-10338-AK (D. Mass. Feb. 10, 2025) (ECF No. 1) (challenging recent NIH guidance purporting to alter the methodology for calculating "indirect costs"); Complaint, *New York v. Trump*, No. 1:25-cv-39-JJM-PAS (D.R.I. Jan. 28, 2025) (ECF No. 1) (challenging an OMB directive instituting a temporary funding pause across federal agencies). The agency actions at issue in those cases are distinct from the acts and omissions at issue here.

provisions directing NIH to support diversity in the scientific workforce and to promote the health of racial, ethnic, sexual, and gender minorities. In this way, NIH's directives are contrary to law. 5 U.S.C. §706(2)(A), (C). Defendants have also departed from NIH's own prior position on the now-blacklisted topics, without acknowledging—let alone providing "good reasons for"—their change in position. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And what little reasoning that defendants have offered in support of their new blacklisting directives fails to grapple with relevant considerations and runs counter to the available evidence. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). For these reasons, defendants' directives are also arbitrary and capricious. 5 U.S.C. §706(2)(A). Defendants' recent actions also violate the APA because they have led to unreasonable and intentional delays in the grant-application process, including cancellation of the "study sections" and "advisory councils" that review and approve requests for NIH funding. Accordingly, defendants have "unlawfully withheld" and "unreasonably delayed" required action. *Id.* §706(1).

7. Second, defendants' policies and actions contravene Spending Clause and other separation-of-powers constraints and constitute *ultra vires* executive action. The Constitution "grants the power of the purse to Congress, not the President." *City & County of San Francisco v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018). The purpose and effect of defendants' new blacklisting policies, however, is to refuse to spend duly appropriated funds. These new policies also work to retroactively alter the terms of federal programs. For these reasons, the challenged policies violate the Constitution. And federal courts have well-established equitable powers to enjoin federal officials from exceeding the bounds of their constitutional and statutory authority. *See, e.g.*, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326-27 (2015).

8. In implementing and enforcing the challenged policies, defendants have caused—and, left unchecked, will continue to cause—direct, immediate, significant, and irreparable harm to plaintiffs and their public research institutions. Plaintiffs are collectively awaiting NIH's decisions on billions of dollars in requested research funding, including millions of dollars in funding for projects that received top marks from the relevant NIH study section. Despite securing a "fundable" score, these applications remain in suspended animation—neither approved nor denied—making it impossible for plaintiffs to plan for the future. And now, NIH's enforcement of the blacklisting policies has led to the termination of millions of dollars (and counting) in grants already issued to plaintiffs' public institutions. The result of these disruptions has been, in a word, devastating. In Massachusetts, for example, the growing uncertainty has forced the Commonwealth's flagship public research institution, the University of Massachusetts, to rescind several dozen offers from prospective biomedical-sciences graduate students for the upcoming academic year, decimating its graduate student program and jeopardizing important lines of research and risking adverse generational impacts on public health research and innovation.

9. For all these reasons, plaintiffs seek swift relief from this Court. The Court should set aside NIH's unlawful blacklisting policies—and the actions taken to implement those policies—and compel the review of applications that the agency has unlawfully withheld.

JURISDICTION AND VENUE

10. This action arises under U.S. Constitution; the APA, 5 U.S.C. §701 *et seq.*; the Public Health Service Act (PHSA), 42 U.S.C. §201 *et seq.*; and federal regulations governing NIH grants. This Court has jurisdiction under 28 U.S.C. §1331.

11. Venue is proper in this district under 28 U.S.C. §1391(e)(1). Defendants are federal agencies and officers sued in their official capacities. The Commonwealth of Massachusetts is a

resident of this judicial district and a substantial part of the events or omissions giving rise to this Complaint occurred within this district.

PARTIES

I. Plaintiffs

12. The Commonwealth of Massachusetts is a sovereign state of the United States of America. Massachusetts is represented by Attorney General Andrea Joy Campbell, the Commonwealth's chief legal officer.

13. The State of California is a sovereign state of the United States of America. California is represented by Attorney General Rob Bonta, the State's chief legal officer.

14. The State of Maryland is a sovereign state of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Anthony G. Brown.

15. The State of Washington is a sovereign state of the United States of America. Washington is represented by Attorney General Nicholas W. Brown, the State's chief legal officer.

16. The State of Arizona is a sovereign state of the United States of America. Arizona is represented by Attorney General Kristin K. Mayes, the State's chief law enforcement officer.

17. The State of Colorado is a sovereign state of the United States of America. Colorado is represented by and through its Attorney General Phil Weiser. The Attorney General acts as the chief legal representative of the State and is authorized by Colo. Rev. Stat. §24-31-101 to pursue this action.

18. The State of Delaware is a sovereign state in the United States of America. Delaware is represented by Attorney General Kathy Jennings, who is the State's chief law enforcement officer.

19. The State of Hawai‘i is a sovereign state of the United States of America. Hawai‘i is represented by Attorney General Anne Lopez, who is the State's chief law enforcement officer.

20. The State of Minnesota is a sovereign state of the United States of America. Minnesota is represented by Attorney General Keith Ellison, the State's chief legal officer.

21. The State of Nevada, represented by and through Attorney General Aaron D. Ford, is a sovereign State within the United States of America. The Attorney General is the chief law enforcement of the State and is authorized to pursue this action under Nev. Rev. Stat. §228.110 and Nev. Rev. Stat. §228.170.

22. The State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the State's chief law enforcement officer.

23. The State of New Mexico is a sovereign state of the United States of America. New Mexico is represented by Attorney General Raúl Torrez, the State's chief law enforcement officer.

24. The State of New York is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, and political subdivisions of New York. Attorney General Letitia James is the chief law enforcement officer for New York.

25. The State of Oregon is a sovereign state in the United States of America. Oregon is represented by Attorney General Dan Rayfield, who is the State's chief legal officer. Attorney General Rayfield is authorized by statute to file suit in federal court on behalf of the State of Oregon to protect the interests of the State. Or. Rev. Stat. §180.060.

26. The State of Rhode Island is a sovereign state of the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, the State's chief legal officer.

27. The State of Wisconsin is a sovereign state in the United States of America. Wisconsin is represented by Josh Kaul, the Attorney General of Wisconsin, who is the chief law enforcement officer of Wisconsin and is authorized to sue on behalf of the State, including its public universities.

II. Defendants

28. Robert F. Kennedy, Jr., is the Secretary of Health and Human Services. He is sued in his official capacity.

29. The United States Department of Human and Health Services (HHS) is a federal cabinet department.

30. Jayanta Bhattacharya is the Director of NIH. He is sued in his official capacity.

31. NIH is a federal agency organized under the PHSA, *see* 42 U.S.C. §§203, 281; it is housed within HHS.

32. The following institutes and centers are federal agencies established under the PHSA, *see* 42 U.S.C. §281, and housed within NIH: the National Cancer Institute; the National Eye Institute; the National Heart, Lung, and Blood Institute; the National Human Genome Research Institute; the National Institute on Aging; the National Institute on Alcohol Abuse and Alcoholism; the National Institute of Allergy and Infectious Diseases; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Biomedical Imaging and Bioengineering; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; the National Institute on Deafness and Other Communication Disorders; the National Institute of Dental and Craniofacial Research; the National Institute of Diabetes and Digestive and Kidney Diseases; the National Institute on Drug Abuse; the National Institute of Environmental Health Sciences; the National Institute of General Medical Sciences; the National Institute of Mental Health; the National Institute on Minority Health and Health Disparities; the

National Institute of Neurological Disorders and Stroke; the National Institute of Nursing Research; the National Library of Medicine; the National Center for Advancing Translational Sciences; the John E. Fogarty International Center for Advanced Study in the Health Sciences; the National Center for Complementary and Integrative Health; and the Center for Scientific Review.

FACTUAL AND LEGAL BACKGROUND

III. Congressional Authorization and Appropriation for NIH Research

A. Creation and Structure of NIH

33. NIH traces its origins to the 1887 establishment of the Hygienic Laboratory, a component of the Marine Hospital Service dedicated to the study of epidemic diseases. Subsequent statutes have transformed that single laboratory into the multifaceted agency at the center of this suit. In 1902, the laboratory assumed responsibility for testing and regulating vaccines and biologic products with the passage of the Biologics Control Act, ch. 1378, 32 Stat. 728. In 1930, Congress redesignated the laboratory as the National Institute (singular) of Health and established fellowships for biological and medical research. *See* Ransdell Act, ch. 251, 46 Stat. 379. In 1937, Congress created the National Cancer Institute, authorizing the new institute to award research grants to nonfederal scientists and to fund fellowships for young researchers. *See* National Cancer Institute Act, ch. 565, 50 Stat. 559. In 1944, Congress made the National Cancer Institute a division of NIH and expanded NIH's support for biomedical research. PHSA, ch. 373, 58 Stat. 682. And in 1948, following the creation of several additional subsidiary institutes, Congress gave the umbrella agency its current name: the National Institutes (plural) of Health. *See* National Heart Act, ch. 481, 62 Stat. 464.

34. Today, NIH is made up of 27 institutes and centers—or "ICs," in NIH parlance—that each specialize in discrete diseases or body systems or carry out distinct projects. According to the agency, "NIH's mission is to seek fundamental knowledge about the nature and behavior of

living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."[8]

35. NIH carries out its mission through both "intramural" research (that is, research conducted in-house at NIH) and "extramural" research (that is, research conducted at outside institutions with NIH financial support). Twenty-five of the agency's institutes and centers—all named as defendants in paragraph 32 above—are involved in issuing or reviewing applications for extramural funding opportunities.[9]

36. NIH is the primary source of federal funding for biomedical and public health research in the United States. In fiscal year 2024, NIH spent over $36 billion on over 60,000 research grants, awarded to recipients in each of the fifty States and the District of Columbia.[10]

37. In addition to supporting numerous scientific breakthroughs (*see supra*, paragraph 2), NIH funds are also critical to the education and training of the next generation of scientists and researchers. NIH's financial awards support postdoctoral fellows, graduate students, and early-career investigators whose work advances scientific discovery and innovation. These funds not only provide financial support, but also enable mentorship, access to cutting-edge resources, and participation in collaborative research environments that are essential for developing the skills, experience, and professional networks needed to sustain the biomedical research enterprise.

[8] *Mission and Goals*, NIH (Oct. 24, 2024), https://www.nih.gov/about-nih/what-we-do/mission-goals.

[9] The remaining two are the NIH Clinical Center (a research hospital) and the NIH Center for Information Technology (an administrative component responsible for computing and information technology).

[10] *See* United for Medical Research, *NIH's Role in Sustaining the U.S. Economy*, United for Medical Research, at 5 (Mar. 2025), https://bit.ly/3Xz6Wry (tabulating NIH research grants awarded, FY2024); *see also NIH Awards by Location & Organization*, NIH, https://report.nih.gov/award/index.cfm (searchable results); *Research Project Grants*, NIH, https://report.nih.gov/nihdatabook/category/4 (Jan. 2024) (identifying historical data through 2023, and reporting more than 40,000 competitive grant awards in 2022 and 2023).

B. Congressional Authorization for NIH Research

38. NIH's extramural research activities stem from statutory directives: Congress has enacted laws authorizing NIH and its constituent institutes and centers to conduct research and award grants, and it has supplied funding for those activities through regular appropriations.

39. Section 301 of the PHSA, 42 U.S.C. §241, contains Congress's overarching authorization for NIH (as a component of the "Public Health Service") to conduct research and award grants. Subsection (a) of that paragraph states:

> The Secretary [of Health and Human Services] shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams.

And subsection (a)(1) states that:

> The Secretary may make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research.

40. Section 405 of the PHSA, 42 U.S.C. §284, imposes similar responsibilities and confers similar authority on the directors of NIH's institutes and centers. Among other things, each director "shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences," *id.* §284(b)(1)(A), and, to that end, "may make grants and cooperative agreements . . . for research, training, or demonstrations," *id.* §284(b)(2)(A). *See also* 42 U.S.C. §282 (similar, for the NIH director).

C. Congressional Authorization for Specific Programs and Priorities

41. Other sections of the PHSA provide more specific directives to each of NIH's constituent institutes and centers, detailing the ICs' general purposes and establishing initiatives and programs within each of them. *Cf.* 42 U.S.C. §284(b)(1) (providing that, in carrying out the purposes of section 301 of the PHSA, the Secretary, acting through the Director of each research institute within NIH, "shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences" with respect to the human disease or disorder or other aspects of human health for which the national research institutes were established). Some of these statutory provisions are directly at odds with the "agency priorities" articulated in defendants' new blacklisting policies.

42. To take just one example, as described in greater detail below (*see infra*, paragraphs 94-117), defendants have adopted a policy blacklisting research projects with a perceived connection to "DEI." This newly stated policy against diversity, equity, and inclusion is inconsistent with at least the following express statutory directives:

- Congress has provided that the NIH director "shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." 42 U.S.C. §282(h).

- Congress has provided that the NIH director shall "encourage efforts to improve research related to the health of sexual and gender minority populations, including by (1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable; (2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and (3) addressing methodological challenges." *Id.* §283p.

- Congress has directed various NIH institutes and centers to conduct research related to women's health or reproductive health. For example, it has instructed the National Cancer Institute to "expand, intensify, and coordinate the activities of the Institute with respect to research on breast . . . cancers of the reproductive system of women." *Id.* §285a-6. And it has required the National Heart, Lung, and Blood Institute to conduct research into the

prevalence of certain heart conditions in women, "including African-American women and other women who are members of racial or ethnic minority groups." *Id.* §285b-7a(c)(1)

- Congress has established a National Institute on Minority Health and Health Disparities to support research and training "with respect to minority health conditions and other populations with health disparities." *Id.* §285t(a).[11]

- Congress has established an Office of Research on Women's Health within NIH to "determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation." *Id.* §287d(e).

- Congress has instructed the Secretary of Health and Human Services to award Ruth L. Kirschstein National Research Service Awards "in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals." *Id.* §288(a)(4).

D. Congressional Directives Regarding NIH Priority-Setting

43. In addition to the above directives, Congress has also established a public process to identify the research priorities of NIH and its institutes and centers. Every six years, the NIH director must "develop and submit to the appropriate committees of Congress and post on the [NIH's website] a coordinated strategy (to be known as the 'National Institutes of Health Strategic Plan') to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine." 42 U.S.C. §282(m)(1). Each of NIH's institutes and centers similarly develops and promulgates a strategic plan that publicly articulates its research priorities. *Id.* §282(m)(3).

[11] The statutory term "minority health conditions" is defined to mean conditions that are unique to, or more prevalent among, or treated differently in, or understudied with respect to "individuals who are members of" "racial and ethnic minority group[s]"—*i.e.*, "American Indians (including Alaska Natives, Eskimos, and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics." 42 U.S.C. §§285t(c)(2)-(3), 300u-6(g)(1).

44. NIH has previously followed Congress's direction and publicized its research priorities. In September 2019, the NIH director began the process of updating the agency's priorities in biomedical and behavioral research areas, research capacity, and research conduct. Between October 2019 and July 2020, NIH gathered feedback from its institutes and centers, their advisory councils, external stakeholders, and the general public. The final Strategic Plan, published in 2021, stated that, among other things, NIH would prioritize "improving minority health and reducing health disparities; enhancing women's health; addressing public health challenges across the lifespan; promoting collaborative science; and leveraging data science for biomedical discovery."[12] Similarly, the plan stated that NIH "supports a comprehensive spectrum of immunology and infectious disease research focused on developing improved or novel vaccines, including the rapid development of new vaccines to mitigate emerging infectious disease outbreaks, such as COVID-19, Ebola virus disease (EVD), and influenza (flu)."[13]

E. Congressional Appropriations for NIH Extramural Research

45. Most of NIH's funding comes from annual discretionary appropriations from Congress.[14] For years, Congress has made appropriations for NIH research with this statutory and regulatory framework in mind and generally has appropriated specific amounts to each of NIH's institutes and centers to carry out the purposes set forth in the authorizing statutory provisions described above.[15]

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[12] NIH, *NIH-Wide Strategic Plan, Fiscal Years 2021-2025* at 3 (2021), https://bit.ly/NIHSP2125.

[13] *Id.* at 8.

[14] Some of NIH's funding is from mandatory funding sources or available due to specific transfer or budgetary rules, but the "vast majority" comes from annual discretionary appropriations. *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341.

[15] *See, e.g.*, Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. H, tit. II, 136 Stat. 4459, 4861-65; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H, tit. II, 136 Stat. 49, 448-52; Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. H, tit. II, 134 Stat. 1182, 1573-77; Further Consolidated

46. In recent years, Congress has specifically rejected efforts to significantly cut NIH's funding. For example, in 2017, as part of its fiscal year 2018 budget proposal, the first Trump Administration sought to reduce NIH annualized spending by $5.8 billion, to $25.9 billion.[16] The proposal's primary method of achieving these cuts was by slashing the "indirect cost rate" for NIH grants, capping it at 10% across the board. This proposal drew bipartisan criticism. The Senate Appropriations Committee reported that the proposal would "radically change the nature of the Federal Government's relationship with the research community," would "abandon[]" the Government's "long-established responsibility" for research infrastructure, and would jeopardize "biomedical research nationwide." S. Rep. No. 115-150, at 109 (2017). To avoid this possibility, Congress enacted statutory language (which it has readopted in every subsequent appropriations measure) barring NIH or any other agency from restructuring or modifying the existing approach to indirect costs. *See* Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, §226, 132 Stat. 348, 740. And ultimately, rather than enacting the Administration's proposal of cutting NIH funding to $25.9 billion, Congress's all-in appropriation to NIH for fiscal year 2018 was $37.3 billion—higher than the prior fiscal year's appropriation.[17]

47. In subsequent budget proposals, the Administration generally sought to increase, not decrease, NIH's funding. Its Fiscal Year 2020 budget proposal touted the Administration's prioritization of "critical health research" and proposed a $33 billion appropriation to NIH—about

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Appropriations Act, 2020, Pub. L. No. 116-94, div. A, tit. II, 133 Stat. 2534, 2562-65; Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, div. B, tit. II, 132 Stat. 2981, 3074-77; Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, tit. II, 132 Stat. 348, 720-23; Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, div. H, tit. II, 121 Stat. 135, 524-26; *see also, e.g.*, Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, div. G, tit. II, 121 Stat. 1844, 2173-77.

[16] *See* Off. of Mgmt. & Budget, *Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018*, at 43 (2017), https://bit.ly/OMBFY18.

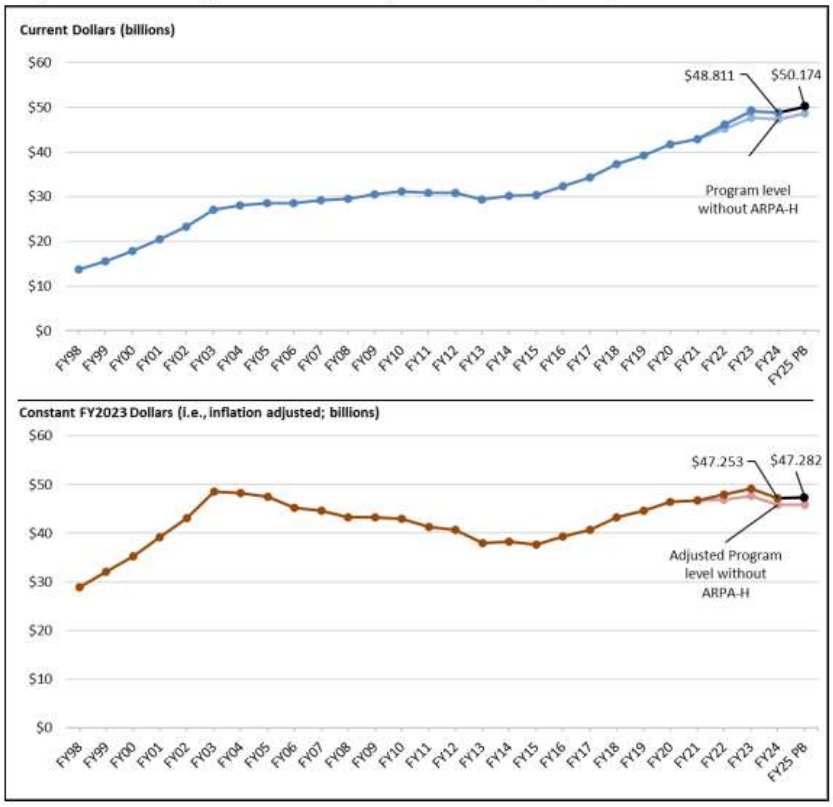
[17] NIH, *History of Congressional Appropriations, Fiscal Years 2010-2019*, at 1, https://bit.ly/42p9Lya.

$6 billion higher than its 2017 proposal.[18] Similarly, the Fiscal Year 2021 budget reiterated the Administration's commitment to prioritizing "critical health research" and "support[ing] innovation," and proposed providing $38 billion to NIH.[19] Ultimately, Congress appropriated even more funds to NIH than the Administration requested for fiscal year 2021: about $42.9 billion.[20]

48. Overall, from Fiscal Years 2017 through 2023, NIH funding increased annually, which is consistent with NIH's stable, and generally increasing, funding for more than 20 years:[21]

Figure 1. NIH Funding, FY1998-FY2025 Request

Program Level Funding in Current and Projected Constant (FY2023) Dollars.



[18] Off. of Mgmt. & Budget, *Budget of the U.S. Gov't, Fiscal Year 2020*, at 46, https://bit.ly/OMBFY20.

[19] Off. of Mgmt. & Budget, *A Budget for America's Future, Fiscal Year 2021*, at 54, bit.ly/OMBFY2021.

[20] NIH, *Supplementary Appropriation Data Table for History of Congressional Appropriations, Fiscal Years 2020-2025*, at 1, bit.ly/42dM1M4.

[21] *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341.

49. Congress's appropriations to NIH for Fiscal Year 2024 were no different. Consistent with past appropriations for NIH activities, the Further Consolidated Appropriations Act of 2024 (2024 CAA) appropriates to each of NIH's Institutes and Centers specific amounts "for carrying out section 301 and title IV of the [Public Health Service] Act" with respect to their specific, respective statutory purposes. Pub. L. 118-47, div. D, tit. II, 138 Stat. 460, 656-57. For example, the 2024 CAA appropriates $7,224,159,000 to the National Cancer Institute "for carrying out section 301 and title IV of the [PHSA] with respect to cancer"; $3,982,345,000 to the National Heart, Lung, and Blood Institute to carry out the same statutory purposes "with respect to cardiovascular, lung, and blood diseases, and blood and blood products"; and $2,603,925,000 to the National Institute for Neurological Disorders and Stroke to carry out the same statutory purposes "with respect to neurological disorders and stroke." *Id.*

50. Congress has not enacted a Consolidated Appropriations Act for Fiscal Year 2025, but on March 15, 2025, the President signed the Full-Year Continuing Appropriations and Extensions Act, 2025, commonly known as a "Continuing Resolution" or "CR" (2025 CR). Pub. L. 119-4, 139 Stat. 9. Pursuant to the 2025 CR, Congress appropriated "[s]uch amounts as may be necessary . . . under the authority and conditions provided in applicable appropriations Acts for fiscal year 2024, for projects or activities . . . that are not otherwise specifically provided for, and for which appropriations, funds, or other authority were made available" in the specific appropriations Acts. *Id.*, div. A, §1101(a), 139 Stat. at 11. Congress made limited changes in the 2025 CR with respect to the appropriation to NIH, including rescission of a portion of NIH funding ($221,000,000 of a $1.25 billion appropriation) previously appropriated to the "NIH Innovation Account, CURES Act," which is separate from Congress's discretionary appropriations to NIH's

institutes and centers. *Id.*, div. A, §1905, 139 Stat. at 32.[22] Otherwise, Congress did not rescind any amounts appropriated to NIH's ICs and maintained the same level of funding as set forth in the 2024 CAA, through September 30, 2025. *See id.*, div. A, §1101(a)(8), 139 Stat. at 11.

IV. The Grant Application and Award Process

51. NIH generally awards extramural grants through a competitive process. At any given time, NIH has over a thousand active funding opportunities supporting a broad range of programs.

52. HHS has promulgated regulations at 45 C.F.R. part 75, governing the award of grants by HHS and its agencies, including NIH. This includes 45 C.F.R. §52.6(c), which allows HHS to notice a grant award for a "project period," during which HHS intends to support the project "without requiring the project to recompete for funds."

53. NIH uses three-character "activity codes" to group and classify these funding opportunities, with the first character typically identifying the major funding category or program type. "For example, activity codes for research and development often start with 'R,' training with 'T,' fellowship with 'F,' and career development with 'K.'[23] The "R01" code, for example, denotes grants "[t]o support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies."

54. The NIH competitive grantmaking process begins with a notice of funding opportunity (NOFO)—*i.e.*, a public announcement in which NIH declares its intention to award

[22] Appropriations to the account created by the Cures Act are, "[i]n effect," "not subject to discretionary spending limits." *Nat'l Insts. of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341. Funds may be transferred from the Cures Act account to other NIH accounts "only for the purposes specified in the Cures Act." *Id.* Congress exempted from any rescission amounts previously designated by Congress as for an "emergency requirement" under the Balanced Budget and Emergency Deficit Control Act of 1985. 2025 CR, div. A, §1101(a)(8), 139 Stat. at 11

[23] *Activity Codes*, NIH (March 28, 2025), https://grants.nih.gov/funding/activity-codes; *see Funding Categories*, NIH (Feb. 3, 2025), https://grants.nih.gov/funding/funding-categories.

funds and outlines the program goals and objectives and conditions for applying. *See* NIH Grants Policy Statement, U.S. Dep't of Health & Hum. Servs. §2.3.5, at I-51 (Apr. 2024) (NIHGPS).

55. A researcher interested in responding to a NOFO will typically work with the "sponsored research" department at his or her institution to understand what NIH requires in its application submission. At UMass Medical School, for example, the Office of Sponsored Programs assists faculty and staff in locating sources of funding, reviewing and approving proposals, and negotiating grants and contracts.

56. Once a researcher develops a project proposal, that person then submits an electronic grant application to NIH. Applications must conform to 45 C.F.R. part 75, and must include a detailed research plan outlining the study's objectives, methodology, and significance; a proposed budget and justification; biosketches for key investigators; and any necessary compliance documentation, such as Institutional Review Board approval for human subject research.

57. A submitted grant application undergoes two layers of evaluation: an initial layer of review by a "scientific review group" (also known as a "study section"), followed by a round of review by an "advisory council." *See* 42 U.S.C. §§284a, 289a; *see also* NIHGS §2.4, at I-71 ("The peer review system used by NIH, often referred to as the 'dual review system,' is based on two sequential levels of review for each application—initial review by [a study section], and a second level of review for scientific merit by the IC National Advisory Council/Board."). According to NIH, this process "is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias." NIHGS §2.4, at I-71.

58. As noted, the first level of application review is carried out by a study section. The role of study sections is to assess applications' scientific merit and to determine the overall impact

that proposed projects will likely have on the relevant field. Governing statutes and regulations require this layer of review—*i.e.*, a favorable study-section recommendation is a prerequisite to a final award of any NIH grant. *See* 42 U.S.C. §§ 284(b)(2)(B), 289a(a); 42 C.F.R. pt. 52h.

59. These groups consist primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. 42 C.F.R. §52h.4. NIH has hundreds of study sections, organized by specialty. In the field of Kidney, Urology, and Digestive Systems, for example, NIH maintains study sections on (a) Drug and Biologic Disposition and Toxicity; (b) Digestive System Host Defense, Microbial Interactions, and Immune and Inflammatory Diseases; (c) Digestive and Nutrient Physiology and Diseases; (d) Environmental Determinants of Disease (e) Hepatobiliary Pathophysiology; (f) Kidney and Urological Systems Function and Dysfunction; and Pathobiology of Kidney Disease, as well as two "special emphasis panels" on Digestive Sciences Small Business Activities and Renal and Urological Sciences Small Business Activities. Some study sections are housed in NIH's individual institutions and centers, while others are organized centrally in the agency's Center for Scientific Review.

60. Study sections carry out their work—including review of pending applications—at regularly scheduled meetings. These meetings must be noticed in advance in the Federal Register. *See* 42 C.F.R. §52h.3 ("To the extent applicable, the Federal Advisory Committee Act, as amended . . . shall govern the establishment and operation of peer review groups."); 5 U.S.C. §1009(a)(2) ("[T]imely notice of each meeting [subject to the Federal Advisory Committee Act] shall be published in the Federal Register . . . .").

61. Study sections review and score each grant application according to established criteria set forth in regulations and the NOFO. In particular, the study section assesses the overall impact that the project could have on the research field involved, taking into account:

(a) The significance of the goals of the proposed research, from a scientific or technical standpoint;

(b) The adequacy of the approach and methodology proposed to carry out the research;

(c) The innovativeness and originality of the proposed research;

(d) The qualifications and experience of the principal investigator and proposed staff;

(e) The scientific environment and reasonable availability of resources necessary to the research;

(f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;

(g) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

42 C.F.R. §52h.8; *see also* 42 C.F.R. §52a.5 (describing review criteria for NIH research center grants); 42 C.F.R. §52h.11 (describing review criteria for NIH research contracts).

62. As a result of that review, each grant application receives an "overall impact score" from 10 (the best score, denoting high impact) to 90 (the worst score, denoting low impact). Each application also receives a percentile rank expressing the impact score in relation to other applications in that particular institute. Projects deemed "unfundable" by the study section are not given a score and are removed from further consideration.

63. Each fiscal year, NIH's institutes and centers publish guidance called "paylines" to help applicants interpret their study-section results. These paylines reflect a sort of cutoff: for each category of grants, the payline shows the impact score (or percentile) above which a project is highly likely to be funded. In Fiscal Year 2025, for example, published guidance from the National Institute of Allergy and Infectious Diseases (NIAID) established a 12th-percentile payline for

"R01" awards with new or early-stage principal investigators.[24] In other words, an applicant in that category who received a score from the relevant study section within the 12th percentile could anticipate that NIAID would likely fund his or her project. Study-section scores that meet or exceed the payline in this way are commonly referred to as "fundable" scores.

64. In addition to providing scores and percentiles, study sections also provide each applicant with a "summary statement" that contains, among other things, a brief summary of the study section's discussion, bulleted critiques from assigned reviewers, and any administrative comments. Applicants can use these summary statements to revise applications and address concerns, if necessary.

65. As noted, the second level of application review is carried out by an advisory council. Unlike the numerous study sections, each NIH institute or center that funds grants has a single advisory council (*i.e.*, there is one advisory council for NIAID, one for the National Cancer Institute, and so on). By statute, NIH advisory councils must meet at least three times per fiscal year. 42 U.S.C. §284a(3). Like study section meetings, advisory council meetings must be noticed in advance in the Federal Register. *See* 41 C.F.R. §102-3.150 (requiring 15 days' notice).

66. Whereas a study section's review focuses on scientific merit, an advisory council's review weighs programmatic and institute-wide considerations. A council considers, among other things, the extent to which an application aligns with the institute or center's priorities, public health needs, and overall funding availability. The council also reviews the application for other potential barriers, such as ethical issues around human or animal test subjects.

67. An advisory council makes one of three decisions on each application: an application is recommended for funding, not recommended for funding, or deferred for re-review

[24] *NIAID Paylines*, NIAID (Dec. 17, 2024), https://www.niaid.nih.gov/grants-contracts/niaid-paylines.

by the study section. A favorable recommendation from the relevant institute's advisory council is a prerequisite to final award of any grant in excess of $50,000. 42 U.S.C. § 284(b)(2); *see also* §284a(a)(3)(A)(ii).

68. The advisory council makes funding recommendations to the institute or center director, who ultimately makes the funding decision. In making that decision, the institute or center director shall consider, consistent with the peer-review process: (i) the mission of the national research institute or national center and the scientific priorities identified in the institute or center's strategic plan; (ii) programs or projects funded by other agencies on similar research topics; and (iii) advice by staff and the advisory council or board of such national research institute or national center. 42 U.S.C. §284(b)(3).

69. If the decision is in favor of funding, NIH issues a legally binding Notice of Award (NOA) to the selected grant recipients stating that funds may be requested. NIHGMS §5, at IIA-59.

70. NIH typically does not issue grants as lump-sum awards. Instead, NIH uses a cost-based accounting system, under which grant recipients are authorized to recover their actual, documented costs for conducting research after the grant is awarded. Institutions can then use awards—and indeed, rely on those awards—to obtain a line or letter of credit for the procurement of the resources needed for the project.

71. If NIH approves a project with a multi-year period, the agency typically awards the grant for the first year (the "award year") at the outset, with funding for subsequent years (the "out years") subject to a renewal process. In these "non-competing" renewals, the application does not undergo a fresh round of peer review—instead, applicants submit progress reports demonstrating that the grantee is making progress and complying with applicable policies and practices. *See* 42

C.F.R. §52a.6. So long as grantees demonstrate progress and compliance with applicable policies and practices, non-competing renewals are approved as a matter of course.

72. NIH's application and award process follows a predictable calendar each year that is posted in advance. The agency has three standard application cycles per year, with published schedules identifying application due dates, the timing of study section and advisory council review, and the earliest permissible start date for the project. As reflected on the agency's website,[25] the current triannual schedule is as follows:

Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

73. According to Michelle Bulls, NIH's Chief Grants Management Officer, before 2025, NIH typically only terminated grants either with the consent of the award recipient or where the recipient failed to comply with the terms and conditions of the award and NIH was unable to identify corrective action. Mutual terminations can occur when the principal researcher associated with a grant can no longer undertake research. According to Ms. Bulls, since 2012, NIH has terminated less than five grants for non-compliance with the terms and conditions of the original grant award.

[25] *Standard Due Dates*, NIH (Aug. 23, 2024), https://grants.nih.gov/grants-process/submit/submission-policies/standard-due-dates.

V. Plaintiffs' Receipt of NIH Grants

74. Plaintiffs' state universities and colleges, as well as other research institutions, depend heavily on NIH funding to support biomedical and public health research. At any given time, individual research universities may depend on thousands of NIH grants that support independent research projects across multiple university facilities.

75. Plaintiff Massachusetts operates the University of Massachusetts (UMass), the Commonwealth's flagship public research institution, which consists of the UMass Amherst, UMass Boston, UMass Dartmouth, UMass Lowell, and the UMass Chan Medical School. *See generally* Mass. G.L. c. 75, §1. In Fiscal Year 2024, UMass campuses collectively received $248 million in NIH funding, supporting at least 501 projects.

76. The University of California (UC) is a corporation established under article IX, §9, of the California Constitution and located within the State of California; it is an exempt state government entity. The UC system consists of 10 research-intensive campuses, 21 health professional sciences schools, 5 NCI-designated cancer centers, and 6 academic medical centers. The UC system's constituent schools and institutions are widely recognized as among the best in the nation, serving as international leaders in the education of health professionals, the development of new cures and treatments, and the provision of healthcare for all Californians regardless of ability to pay. The University of California is one of the nation's leading research institutions, with almost 9% of all U.S. academic research being conducted by UC researchers. Biomedical advancements at UC include the first radiation treatment for cancer, research contributing to the first flu vaccine, the discovery of the role of LDL and HDL cholesterol in heart disease, the invention of modern gene editing, and much more. Every year, UC system researchers submit thousands of NIH grant applications, and the world-leading researchers on UC's faculty serve on numerous NIH study sections and advisory councils to assess grant applications for

scientific and technical merit. NIH contracts and grant funding support many of the clinical trial studies at UC's six medical centers.

77. Federal funds are UC's single most important source of support for its research, accounting for more than half of UC's total research awards. In Fiscal Year 2024, UC received a total of over $2 billion in NIH contract and grant funding to support more than 5000 research projects. The estimated value of just the NIH grant proposals submitted by the five UC Health Centers as of December 31, 2024, that have not yet been acted upon is approximately $563 million. Grant proposals awaiting study sections before July 1, 2025, have an annual value of approximately $312 million, while grants awaiting advisory councils and Notices of Awards have an annual value of approximately $251 million. The UC Health Center in San Francisco (UCSF) alone is has 1,650 unique principal investigators with 4,110 active NIH awards.

78. Plaintiff California also operates the California State Universities (CSU), the largest four-year public university system in the United States. The purpose of the CSU system as established by statute is to provide access to education and the opportunity for educational success for all qualified Californians. Cal. Educ. Code §66010.2. CSU consists of 23 campuses, nearly a dozen off-campus centers, and over 90 auxiliary organizations (several dedicated to sponsored research). During Fiscal Year 2024, the CSU expended nearly $90 million in NIH contract and grant funding to support approximately 250 projects across 18 universities with the total multi-year award funding in the hundreds of millions.

79. Plaintiff Maryland operates the University System of Maryland (USM), a system of 12 constituent institutions, including leading research institutions at the University of Maryland, Baltimore (UMB), and the University of Maryland, College Park (UMCP). In fiscal year 2024, UMB received $213.9 million in active NIH awards and an additional $34.2 million in NIH pass-

through funding; UMCP received $68 million in funding awarded directly by the NIH and $9 million in funding awarded on a pass-through basis from the NIH.

80. Plaintiff Washington operates the University of Washington, the largest recipient of federal research funding of any public university in the country. In Fiscal Year 2024, University of Washington received over $648 million in NIH funding, supporting over 1,220 projects.

81. Arizona State University, Northern Arizona University, and the University of Arizona are instrumentalities of the State of Arizona. In Fiscal Year 2024, those universities together managed approximately 426 NIH awards totaling over $286 million.

82. Colorado established the University of Colorado Anschutz Medical Campus (CU Anschutz) as the only academic medical research campus in Colorado. *See generally* Colo. Rev. Stat. §23-21-101, *et. seq.* In Fiscal Year 2024, CU Anschutz received $360 million in NIH funding, which represented 48% of all sponsored awards for the year.

83. Plaintiff Delaware's flagship research institution, The University of Delaware, received $66 million in NIH funding, supporting 135 projects in Fiscal Year 2024.

84. Plaintiff Hawai‘i operates the University of Hawai‘i, which houses some 3,000 researchers and enrolls around 30,000 students across 10 campuses. The University of Hawai‘i includes the John A. Burns School of Medicine, the University of Hawai‘i Cancer Center, the Daniel K. Inouye School of Pharmacy, the School of Nursing and Dental Hygiene, the Thompson School of Social Work, and several other schools that conduct fundamental, translational, clinical and community-based participatory research in health sciences and health care. In Fiscal Year 2024, the University of Hawai‘i received more than $65 million in direct NIH funding, supporting 75 projects.

85. With respect to Plaintiff State of Minnesota, NIH has awarded tens of millions of dollars to the University of Minnesota. For example, in Fiscal Year 2024 alone, the University of Minnesota received 808 awards directly from NIH which obligated funding to the University of approximately $355.6 million.

86. Nevada operates the Nevada System of Higher Education, which includes the University of Nevada, Las Vegas, and the University of Nevada, Reno. In Fiscal Year 2024, the University of Nevada, Las Vegas received $11.9 million and the University of Nevada, Reno received $9.5 million dollars in NIH funding.

87. With respect to Plaintiff New Jersey, three major State research institutions—Rutgers, the State University of New Jersey (Rutgers), New Jersey Institute of Technology (NJIT), and Kean University (Kean)—have a significant academic and clinical health sciences presence across the State, including numerous research centers and institutes, academic medical centers, and colleges of liberal arts and sciences, schools of environmental and biological sciences, engineering, and other professional schools and graduate programs. In Fiscal Year 2024, these three institutions and their affiliated campuses collectively received approximately $250 million in NIH funding to support approximately 1,200 projects, including grants that support undergraduate students from under-represented populations pursuing biomedical sciences and engineering degrees and graduate programs.

88. Plaintiff New Mexico operates the University of New Mexico (UNM), which is the state's flagship research university with research centers spanning the fundamental sciences, technology and engineering research, education, humanities and social sciences, and human health. UNM is the only academic health system in the state; it pursues research on improving human health, including substance use disorders, cardiovascular and metabolic disease, infectious

diseases and immunity, Alzheimer's disease, kidney disease, cancer, and pediatrics, and more. This research was supported by $107 million from the NIH in Fiscal Year 2024 and, through early February 2025, estimated NIH funding for Fiscal Year 2025 is over $126 million. Plaintiff New Mexico also operates New Mexico State University (NMSU), a university with over sixty research facilities focusing on fundamental sciences, physical sciences, agriculture, the arts, humanities and social sciences, economics, engineering, and human health. This research was supported by over $10 million from the NIH in Fiscal Year 2024 and, through early February 2025, estimated NIH funding for Fiscal Year 2025 is over $30 million.

89. New York operates the State University of New York (SUNY), which is comprised of 64 colleges and universities, of which four campuses are designated R1 research institutions. In fiscal year 2024, SUNY received $237.5 million from NIH to support 894 projects.

90. The Oregon Health and Science University (OHSU) is a public corporation of the State of Oregon and is Oregon's only public academic health center. OHSU is not the only public recipient of NIH funding in Oregon, but it receives the largest amount of NIH funding. In fiscal year 2024, OHSU received over $350 million in NIH funding to support 784 projects and over 1,400 researchers. The University of Oregon, Oregon State University, and Portland State University are also public recipients of NIH funding.

91. The University of Rhode Island (URI) is Rhode Island's flagship public university. *See* 16 R.I. Gen. Laws Ann. §16-32-3. In fiscal year 2024, URI received $22.1 million in NIH funding to support over 90 projects.

92. Plaintiff Wisconsin operates the Universities of Wisconsin, which includes prominent research institutions at the University of Wisconsin-Madison (UW-Madison) and University of Wisconsin-Milwaukee (UW-Milwaukee). UW-Madison's research enterprise is

particularly robust, encompassing more than $1.7 billion in annual research expenditures. Approximately one third of sponsored research at UW-Madison is awarded by the NIH. In fiscal year 2024, UW-Madison received direct funding from NIH to support 588 projects, totaling more than $404 million. UW-Madison funds 4,942 researchers and staff through direct NIH grants, and its work on NIH-funded projects provides scientific education and research training in medical and health sciences, biology, public health, biochemistry, psychology, and other disciplines. In fiscal year 2024, UW-Milwaukee also received funding from NIH to support dozens of projects, totaling $7.9 million.

CHALLENGED AGENCY ACTIONS

93. This lawsuit arises because defendants are flouting the statutory and regulatory rules governing NIH grantmaking. As explained below, defendants have adopted a series of directives that blacklist certain topics—*e.g.*, "DEI," "gender," or "vaccine hesitancy"—that the Administration disfavors. In adopting, implementing, and enforcing those directives, defendants have systematically disrupted the review of pending grant applications, delayed the annual renewal of already-approved multi-year awards, and terminated huge tranches of grants in the middle of the project year. Those disruptions have caused—and will continue to cause—significant harm to plaintiffs and their institutions.

I. The Administration's Adoption of Executive Orders and OMB Directives Identifying Politically Disfavored Topics

94. The NIH-specific directives that plaintiffs challenge here (*see infra*, paragraphs 102-117) in large part implement a series of executive orders and Administration directives issued on or shortly after Inauguration Day.

95. On January 20, 2025, President Trump signed Executive Order 14151, entitled "Ending Radical Government DEI Programs and Preferencing" (DEI Order). The DEI Order aims

to terminate any federal programs that promote "diversity, equity, and inclusion," "diversity, equity, inclusion, and accessibility," and "environmental justice." The order does not define those terms. The order further directs "[e]ach agency, department, or commission head, in consultation with the Attorney General, the Director of OMB, and the Director of OPM" to "terminate, to the maximum extent allowed by law, . . . all . . . 'equity-related' grants or contracts." DEI Order §2(b)(1). The order does not define "equity-related."

96. The same day, the President signed Executive Order 14168, entitled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" (Gender Ideology Order). The order denies the existence of transgender, nonbinary, intersex, or other gender-nonconforming people and rejects "gender ideology," which it vaguely defines as "replac[ing] the biological category of sex with an ever-shifting concept of self-assessed gender identity, permitting the false claim that males can identify as and thus become women and vice versa, and requiring all institutions of society to regard this false claim as true." Gender Ideology Order §§1-2. The order directs all federal agencies to "take all necessary steps, as permitted by law, to" strip federal funds from anyone who promotes "gender ideology," demanding that "[e]ach agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology." *Id.* §3(e), (g).

97. The following day, the President signed Executive Order 14173, entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity" (Discrimination Order). The order targeted what it called "race- and sex-based preferences under the guise of so-called 'diversity, equity, and inclusion' (DEI) or 'diversity, equity, inclusion, and accessibility' (DEIA),'" but again failed to define those terms. The order requires that "[t]he head of each agency shall include in every contract or grant award . . . [a] term requiring" any federal grant "recipient

to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws." *Id.* §3(b)(iv)(B). It also threatens civil False Claims Act enforcement against any grantee failing to comply with the Discrimination Order's vague and undefined terms. *Id.* §3(b)(iv)(A). Likewise, the Discrimination Order threatens lawsuits against private entities that promote DEI. *Id.* §4(b)(v).

98. On January 27, the acting director of the Office of Management and Budget (OMB) issued OMB Directive M-25-13 (OMB Directive). The OMB Directive targeted a broad swath of federal fund disbursements for a near-immediate freeze. This directive stated that all federal agencies "must complete a comprehensive analysis of all of their Federal financial assistance programs to identify programs, projects, and activities that may be implicated by any of the President's executive orders." While this analysis is ongoing, "[i]n the interim, to the extent permissible under applicable law, Federal agencies **must temporarily pause** all activities related to obligation or disbursement of all Federal financial assistance, and other relevant agency activities that may be implicated by the executive orders, including, but not limited to, financial assistance for foreign aid, nongovernmental organizations, DEI, woke gender ideology, and the green new deal" (emphasis in original). The OMB Directive ordered that the temporary pause take effect the following day, on January 28, 2025, at 5:00 PM.

99. On January 28, the U.S. District Court for the District of Columbia ordered an administrative stay of the OMB Directive pending a hearing on a motion for a temporary restraining order. Order of Administrative Stay (ECF No. 13), *Nat'l Council of Nonprofits, et al. v. Trump, et al.*, No. 1:25-cv-239-LLA (D.D.C. filed Jan. 28, 2025). At approximately 1:00 PM Eastern Time on January 29, OMB issued M-25-14, a memorandum purportedly rescinding the OMB Directive in two sentences: "OMB Memorandum M-25-13 is rescinded. If you have

questions about implementing the President's Executive Orders, please contact your agency General Counsel."

100. Shortly after OMB purported to rescind the OMB Directive, however, White House Press Secretary Karoline Leavitt stated that the federal funding freeze remained in place, notwithstanding the rescission of the OMB Memorandum. Leavitt announced on social media: "This is NOT a rescission of the federal funding freeze. It is simply a rescission of the OMB memo. Why? To end any confusion created by the court's injunction. The President's EO's on federal funding remain in full force and effect and will be rigorously implemented."

101. At a press conference that same day, Leavitt stated: "So, what does this pause mean? It means no more funding for illegal DEI programs. It means no more funding for the Green New Scam that has . . . cost American taxpayers tens of billions of dollars. It means no more funding for transgenderism and wokeness across our federal bureaucracy and agencies. No more funding for Green New Deal social engineering policies."

II. Defendants' Adoption of NIH-Specific Directives Blacklisting Politically Disfavored Topics

102. Defendants have subsequently issued directives to and within NIH that carry out and expand upon the foregoing executive orders and policy objectives. Specifically, defendants formulated, adopted, and executed a series of policies blacklisting entire categories of research that the Administration disfavors for political reasons. These categories originally focused on "DEI-related" projects, but have evolved to include other disfavored categories, including projects related to gender identity, vaccine hesitancy, COVID-19, and climate change.

103. On January 21, Acting Secretary of Health and Human Services Dorothy Fink issued a memorandum to all HHS subcomponents entitled "Immediate Pause on Issuing Documents and Public Communications" (Notice Pause Directive). A copy of the Notice Pause

Directive is attached as Exhibit 1 to this Amended Complaint and is incorporated herein by reference. The Notice Pause Directive instructed, among other things, that no notices be submitted for publication to the Federal Register unless approved by a presidential appointee.

104. On February 10, 2025, Acting Secretary of Health and Human Services Dorothy Fink issued a "Secretarial Directive on DEI-Related Funding" (Secretarial Directive). A copy of the Secretarial Directive is attached as Exhibit 2 to this Amended Complaint and is incorporated herein by reference.

105. The Secretarial Directive stated, in relevant part:

> The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

The Secretarial Directive went on to state:

> For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. §75.371-372, the Secretary of Health and Human Services hereby DIRECTS as follows:
>
> > **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

The Secretarial Directive did not define the term "related to DEI and similar programs."

106. On February 12, Dr. Michael Lauer, then NIH's Deputy Director for Extramural Research, issued a memorandum entitled "NIH Review of Agency Priorities Based on the New Administration's Goals" (Lauer Memorandum). A copy of the Lauer Memorandum is attached as Exhibit 3 to this Amended Complaint and is incorporated herein by reference. The memorandum stated that "NIH is in the process of reevaluating the agency's priorities based on the goals of the new administration," but that, "given recent court orders" in federal court actions related to funding freezes, NIH institutes and centers were "authorized, along with their respective grant management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements . . . grants."

107. On February 13, Dr. Lauer issued a memorandum entitled "Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals" (Supplemental Lauer Memorandum). A copy of the Supplemental Lauer Memorandum is attached as Exhibit 4 to this Amended Complaint and is incorporated herein by reference. The memorandum instructed the ICs' Chief Grants Management Officers that "[i]f the sole purpose of the grant . . . supports DEI activities, then the award must be fully restricted." It also called for "hard funding restrictions" where the program promotes initiatives that "discriminate" on the basis of race, sex, or other protected characteristics, without defining what constituted such discrimination in a research program. The Supplemental Lauer Memorandum did not refer to terminations of awards, but rather NIH's funding of programs more generally. That day, Dr. Lauer resigned from his position with NIH.

108. On or about March 4, NIH issued a directive entitled "Award Assessments for Alignment with Agency Priorities—March 2025" (Priorities Directive). A copy of the Priorities Directive—including the several appendices attached to the Priorities Directive— is attached as

Exhibit 5 to this Amended Complaint and is incorporated herein by reference. The Priorities Directive "rescind[ed]" the Supplemental Lauer Memorandum, attached and reaffirmed the Secretarial Directive, and provided further instructions related to "DEI" research.

109. Specifically, the Priorities Directive stated that "NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI)." To enforce that determination, the directive instructed that, "[p]rior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims [to] assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities." The directive further instructed ICs to "completely excise all DEI activities" using a list of predetermined categories, including awards that "ICs must not issue" (Category 1), awards that ICs could issue on certain conditions (Categories 2 and 3), and awards that ICs "may proceed with issuing" (Category 4).

110. The appendices to the Priorities Directive provided NIH staff with specific language "to use when terminating awards identified by HHS or the IC" related to politically disfavored topics. Among other things, NIH staff were instructed to inform grant recipients that "NIH is taking this enforcement action in accordance with 2 C.F.R. §200.340 as implemented in NIH GPS Section 8.5.2." The Priorities Directive's appendices also identified three specific disfavored topics by name: "China," "DEI," and "[t]ransgender issues."

111. The Priorities Directive classified "diversity supplements" as Category 1 awards—*i.e.*, it instructed that "ICs must not issue the award." Diversity Supplements are grants meant to increase diversity in the scientific profession by providing training, mentorship and career development opportunities to individuals from underrepresented populations. For recent notices of funding opportunity, NIH adopted a policy that defined diversity broadly, to include not only

"[i]ndividuals from racial and ethnic groups that have been shown by the [National Science Foundation] to be underrepresented in health-related sciences on a national basis," but also "[i]ndividuals with disabilities," and "[i]ndividuals from disadvantaged backgrounds," including those who have experienced homelessness, who were in foster care, who experienced poverty, or who are from rural areas.[26]

112. By March 13, the list of scientific research disfavored by the Administration had grown to include yet another topic: vaccine hesitancy. Specifically, Michelle Bulls, NIH's Chief Grants Management Officer, issued guidance entitled "Award Revision Guidance and List of Terminated Grants via letter on 3/12" (Award Revision Guidance). A copy of the Award Revision Guidance is attached as Exhibit 6 to this Amended Complaint and is incorporated herein by reference. The Award Revision Guidance again instructed the individual institutes on how to issue termination letters, and on what bases. Ms. Bulls instructed that termination letters should include the following language: "It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated." The termination category language that Ms. Bulls provided included terminations for a program's relation to China, DEI, gender, and vaccine hesitancy. Hundreds of NIH grants were terminated in the ensuing days.[27]

113. Upon information and belief, on or before March 19, the Office of Extramural Research and the Office of Policy for Extramural Research Administration provided additional guidance on how ICs should process grant terminations and communicate with grant recipients regarding such terminations. Included in these instructions was the instruction to speak only of "changes in NIH and/or HHS priorities" and an instruction to "not refer to any Executive Orders."

[26] *PA-20-222: Research Supplements to Promote Diversity in Health-Related Research*, NIH, https://grants.nih.gov/grants/guide/pa-files/pa-20-222.html.

[27] *HHS Grants Terminated*, HHS, https://taggs.hhs.gov/Content/Data/HHS_Grants_Terminated.pdf.

114. On March 25, NIH issued a directive entitled "NIH Grants Management Staff Guidance—Award Assessments for Alignment with Agency Priorities—March 2025" (Revised Priorities Directive). The Revised Priorities Directive and its appendices are attached as Exhibit 7 to this Amended Complaint and are incorporated herein by reference. The Revised Priorities Directive continued to blacklist research related to DEI, transgender issues, and vaccine hesitancy, but now included yet another topic—COVID-19. As to COVID, the guidance stated that: "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary."

115. Upon information and belief, sometime during mid-March, defendants issued a further directive adding research related to the health effects of climate change as a blacklisted topic (Climate Change Directive).[28]

116. Upon information and belief, on or after January 20, 2025, defendants have issued other directives, including nonpublic and undisclosed directives, that curtail NIH's support for previously advertised funding opportunities and previously awarded grants relating to the blacklisted topics described above.

117. For ease of reference, this Amended Complaint refers to the Secretarial Directive, the Lauer Memorandum, the Supplemental Lauer Memorandum, the Priorities Directive, the Award Revision Guidance, the Revised Priorities Directive, and the Climate Change Directive—as well as other nonpublic and undisclosed directives that curtail NIH's support for previously

[28] Waldman A., *NIH Ends Future Funding to Study the Health Effects of Climate Change*, ProPublica (March 24, 2025), https://www.propublica.org/article/nih-funding-climate-change-public-health.

advertised funding opportunities and previously awarded grants relating to those blacklisted topics—collectively as the "Challenged Directives."

III. Defendants' Implementation of the Challenged Directives Through Elimination of Funding Opportunities and Disruption of Pending Applications

A. Delay and Withholding of Advisory Council and Study Section Meetings

118. Defendants have also been systematically delaying and advisory council and study section meetings in a manner that contravenes prior regulatory notices and NIH's own guidance. As explained above, NIH's own guidance states that "Cycle II" grant applications, which underwent study-section review last fall, were originally scheduled to undergo advisory-council review in January of this year. *See supra*, paragraph 72. And "Cycle III" applications, which researchers submitted to NIH last fall, were scheduled to undergo study-section review in February and March of this year. *See id.* Almost none of that has happened.

119. Although meetings for the advisory councils of 21 different institutes and centers had been scheduled for January and February 2025 via publications in the Federal Register, all but one were abruptly canceled after Inauguration Day. (The remaining meeting, for the advisory council of the National Institute of Child Health and Human Development, had already taken place on January 13, 2025, *i.e.*, seven days before the change in Administration.)

120. In total, over 250 grant-related meetings that had been scheduled for January and February 2025 via publications in the Federal Register were likewise cancelled after Inauguration Day—often with just a day's notice (and no notice of cancellation in the Federal Register). In contrast, in prior years cancellations and amendments to noticed meetings were rare. According to an analysis of Federal Register notices, only an average of four cancellation notices were issued each year between Fiscal Years 2010 and 2024, and even amendments—which typically provide a new date immediately—were uncommon, with an average of around 100 each year.

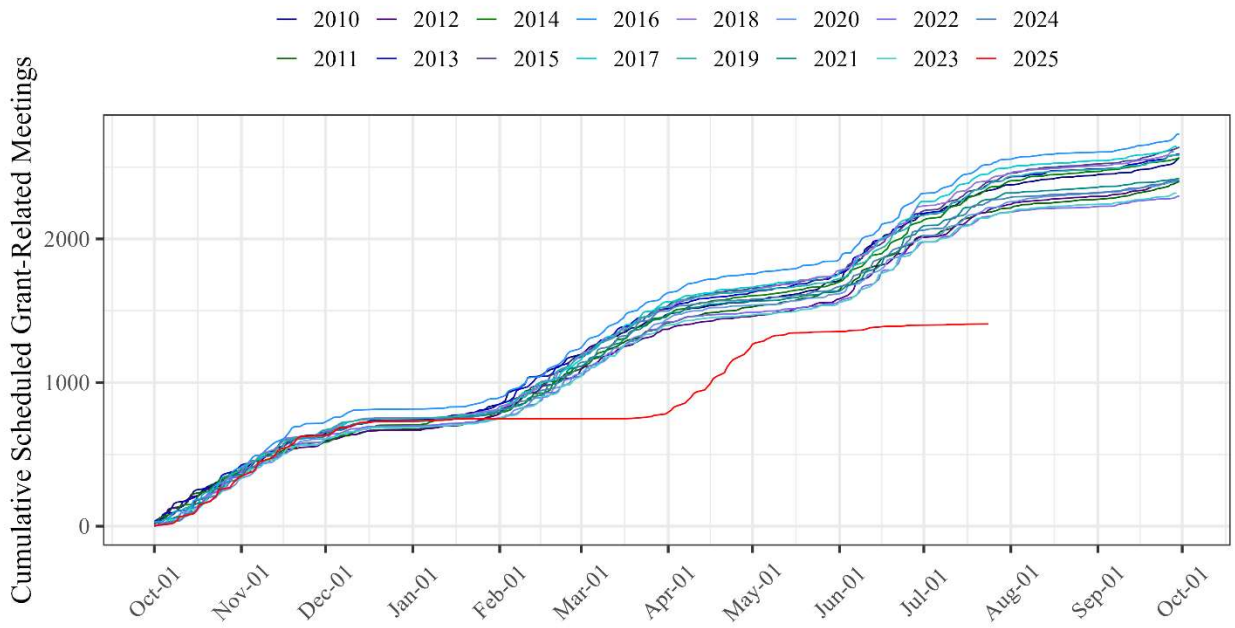
121. Between January 22 and March 3, defendants also suspended the scheduling of future advisory-council or study-section meetings; no notices for future meetings appeared in the Federal Register during that time. As discussed above, on January 21, Acting Secretary Fink issued the Notice Pause Directive, instructing among other things, that no notices be submitted for publication to the Federal Register unless approved by a presidential appointee.

122. On February 7, 2025, upon information and belief, an NIH official emailed a researcher that submissions to the Federal Register "are now on hold indefinitely." Throughout February (and continuing into March), multiple webpages from the NIH institutes stated: "At the present time, all Federal advisory committee meetings have been canceled until further notice. Additional information will be forthcoming as it becomes available. We apologize for any inconvenience."

123. Defendants resumed publishing notices of upcoming study-section and advisory-council meetings in the Federal Register in early March, but the number of meetings scheduled for this fiscal year remains at a level far below the number of such meetings in every fiscal year since 2010, and even further below the number that would be required to make up for the meetings not held in January and February.

124. Based on an analysis of notices posted in the Federal Register, defendants have held around 930 meetings to review grant applications in Fiscal Year 2025 to date. That represents a sharp and unprecedented drop from prior years. From Fiscal Years 2010 through 2024, NIH held between approximately 1,410 and 1,700 meetings over the same period, with an average of about 1,540. The Fiscal Year 2025 figure thus reflects a decline of nearly 40% relative to that historical baseline.

125. Despite the shortfalls and cancellations, defendants are not picking up the pace. As shown in the following figure, defendants remain well below the historical average meetings held, and the pace of new meetings scheduled from April to May is similar to that of previous years, when it would need to be substantially higher to make up the pace and spend the money appropriated by Congress:



Note: Values are plotted on the day of the scheduled meeting.

126. According to NIH's contemplated schedule, some Cycle II projects were to start in April 2025. For example, multiple UMass grant applications from Cycle II—with anticipated project start dates on or around April 1, 2025—received fundable scores from their study sections and yet remain in limbo because the relevant January advisory-council meeting was canceled.

127. Upon information and belief, the continued delays described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

B. Delay and Withholding of Final Disposition of Awards

128. In addition to their frustration of the activity of study sections and advisory councils, defendants have also been systematically delaying and withholding final decisions on applications that have already received favorable scores and recommendations from the relevant study section and/or advisory council.

129. Upon information and belief, defendants maintained a total freeze on the issuance of new notices of award, including for non-competing renewals, from January 28, 2025, to February 28, 2025.

130. Defendants appear to no longer maintain a total freeze on the issuance of all new NOAs. However, upon information and belief, defendants are still delaying final decisions on applications in order to implement the Challenged Directives by conducting a review of applications for their relation to subjects and topics disfavored by the Administration. This review process has resulted in a delay on rendering final dispositions and award decisions on pending applications.

131. Upon information and belief, NIH's layoffs of the grant management, programmatic, and scientific staff that advance the grant application and peer review process have exacerbated, and will further exacerbate, these funding delays. NIHGPS §2.1.1, at I-44. The current Administration fired approximately 1,200 probationary workers at NIH, including those scientific, programmatic, and grant management staff members who worked directly on, and were

in charge of, grant approvals, renewals, and disbursements. HHS has started to lay off an additional 1,200 NIH employees.[29] A third round of layoffs is expected by September 30, 2025.[30]

132. In addition, upon information and belief, the recent layoffs included the directors of individual NIH institutes and centers who are responsible for signing off on final grant funding decisions. 42 U.S.C. §284(b)(3). On April 1, 2025, the directors, including acting directors, of the National Institute of Allergy and Infectious Diseases (NIAID), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute of Nursing Research (NINR), and National Human Genome Research Institute (NHGRI) either were placed on administrative leave or offered reassignment to the Indian Health Service in distant States. These institutes' directors were responsible for at least $9 billion in annual Congressional appropriations.[31] These layoffs appear targeted at institutes and centers either established by Congress for purposes that conflict with policies disfavored by the Administration, or which have conducted research on topics disfavored by the Administration.

133. As described in greater detail below (*see infra*, paragraphs 160-207), plaintiffs are awaiting a decision on hundreds of applications currently pending before the agency—including many applications that received favorable reviews from the relevant study section and/or advisory council. For ease of reference, this Amended Complaint refers to the pending applications just described as the "Delayed Applications."

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[29] Whyte L.E. *et al.*, *RFK Jr. Plans 10,000 Job Cuts in Major Restructuring of Health Department*, Wall Street J. (Mar. 27, 2025), https://www.wsj.com/politics/policy/rfk-jr-plans-10-000-job-cuts-in-major-restructuring-of-health-department-bdec28b0.

[30] Molteni M. *et al.*, *Five NIH Institute Directors and Numerous Lab Heads Ousted in Unprecedented Shake-up*, STAT (Apr. 2, 2025), https://www.statnews.com/2025/04/01/nih-rif-1200-layoffs-raise-concerns-health-medicine-biomedical-research.

[31] Kozlov M., *One of the Darkest Days': NIH Purges Agency Leadership amid Mass Layoffs*, Nature (Apr. 1, 2025), https://www.nature.com/articles/d41586-025-01016-z.

134. Upon information and belief, the continued delays described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

C. Delay and Withholding of Renewal of Awards

135. Upon information and belief, the Challenged Directives have likewise governed NIH's review of applications for grant renewals by current grant recipients. Upon information and belief, defendants have required NIH staff to review grant renewal applications to determine whether they relate to subjects that are disfavored by the Administration, which itself has resulted in substantial delays in rendering decisions on applications for grant renewals.

136. As of April 1, plaintiffs are awaiting decision on non-competing renewals that otherwise meet the criteria for renewal but that defendants have declined to process in the ordinary course. For ease of reference, this Amended Complaint refers to the non-competing renewals just described as the "Delayed Renewals."

137. For example, as of April 1, University of Washington is experiencing delayed renewal of 73 grants totaling over $61 million. Some of these renewals have been delayed for months, with the resulting funding disruptions undermining the University's budgeting, forcing pauses in research, and requiring the University to resort to furloughs, staff reductions, and planned layoffs.

138. Upon information and belief, the continued delays described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

D. Defendants' Removal of Notices of Funding Opportunities

139. Upon information and belief, no later than January 31, NIH's institutes and centers were informed that specific Notices of Funding Opportunity were being withdrawn and cancelled.

Similarly, upon information and belief, NIH only published three NOFOs between January 20 and March 26.[32]

140. The withdrawal of NOFOs continued on the grounds, *inter alia*, that the research opportunities involved DEI or gender.

141. The withdrawal of NOFOs occurred in the form of "unpublishing" the NOFOs, referred at times to the "disappearing" of NOFOs.

142. At least some of these NOFOs were withdrawn after grant applications had been submitted in response to them.

143. Upon information and belief, the removal of NOFOs described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

IV. Defendants' Implementation of the Challenged Directives Through Termination of Already-Issued Grants

144. Defendants' implementation and enforcement of the Challenged Directives has also directly resulted in the termination of more than one hundred grants to plaintiffs' instrumentalities on the grounds that they relate to topics now blacklisted by the Challenged Directives. For ease of, this Amended Complaint refers to the terminated grants just described as the "Terminated Grants."

145. On or about February 10, NIH provided individual institutes with a list of grants that were to be terminated. Upon information and belief, the decision to terminate these grants was based on Acting Secretary Fink's Secretarial Directive and on direction from the Executive Office of the President.

[32] Reardon S., *Trump Officials Will Screen NIH Funding Opportunities*, Science (Mar. 26, 2025) (stating that "NIH only published three NOFOs between 20 January and 26 March, compared with 163 in 2023 and 147 in 2024 between the same dates"), https://www.science.org/content/article/trump-officials-will-screen-nih-funding-opportunities.

146. Upon information and belief, the lists of to-be-terminated grants provided by NIH to its individual institutes reflect list of grants to be terminated and template letters provided by HHS and personnel affiliated with the so-called Department of Government Efficiency (DOGE) to NIH. Upon information and belief, shortly after the change in Administration, personnel associated with the DOGE initiative obtained access to NIH's internal grants databases.

147. On February 28, a post on DOGE's official X account announced the cancellation of numerous NIH grants related to China, racial health disparities, and gender-affirming care:

148. The decision to terminate Diversity Supplements not only undermines Congress's and NIH's previously stated goal to promote diversity among scientists, but it also actively harms diverse candidates. This is because, until recently, NIH has been issuing NOFOs for workforce development grants in pairs, with both a "standard" NOFO and a "diversity" NOFO, allowing individuals to self-identify as diverse. But now that Diversity Supplements are being cancelled and not funded, people who identified as diverse in their applications are not even eligible for funding, while people who did not identify as diverse remain eligible.

149. Upon information and belief, on or about March 4, HHS identified additional NIH grants that were to be terminated based on the Challenged Directives, which NIH's Office of Extramural Research then communicated to the individual institutes.

150. Upon information and belief, on or about March 12, 2025, NIH provided staff at the individual institutes with a list of grants to be terminated, which were identified based on the factors identified in the Priorities Directive. NIH has used the Priorities Directive staff guidance to implement and assess the grant research portfolios of each of the ICs.

151. As already discussed, in the March 13 Award Revision Guidance, Michelle Bulls instructed the ICs' Chief Grants Management Officers on how to issue termination letters. Bulls instructed that termination letters should include the following language: "It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated." The instructions included the language that termination letters should include for the disfavored category on which the termination was based, including the following:

- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

- Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in

> ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

152. Upon information and belief, on or about March 14, Bulls met with the ICs' Chief Grants Management Officers and reported approximately 945 terminated grants. Bulls forwarded the grant terminations to ICs in batches for issuance of termination letters.

153. Upon information and belief, NIH has terminated more than 100 grants at plaintiffs' public institutions since January 20, 2025, in accordance with the Challenged Directives.

154. Plaintiffs' universities have received grant termination letters that include the boilerplate termination language provided by Bulls to the ICs.

155. These grants support a wide range of scientific inquiry and were awarded after a thorough review process for scientific merit, consistency with agency priorities, and other qualities.

156. Upon information and belief, actors outside NIH have identified the grants that should be terminated based on the Challenged Directives and their broad implementation, and the grants have been terminated without the input—and sometimes without the knowledge—of the NIH program officers who ordinarily manage the grants. In other words, NIH terminated these grants without consulting with the NIH career scientists with scientific knowledge about the research being funded.

157. Upon information and belief, to date, defendants have yet to identify any basis for its alleged priorities, as reflected in the Challenged Directives, other than the Executive Orders and the Administration's political views on certain subjects.

158. Upon information and belief, defendants have not made or finalized any change in NIH agency or IC priorities as identified in either the NIH's strategic plan or NIHGPS.

IMPACT OF THE CHALLENGED AGENCY ACTIONS

159. Institutions in each of the plaintiff states have experienced delays and other funding disruptions as a result of defendants' adoption, implementation, and enforcement of the Challenged Directives and the other acts and omissions described above.

I. Harms to Massachusetts

160. UMass has directly experienced harm as a result of defendants' treatment of the Delayed Applications.

161. As of March 31, 2025, UMass has 353 applications for NIH funding that are overdue for review based on NIH's published schedule of cycles. Of these, (a) 272 are awaiting study section review; (b) 43 have received fundable scores from study section review and are awaiting advisory council review; (c) 14 have received possibly fundable scores from study section review and are awaiting advisory council review; and (d) 18 have received fundable scores and been reviewed an advisory council but have not been notified of a final determination on funding. In total, $848,332,898 in sought funding is awaiting approval across all active applications, $133,234,318 of which is for projects that have already been scored as fundable.

162. A project entitled, "Elucidation of the mechanisms by which Ms4a genes regulate neurodegeneration in Alzheimer's Disease and related disorders," grant number R01AG089801, is representative of the delays UMass has experienced. One major obstacle of treating Alzheimer's disease is the paucity of genetic targets against which to direct therapeutic efforts; this project aims to investigate a recent and promising gene which could inform the development of new treatments for this and other neurodegenerative diseases. UMass researchers submitted the application for this grant on July 9, 2024, with an anticipated start date of April 1, 2025. Study section review placed it in the 13th percentile of all contemporaneous projects submitted to the IC, which has a payline of 17th percentile—thus, this was a fundable study with an overwhelming likelihood of

receiving funding. This project was scheduled for advisory council review on January 28, 2025; that session was canceled, then rescheduled for April 22, 2025, three weeks after the project was intended to begin. In preparation for the start date of this grant, UMass Chan Medical School hired two postdoctoral fellows, which is standard practice and timing for this manner of research. Additionally, a significant number of genetically modified mouse cell lines had to be bred and aged so that neurogenerative phenotypes would appear. Due to the delay in evaluating this grant, UMass must continue funding these preparatory steps well into the life of the project with the uncertainty that funding will arrive, or else scrap this promising research project entirely, foreclosing research into a promising area of new treatment for sufferers of Alzheimer's disease and related diseases.

163. Delays in funding decisions and evaluation of applications have already caused numerous and critical harms to UMass. Due to uncertainty of the funding of multiple projects ranked as fundable, UMass schools have made dramatic cuts to the size of programs that rely significantly on NIH support. UMass Chan Medical School has rescinded acceptances to the vast majority of students admitted to its PhD program in Biomedical Sciences, reducing that program from 70 to approximately 10. UMass Amherst has reduced Fall 2025 graduate admissions to its doctoral programs from 1099 admittees to 805, rescinding financial awards to 100 accepted applicants. UMass Medical School has arranged for emergency funding to continue paying stipends of current graduate students and post-baccalaureate scholars through June 30, 2025, but does not have emergency funds sufficient to replace those lost in terminated grants or to pay further costs associated with delayed grant awards. UMass Amherst will use available emergency funds to support students, staff, research faculty, and preservation of research materials for in-progress experiments until August 31, 2025, but projects that the funds will be exhausted by that date. This

relief is intended to soften the impacts to staff and research efforts but is incapable of replacing lost federal funding. These funds are being diverted from other important needs, such as deferred maintenance, strategic investments, and repayment of bond funds.

164. Additionally, numerous irreparable harms impend. Future recruitment of doctoral students, postdoctoral researchers, faculty, and staff will be negatively impacted by diminished funding. And without incoming streams of grant funds and the attached facilities costs used to oversee the research facilities which make these projects possible and economically viable, UMass will risk a reduced ability to meet existing obligations to repay bond funds used to construct those facilities. Any reduction in the university's bond rating will in turn increase the expense of augmenting research facilities in the future.

165. As a result of defendants' implementation and enforcement of the Challenged Directives, UMass has had at least five active grants and at least three additional passthrough awards terminated, without warning or cause, since March 21, 2025. UMass has also received "program cancellation notifications" related to three grants. Terminated grants include a study on the effects of the quality of behavioral health care on children, "Effect of Medicaid accountable care organizations on behavioral health care quality and outcomes for children," award number 3R01MH134176-02S1, funded for $99,974; and three studies aimed at understanding and reducing the spread of HIV amongst different vulnerable populations: "Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults," award number 5R33HD107988-04, with an award of $278,952; "Adapting mHealth interventions to improve self-management of HIV and substance use among emerging adults in Zambia," award number 5R34MH124081-02, with an award of $671,459; and "Applying deep learning for predicting retention in PrEP care and effective PrEP use among key

populations at risk for HIV in Thailand," award number 5R03MH130275-02, with an award of $76,214. In the two other terminated grants—"Faithful response II: COVID-19 rapid test-to-treat with African American churches," award number U01MD018310, with an award of approximately $126,000; and "Training the long-term services and supports dementia care workforce in provision of care to sexual and gender minority residents," award number 3R01AG075734-02S1, with an award of approximately $65,000—UMass was the subawardee.

166. UMass has also had ten applications for grants summarily denied without any form of scientific review. These include grants submitted in response to subsequently withdrawn NOFOs, including PAR-23-271, PAR-21-358, and PAR-24-077.

II. Harms to California

167. California has experienced direct and irreparable harm as a result of the Challenged Directives. Disruptions in the conduct of biomedical research and training in California directly impact the employment and economic well-being of the biotechnology and pharmaceutical industries headquartered in California. NIH grant terminations and funding delays have deterred prospective students and faculty who would have otherwise worked at universities and companies in California. Also, California has a direct interest in the health and safety of its residents, the prevention of both chronic and communicable diseases in the State, and in the State's economic wellbeing. The termination of NIH funding into research interventions to prevent or treat the spread of HIV/AIDS, sexually transmitted illnesses, COVID-19, and other virus families of pandemic concern—including diseases of emerging concern such as Dengue, Chikungunya, and Zika—and shingles, increases the risk of and incidence of these diseases in California. The terminations resulting from the enforcement of the Challenged Directives have specifically targeted some of the most vulnerable Californians, including women experiencing domestic violence, children at risk of suicide, and minorities at a higher risk of chronic or infectious diseases.

168. Since February 20, 2025, as a result of the Challenged Directives, UC has had at least 52 NIH grants terminated, amounting to over $37 million. The impact on UC Health Centers like UCSF that conduct clinical trials, its researchers, and the larger research community have been substantial. When UCSF receives a research grant from the NIH, the funds must be used to support the specific research project identified in the grant consistent with the terms of the notice of award. The grant funds are used to support all aspects of the grant, including personnel costs, drug and medication costs, technology, and equipment. When a grant is terminated, there are no longer any funds available to pay the salaries of the research staff or to cover significant expenses. When research staff are laid off, the institution loses the knowledge and experience those research staff members possess and that was attained through the research project. Once canceled, most research projects cannot immediately resume. Many of these projects entail longitudinal studies. When scientific studies stop in full swing, their partial results often lose validity.

169. Among these terminations apparently for "gender identity" and "vaccine hesitancy" are studies key for understanding the health of all Americans. They included a grant for a UC Davis research project investigating the biological risk factors for dementia among target populations with early signs of cognitive dysfunction, including white, Hispanic, and black participants that had already enrolled over 1,700 participants, and a grant to UCSF Professor Nisha Acharya who studied the effectiveness and potential adverse effects of a vaccine for shingles, a disease that one in three Americans are likely to develop in their lifetimes that cancelled $1,248,374 in funding. A third study involved the study of doxycycline, a common antibiotic used to treat sexually transmitted diseases and serious infections; defendants cancelled $3,243,539 in funding. The doxycycline study assesses the metabolization of the drug in men and women, supporting insights into whether microbial resistance will undercut the utility of the drug. While

the study, consistent with prior NIH policy, allows transgender individuals to participate, the focus of the study was not on gender identity. The harms from these terminations underscore the damage that flow from the abrupt nature of defendants' terminations. Safety monitoring during and after doxycycline dosing is critical to protecting the safety of participants already enrolled in the study. Doxycycline may cause liver injury and allergic reactions days to weeks after administration of the drug. As a result of these terminations, UCSF is preparing to lay off the staff members responsible for clinical monitoring, full-time postdoctoral researchers responsible for analyzing research data, and is unable to pay salary owed to senior scientists and principal researcher for research. Thus, these categorical terminations have already caused numerous and critical harms to the UC.

170. The delays in funding decisions and evaluation of applications have further harmed the UC system. First, the UC system has instituted a system-wide hiring freeze on new faculty and staff. Top-ranked departments across UC campuses in chemistry, biology, public health, and more may reduce their graduate student classes. UC departments have had to consider rescinding offers of funding to some students admitted to doctoral programs. The expected grant funds are also necessary to the research facilities that make these projects possible and economically viable.

171. Second, the delays in funding and terminations harm the UC's educational and research mission. Doctoral students, postdoctoral researchers, faculty, and staff from around the world collaborate with or come to California to join the UC research enterprise. Future recruitment of these young scientists and researchers will be negatively impacted by diminished funding and arbitrary terminations aimed at international collaboration and research projects. Further, terminations have specifically impacted the communities that come to the UC system for clinical trials and other community health interventions. Midstream terminations of long-term projects

meant to reduce health disparities in projects like maternal mortality, the spread of HIV/AIDS, and services to other underserved communities directly undermines the trust necessary to convince individuals to participate in UC research projects.

172. Since February 20, 2025, the CSU has received over 17 termination notices, including 5 where it serves as the primary awardee. They collectively amount to a loss of over $20.2 million in budgeted funding to the CSU, but CSU estimates the number may be much higher as grants continue to be cancelled. One of its universities, San Diego State University (SDSU) alone currently has 23 non-competing renewals pending action by the grants office to authorize the next segment of funding, 34 new proposals and competing renewals totaling approximate $16 million awaiting NIH study section review, and 10 new proposals and competing renewals totaling approximately $3.2 million that received fundable scores awaiting NIH advisory council and Notice of Award.

173. Unless funding of each NIH grant is restored to each of the affected CSU university campuses, neither the California State University nor any of its auxiliary organizations will have the financial resources to keep the research programs running. Neither does the CSU's operating budget have any available funds to cover these programs, should additional federal funding be terminated. The CSU's operating budget has two main funding sources: the state General Fund (as appropriated by the Legislature annually) and student tuition and fees to cover the educational budget. Due to ongoing gaps in annual funding, the CSU system has in past years already had to reduce student enrollment and suspend degree programs. However, because the statutory purpose of CSU to provide education to all qualified Californians, CSU does not have the discretionary option not to spend its funds as required to fulfill its educational mission. There is hence no

additional funding available to cover another $20 million in lost NIH grant program funding which, up to this point, has been reliably predictable as a funding source over multiple years.

174. NIH terminations are particularly egregious when budget planning must be done years in advance. CSU's education budget includes many items that are based on long-term commitments and planning efforts, including phased campus development under multi-year master plans, deferred maintenance schedules, and bond financing repayments. These funds are already committed are not available to replace lost funds from the NIH programs. NIH grant funding is also sought and secured well in advance of its use, necessitating personnel and equipment purchases based on those commitments.

175. Over the last fifteen years, CSU campuses have made concerted investments in student training, faculty hiring, and institutional support of medical and public health research. Delays in NIH funding decisions and evaluation of applications and terminations now endanger all of those efforts. SDSU, for example, has instituted a hiring freeze on new faculty and staff, and will now defer long-term research projects. Terminations over grants studying health disparities and sexual and minority health have directly impacted the salaries of SDSU staff, faculty, and students. Without NIH funding, some students may need to discontinue their studies and in the case of international students, leave the country.

176. The damage from grant terminations to CSU campuses' relationship with the surrounding community and patients is similarly irreparable. For example, federally funded studies establish that sexual and gender minority youth are at a higher risk of suicide and suicide ideation.[33] Yet one of the grants terminated funded suicide prevention services to sexual and

[33] Luk J.W. *et al.*, *Sexual Minority Status and Age of Onset of Adolescent Suicide Ideation and Behavior*, 148 Pediatrics, no. 4 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC9446478.

gender minority youth, and was terminated in the middle of their multi-year period without any opportunity to bridge individuals at high-risk of suicide to new services providers.

177. CSU campuses to date have received no funding or direction from NIH concerning the participants enrolled in terminated trials even where the potential for increased suicide attempts and subsequent death is high because every single participant in a study is at high risk for suicide. This is particularly damaging to CSU's relationship with the community health providers that often support enrollment in intervention studies.

178. The termination of the grants often means that researchers cannot fully evaluate whether an intervention is statistically effective—essentially wasting the valuable resources already expended and delaying scientific progress, stifling innovation, and impeding the development of new medical treatments, technologies, and public health initiatives.

179. Grant terminations, especially without warning, are also directly affecting students at the CSU. Graduate students, who are at the core of research laboratories, rely on NIH grants not only for resources to support research, but also for their own stipends, tuition support, and training programs. Sudden cuts have immediate and consequential impacts to these students, who often live paycheck to paycheck, putting their housing and basic needs at risk.

180. NIH grants also support undergraduate students at CSU. For example, the CSU U-RISE program is funded through a grant from the National Institute of General Medical Sciences and is meant to broaden perspectives in future scientific and biomedical research by identifying students' interest in pursuing research as a career and by providing training opportunities to be competitive for entering graduate programs. Students accepted into the U-RISE program receive trainee stipends to defray living expenses during research training experiences, and also support student trainee travel expenses to attend scientific meetings with their mentors and help defray

university personnel expenses and supplies. At least 9 CSU universities received a notice from NIH stating that the university must "cease project activities as of the current budget period end date of 3/31/2025," and as a result these 9 CSU universities must immediately terminate stipends for students in the middle of the semester, causing participating students direct and significant harm, as their financial aid packages account for U-RISE stipends.

181. The impact from the termination of grants funding training programs like U-RISE is also profound. It inflicts emotional and academic distress upon students, damaging the pipeline of future researchers. The CSU, with limited resources, bears a disproportionate burden, exacerbating financial strain and competitive disadvantages.

182. At this point, delays in the review of NIH grant applications have also prevented the researchers from planning for the implementation of the grants and stalled important research programs from moving forward at multiple CSU campuses.

183. A five-year grant designed for universities without significant NIH funding that serve historically underrepresented student populations in communities with significant populations with unmet health needs in Fresno, California, has been delayed multiple times in its review and currently has no advisory-council review date. A grant of this size requires many people working collaboratively. The grant application has 12 staff associated with it. Faculty working on this grant will receive time released from teaching ranging from 25 percent to 50 percent but cannot plan for this while the grant remains under review with changing implementation dates.

184. Another five-year grant intended to study how cells differentiate themselves for specific uses, which would advance the understanding of certain genetically linked illnesses, has similarly been delayed. The proposal was written and submitted with review guidelines and

criteria that has since been changed after the grant has been submitted. Delays in review have similarly delayed graduate student hiring associated with the grant.

III. Harms to Maryland

185. Delays in the grant review process and terminations of existing grants have disrupted valuable research at Maryland's research universities.

186. UMB has nearly 500 proposals totaling $1.1 billion in the NIH review pipeline. This includes 380 proposals totaling $1.04 billion awaiting study section review, 32 proposals totaling $21.4 million that received fundable scores and are awaiting advisory council review, 12 proposals totaling $37.5 million that received fundable scores and have been reviewed by NIH advisory councils, and 44 proposals totaling $33.2 million that received possibly fundable scores and are awaiting advisory council review. UMCP has approximately 200 proposals pending with NIH, totaling about $354 million.

187. The delays in the review process have harmed the universities in myriad ways, disrupting ongoing research, interfering with planning and budgeting, forcing the universities to divert resources from other needs, and restricting their ability to accept new graduate students and recruit and retain quality research trainees. The delays also directly harm patients and the public. Among the UMB studies that are stalled in the review process despite having already received fundable scores and undergone advisory council review are a clinical trial involving assisted living residents with Alzheimer's disease and related dementias and another study that seeks to assist selection of antidiabetic drugs for individual patients. One of UMCP's stalled submissions is the Bucharest Early Intervention Project, a landmark child development study that has followed a group of individuals, some of whom were raised in institutions, for more than 20 years. The study was reviewed by a study section in October 2024 and received a score of 12th percentile, but advisory council review has since been delayed three times.

188. Arbitrary grant terminations have also devastated research at UMB and UMCP. UMB has received termination notices for 14 NIH awards representing about $33 million in lost research funding. One terminated grant funded a study at UMB involving more than 1,000 human subjects who underwent diagnostic tests as part of the funded study. The human subjects consented to the study based on the understanding that they would be provided with test results that could be important to their health. The abrupt termination of the grant takes away federal funding for providing subjects with those test results. Another affected UMB project examined differences in brain and hormonal mechanisms between males and females in relation to pain conditions. The project earned the highest score in its study section. UMCP has received notice of termination of nine grants, representing about $1 million in lost research funding. Examples of the affected studies include a study examining alcohol use among sexual orientation and gender identity minority youth and another study assessing the needs of persons who suffer biological disorders in sex development.

IV. Harms to Washington

189. The University of Washington has experienced significant harms as a result of defendants' implementation of the Challenged Directives.

190. As of April 1, the University of Washington has more than 500 proposals awaiting NIH study section review. It has 54 proposals for $138 million in total funding requested that received fundable scores, awaiting NIH advisory council and Notice of Award. And it has 76 proposals for $260 million in total funding requested with fundable scores that for which the NIH advisory council has met or voted electronically to approve a grant for funding, but the NOA has not yet been issued.

191. Additionally, the University of Washington has 73 overdue non-competing renewals totaling over $61 million that have yet to receive NOAs. Delays in this funding has

already had potentially irreversible effects on the University of Washington. To take just one example, the University of Washington's Institute of Translational Health Sciences (ITHS) has been awaiting an overdue non-competing renewal on a $10.5 million annual grant for over a month.

192. ITHS is a partnership between the University of Washington, Fred Hutchinson Cancer Center, Seattle Children's, and regional institutions to promote the translation of scientific discovery to clinical practice. One example of the innovative work performed at ITHS is the Gene & Cell Therapy Lab's (GCTL) accelerated development of a therapy to treat advanced ovarian cancer, called UltraCAR-T Cell therapy. Scientists in the GCTL worked with a biopharmaceutical company to transfer the technology so that the product could be made quickly and effectively. A separate unit of ITHS, the Translational Research Unit, conducted the rigorous clinical trials necessary to advance the technology towards a clinical use. But now, without funding for over thirty days, the University of Washington has been forced to institute staff reductions, furloughs, and elimination of positions at ITHS.

193. Other important research centers that are at risk because of delays in the grants review and award processes at NIH include the University of Washington's Alzheimer's Disease Research Center (ADRC), the Nathan Shock Center of Excellence (NSC) in the Basic Biology of Aging, and the joint University of Washington /Allen Center. These Centers are funded by the National Institute on Aging (NIA) and received excellent scores during their reviews in study section in the fall. Because the NIA Council did not meet as scheduled in the January, these large grants were not approved for award. They all end in April or May and would leave large research teams without support. The work being done by these centers is longitudinal and lapse in funding will mean loss of critical cohorts that have been studied in some cases up to 40 years.

194. On top of these, University of Washington researchers have also had at least 11 grants terminated by NIH, totaling over $3 million to support innovative work in trauma research for victims of sexual assault, prevention of chlamydia infections, and the impact of air pollution on Alzheimer's disease and related dementias, among other topics.

195. The implementation of the Challenged Directives, and the resulting delays and terminations, have not only disrupted this critical research, they have also led to University-wide harms. The failure of NIH to communicate deviation from the normal funding application cycle for reviews and approval of funding means that research team which often plan grant applications years in advance to maintain necessary funding to support their research teams are left without consistent funding and in some cases are needing to furlough or layoff research team members. The University of Washington has paused some new hires whose research programs depend on timely NIH awards, including several where candidate interviews were already underway, and programs have been forced to reduce graduate admissions between 25 and 50%. Moreover, the terminations, delays, and unprecedented disruptions in funding have had a profoundly negative effect on morale University wide. Faculty and staff don't know if their funding will be cut, if their research will be terminated, whether they will be able to attend conference, or even whether they will continue to have jobs. The stress of these funding disruptions is palpable and has negatively affected the University of Washington's mission. Research staff that are stressed about losing their jobs on a daily basis are not able to focus their full creative energy on innovation and discovery.

V. Harms to the Remaining Plaintiffs

196. In Arizona, five of Arizona State University's NIH-funded projects have been paused or terminated, and the university continues to receive new grant-related notices on an ongoing basis. Arizona State University has more than 450 proposals with an estimated amount

of $771 million that have been submitted to NIH but for which it has not received a response. Northern Arizona University received a termination notification of an award, "*Bridging Arizona Native American Students to Bachelor Degrees*," which funds a transfer program of students from two-year associate degree programs at Coconino Community College to four-year baccalaureate degree programs at Northern Arizona University. This program will cease for current students, jeopardizing the likelihood that they transfer to Northern Arizona University and complete a baccalaureate degree. Northern Arizona University will forgo recruitment of the final cohort of students who would have benefitted from this program, and program activities will cease on July 31, 2025. Northern Arizona University has 34 proposals, representing approximately $47 million, submitted to NIH for which it has not received a response.

197. CU Anschutz is Colorado's only public academic medical center. CU Anschutz has more than 500 research laboratories on campus pursuing their research mission. This work supports important basic science and clinical research, graduate students, clinical trials, and other work in a broad array of areas on the health spectrum. Currently, 479 doctoral graduate students are reliant on the grant funding of the institution to complete their education and work toward finding new discoveries. Upon information and belief, because of NIH's actions, CU Anschutz has experienced direct harm, including but not limited to (a) a 23% decline in NIH grant awards for the period of time from January through March 2025 as compared to the period of time from January through March 2024, and (b) termination of numerous existing grant awards. CU Anschutz has received 18 NIH grant terminations to date with a total loss of funds of at least $8,455,794.17. CU is a direct grantee of seven of those grants, totaling $2,921,217.25 in funding loss. These grants would have funded CU Anschutz's continued work on a variety of health studies including hormones, vaccines, Alzheimer's disease and other important studies. CU is a

subgrantee on 11 additional grants terminated by NIH, totaling a funding loss of at least $5,534,576.92. These grants would have continued to fund CU Anschutz's work and partnership with their grant sponsors on work related to antiviral measures, impact of environmental toxicants on diabetes, and adolescent medicine trials for HIV/AIDS interventions, among other studies.

198. The University of Delaware has directly experienced harm as a result of defendants' treatment of the Delayed Applications. As of March 31, 2025, the University of Delaware has (a) 77 proposals totaling $177 million awaiting NIH study section review; (b) at least 13 proposals totaling $59.8 million that received fundable scores, awaiting NIH advisory council and Notice of Award; and (c) 102 proposals totaling $234.9 million that received possibly fundable scores, awaiting NIH advisory council and Notice of Award. "Since late January 2025, the University of Delaware has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed." The University of Delaware uses information regarding NIH grant applications and award rates to inform its graduate admissions process. Due to uncertainty of incoming grant funding related to the delays in reviewing and awarding grants by NIH, the various PhD programs at the University of Delaware that rely on NIH funding for graduate student support have reduced admission offers for their incoming class of graduate students by up to 50%. Such instability in funding is affecting the recruitment and retention of high-caliber quality research trainees. The inability to retain quality research trainees will have ongoing effects on the research capabilities of the University of Delaware, including by limiting the individuals qualified to conduct certain research. The delays have disrupted ongoing research, as well as actively setting back the University of Delaware's ability to conduct critical research now and in the future. Funding gaps have already forced

researchers to abandon promising studies, miss key deadlines, or lose highly trained personnel. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding. This results in not only ethical and financial losses but also wasted scientific opportunity, as experiments cannot simply be restarted once interrupted. In many cases, there is no way to recover the lost time, research continuity, or training value for graduate students and postdoctoral researchers once disrupted. Promising discoveries may be delayed indefinitely, and, in some cases, entirely lost.

199. Between March 21 and 31, 2025, the University of Hawai‘i received two notices of cancellation of direct NIH grants. The affected grants total approximately $344,000. In addition, since late January of 2025, pending University of Hawai‘i grant applications have experienced unusual delays resulting in substantial uncertainty. As of March 30, 2025, the University of Hawai‘i had approximately 65 proposals awaiting NIH study section review. As of the same date, the University of Hawai‘i had 31 proposals that received fundable scores but are awaiting NIH advisory council review and a final decision whether to award the grant. These unusual delays in NIH processing are affecting University of Hawai‘i budgeting and planning for fiscal year 2025-2026, creating uncertainty around department budgets, teacher workload, and the hiring of additional faculty, teaching assistants and graduate assistants. Although University of Hawai‘i has deployed bridge funding for impacted students, those resources are limited. Long-term use of non-federal funding is not a viable option.

200. In Minnesota, the University of Minnesota has had 21 NIH grants and subawards terminated. The terminations will result in the loss of approximately $8.5 million in research money to the University. In addition, NIH’s delay and/or cancellation of study sections have had a negative impact because significant numbers of grant proposals due for funding have remained

unfunded for at least one grant cycle, and they will potentially be unfunded indefinitely. These actions have been very disruptive to the University of Minnesota's ongoing research—including research involving clinical trials for life-saving medications or procedures. For example, the University of Minnesota is a major partner in the NIH U01 Diabetes Prevention Programs Outcomes Study (DPPOS), serving as the central biochemistry lab for 25 clinical sites and serving on the project's Steering Committee. This project addresses the National Alzheimer's Project Act's goal to "prevent, halt or reverse Alzheimer's Disease" in the high-risk group of persons with pre-diabetes and type 2 diabetes, who represent over half of the population aged 60 years or older in the United States. The terminations and delays threaten the University of Minnesota's ability to proceed with important projects like DPPOS.

201. As the result of three grant terminations, the University of Nevada, Las Vegas, has lost $2.4 million in research funding that supports projects focusing on, and advancing research related to, Alzheimer's disease. The funding losses limit access to research and findings on Alzheimer's disease. These grant terminations harm Nevada by defunding critical research that advances public health and educational opportunities in Nevada. And although the University of Nevada, Reno, has not reported receipt of any grant terminations, ongoing delays in review of numerous research proposals are negatively impacting the University's recruitment and retention efforts. This includes having to pause ongoing efforts to onboard new hires after the University had already provided those individuals with offer letters for positions with research programs that depend on timely NIH awards.

202. In New Jersey, Rutgers has directly experienced harm stemming from its pursuit of scientific research blacklisted by defendants, specifically studies with a perceived connection to DEI and COVID. As of April 10, 2025, faculty and staff at Rutgers have received termination

notices for at least six NIH grants, resulting in a loss of more than $7 million in funding. Rutgers will be unable to reallocate funds to offset these federal grant losses, triggering numerous irreparable harms. Ongoing experiments have stopped, suspending hiring and reducing staff research hours—all due to research perceived to be related to DEI and/or COVID. Such terminated grants relate to studies regarding HIV prevention, mental health, suicidal ideation, HPV vaccines, and COVID antiretroviral treatment. More broadly, the Challenged Directives have resulted in the cancellation of programs funded by NIH grants directed at supporting minority and underrepresented students pursuing training and graduate degrees in biomedical sciences and engineering at Rutgers, NJIT, and Kean—with NJIT and Kean losing approximately $1.2 million, respectively, as a result. Undergraduates at these institutions will lose out on opportunities to train in research excellence, unite in a diverse cohort to build identity, and prepare for the next phase of their biomedical research career pathway. In addition, since late January of 2025, pending grant applications at Rutgers, Kean, and NJIT have experienced unusual delays resulting in substantial uncertainty. As of April 11, 2025, Rutgers has approximately 13 proposals totaling $26,990,860 awaiting NIH study-section review; approximately six proposals totaling $19,608,265 that received fundable scores, awaiting NIH advisory-council review and Notice of Award; and 738 grant submissions under sponsor review with a total value of $1,387,066,143. As of April 11, 2025, NJIT has approximately 40 proposals totaling $70,683,171.27 awaiting NIH study-section review; 4 proposals totaling $3,269,729.47 that received fundable scores, awaiting NIH advisory-council review and Notice of Award; and 17 proposals totaling $26,602,999.51 that received possibly fundable scores, awaiting NIH advisory-council review and Notice of Award. As of April 11, 2025, Kean has six proposals totaling approximately $11 million awaiting NIH study-section review, advisory-council review and/or Notice of Award. These unusual delays in NIH processing

are affecting budgeting and planning for fiscal year 2025 at Rutgers, NJIT, and Kean, creating uncertainty around department budgets, teacher workload, and the hiring of additional faculty, teaching assistants and graduate assistants.

203. In New Mexico, NIH has terminated four research training grants at UNM representing over $9 million in lost research funding. These prestigious grants support vital biomedical workforce development programs that provide advanced training for UNM's students: (a) the Institutional Research and Academic Career Development Award (IRACDA) Post-Doctoral program trains post-doctoral fellows for research and teaching careers in academia; (b) the Leading Equity and Diversity in the Medical Scientist Training Program (LEAD MSTP) supports biomedical research training of UNM's MD/PhD students for developing the clinical research workforce, (c) the Initiative to Maximize Student Diversity at the University of New Mexico Health Sciences (IMSD) grant supports predoctoral trainees in the Biomedical Sciences Graduate Program and (d) the Undergraduate Research Initiative for Student Enhancement (U-RISE) trains and prepares undergraduate students for doctoral programs and careers in biomedical research. These training grants provide structured training and mentorship programs as well as financial support, including tuition and stipends, to advance students' education and career opportunities in biomedical research. UNM currently has approximately 50 students enrolled at different stages in these programs. Some of these programs have been at UNM for over 20 years. The aim of these training grants is to develop a group of professionals equipped with the technical, operational, and professional skills necessary for success as biomedical scientists, building capacity for groundbreaking research in New Mexico and representing our state's population in the biomedical workforce. At NMSU, NIH has terminated three research grants representing approximately $6.7 million in lost research funding. All three grants that were terminated funded

and promoted students' participation in the biomedical workforce by strengthening research training and preparing students for a successful transition into higher level biomedical degree programs and the biomedical workforce. NIH's termination of these grants impedes New Mexico's ability to continue developing breakthrough biomedical research and innovations.

204. SUNY has experienced direct harm as a result of the delays and terminations of NIH grants. For example, NIH had committed to five years of funding—a total of $3,596,263—for a project that established a center to train and develop health equity researchers focused on health disparities in and around Buffalo. The grant had met and exceeded all of its milestones, but it was terminated on March 28, 2025. NIH also canceled grants funding research into HIV treatment and care in Ghana; the impact of peer victimization on health outcomes for LGBQ+ youth; improving inclusivity of Alzheimer's disease research; and cardiovascular disease risks among sexual and gender minorities. Additionally, SUNY has been harmed by unexplained delays and procedural breakdowns. The uncertainty has led to reduced staff hours and other harms.

205. In Oregon, OHSU has experienced both NIH grant notices of terminations and delays in the processing of grant applications. Since March 24, 2025, OHSU received notices of termination of one NIH grant awarded directly to OHSU and seven NIH grants awarded to other institutions that issued subawards to OHSU. These terminations will result in the loss of $2.4 million in research funds to OHSU. OHSU has also experienced significant delay in its NIH application processing since January 2025. As of March 31, OHSU has approximately 280 proposals totaling over $730 million awaiting NIH study section review. As of March 31, OHSU has 70 proposals that received fundable scores totaling $172.4 million awaiting NIH advisory council meetings and notices of award. And it has 90 proposals that received possibly fundable scores totaling $194.9 million awaiting NIH advisory council meetings and notices of award.

These terminations and delays have disrupted ongoing research, graduate admissions processes, recruitment of key research personnel, and OHSU's ability to plan its operations. In many cases, once a study is disrupted, it is impossible to recover the lost time, research continuity, or training value of the study. As a result, studies with the potential to achieve breakthroughs in different disciplines and advance public health will simply not occur.

206. In Rhode Island, as a result of defendants' implementation and enforcement of the Challenged Directives, NIH has terminated two research grants at URI representing $3.7 million in lost research funding. One grant funded innovative research that was aimed at advancing the public health of those living with HIV by contributing to the investigation of causal mechanisms among networks of populations at high risk for HIV infection compounded by illicit substance use. The other grant funded the University of Rhode Island's ESTEEMED Scholars Program, a program that provides students from underrepresented backgrounds with the skills and resources necessary to pursue advanced education and degree programs in bioengineering and related disciplines. The impact on student achievement and the inclusive environment at URI will be hit particularly hard. Without URI ESTEEMED, several of the current trainees would have had to drop out of URI due to the lack of academic support the program provided and the stipend that allowed them to focus on their academics and research instead of working an outside job. These grants funded research aimed at advancing public health research for some of the most vulnerable in Rhode Island and allowing those from underrepresented backgrounds unparalleled academic opportunities. NIH's termination of these grants harms Rhode Island by defunding research that advances public health and educational opportunities.

207. In Wisconsin, as of March 31, 2025, NIH has terminated four research grants to UW-Madison. The total amount of funding anticipated under these awards is $25,149,959, and of

that amount, $12,631,870 has not been disbursed to UW-Madison. These grants are to fund research on infectious disease, vaccine development, minority health disparities, and child health and human development. NIH has also terminated two research grants funding research at UW-Milwaukee regarding substance abuse, violence, and suicide prevention. In addition, since late January 2025, UW-Madison has seen an unusual number of delays in the processing of NIH grant applications, rendering institution-wide budgetary planning especially difficult as the budget process at UW-Madison relies upon the NIH grant application, review, and approval cycle. Delays in the review of pending grant applications creates uncertainty and disrupts the funding cycle necessary to maintain continuity of research projects and consistent staffing of trained researchers. In many cases, there is no way to recover the lost time, research continuity, or training value once research is disrupted. Some researchers at UW-Madison have already been unable to commit to bringing on graduate students or maintaining current trainees due to funding uncertainty, and if funding that historically would have been expected is not forthcoming, or funding is indeed terminated, certain research projects will need to be abandoned. For one particular award—an NIH Research Program Grant (P01) supporting three co-investigators—termination with no funding alternative would necessitate the termination of ten research staff (including a postdoctoral trainee) and interrupt the progress of forty undergraduate, graduate, and medical students towards their degrees. NIH's delays and/or cancellations of study sections and advisory council meetings and grant terminations have thus harmed Wisconsin's universities. These actions further harm Wisconsin through the likely reduction of the future scientific workforce and by depriving Wisconsin and the broader community of critical biomedical research.

VI. Impact on Appropriated Funds

208. Notwithstanding Congress's appropriation to NIH, as a result of the implementation and enforcement of the Challenged Directives as described above, NIH has not

awarded billions of dollars in appropriated funding, with only a few months left of available funding.

209. Based on the publicly available NIH RePORTER database, in Weeks 4-11 of 2024 (*i.e.*, January 20, 2024, through March 14, 2024), NIH awarded a total of $4.08 billion to 8,071 projects. By comparison, in Weeks 4-11 of 2025 (*i.e.*, January 20, 2025 through March 14, 2025), NIH awarded a total of $2.45 billion to 4,961 projects—a reduction of approximately 40%.

210. Narrowing the focus to awards (and competing renewals) that require study section and advisory council review prior to award, in those same weeks, NIH awarded $740 million to 1,756 projects in 2024 but only $360 million to 781 projects in 2025. Focusing further still just on Weeks 6-11, the comparison is even more striking: 1,342 projects for $576 million in 2024, compared with 395 projects for $180 million in 2025, a reduction of nearly 70%.

211. The impact on appropriated funds continues to worsen. Looking at multi-year grant awards with April 1 budget start dates, the estimated difference for Weeks 12-13 (*i.e.*, the period from March 14, 2025, to April 1, 2025) is $1.04 billion. Of this, $780 million is due to non-competitive renewal awards that were anticipatable during this period—since many grants were due for renewal by April 1, 2025. In addition, based on the new and competitive renewal awards made during this same period in 2023 and 2024, there is a $260 million reduction in anticipatable new and competitive renewal awards in 2025.

CAUSES OF ACTION

Count 1—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(2): Agency Action Contrary to Statute

212. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

213. The APA requires a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. §706(2)(C), or "otherwise not in accordance with law," *id.* §706(2)(A).

214. In reviewing agency action, a court cannot accept "the agency's policy judgments . . . if they conflict with the policy judgments that undergird the statutory scheme." *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994); *see Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000) (explaining that "federal agencies" cannot "substitute their policy judgments for those of Congress").

215. The Challenged Directives adopt, as a matter of final agency policy, the determination that projects with a perceived connection to "DEI" and other blacklisted topics "no longer effectuate[] agency priorities." The Challenged Directives order defendants not to fund projects with a perceived connection to those blacklisted topics, resulting in the elimination of funding opportunities, disruption of pending applications, and termination of ongoing grants described above.

216. The Challenged Directives are contrary to law and beyond statutory authority because they defy Congress's statutory directives to NIH to support research through publicly promulgated priorities, including those directed to "DEI."

217. Specifically, the Challenged Directives defy statutory directives requiring NIH and its respective ICs to encourage and support research and authorizing them to make grants to institutions and researchers for that purpose, *see* 42 U.S.C. §284(b)(1) (A), (b)(2)(A), as well as statutory directives requiring the NIH Director to, for example, "encourage efforts to improve

research related to the health of sexual and gender minority populations," in conducting and supporting research. *Id.* §283p.

218. The Challenged Directives also defy statutory directives that require NIH to articulate its priorities via the NIH Strategic Plan, which NIH must develop, submit to the appropriate Committees of Congress, and post publicly. *See* 42 U.S.C. §282(m)(1).

219. The Challenged Directives are also contrary to law because they defy Congress's consistent appropriation of funding to NIH's Institutes and Centers to carry out their respective statutory purposes and public priorities. NIH is flouting its statutory responsibilities by terminating so many grants with a dwindling opportunity to reallocate them, which will result in a substantial portion of Congress's appropriation going unspent. The Challenged Directives are therefore contrary to the statutes authorizing and appropriating funds for NIH research and beyond defendants' statutory authority.

220. Accordingly, plaintiffs are entitled to an order and judgment, and to a preliminary and permanent injunction, holding unlawful and setting aside the Challenged Directives and enjoining any action taken to enforce or implement the Challenged Directives.

Count 2—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(2):
Agency Action Contrary to Regulation

221. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

222. The APA authorizes a court to "hold unlawful and set aside agency action, findings, and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and/or "without observance of procedure required by law." 5 U.S.C. §706(2).

223. As discussed above, the Challenged Directives instruct defendants to take adverse action on research projects with a perceived connection to blacklisted subjects under 2 CFR §200.340(a)(2) (2020). However, that regulation does not apply here and does not authorize the termination of any ongoing grants because (1) HHS-specific regulations, not §200.340, govern the termination of NIH awards, and (2) neither 2 C.F.R. §200.340(a)(2) nor 2 C.F.R. §200.340(a)(4) independently authorizes an awarding agency to terminate awarded grants on the grounds that NIH identified "agency priorities" after the award of the grant which the grant does not effectuate.

224. Accordingly, plaintiffs are entitled to an order and judgment, and to a preliminary and permanent injunction, holding unlawful and setting aside the Challenged Directives, and enjoining any action taken to enforce or implement the Challenged Directives.

Count 3—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(2):
Arbitrary and Capricious Agency Action

225. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

226. The APA requires a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A).

227. An agency action is arbitrary and capricious if the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). An agency action is also arbitrary and capricious if, when departing from a prior policy, an agency does not "display awareness that it *is* changing position" or does not

"show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

228. As described above, the Challenged Directives instruct defendants to take adverse action on research projects with a perceived connection to blacklisted subjects.

229. The Challenged Directives are arbitrary and capricious because they do not acknowledge—let alone provide "good reasons for"—any official change in agency "priorities." *Fox Television Stations*, 556 U.S. at 515. Indeed, upon information and belief, defendants have deliberately chosen not to expressly acknowledge any changes in agency priorities regarding research into the blacklisted topics.

230. The Challenged Directives are arbitrary and capricious for the additional reason that, in adopting and implementing them, defendants have not engaged in reasoned consideration of any individual project before terminating a grant.

231. The Challenged Directives are arbitrary and capricious for the additional reason that, in adopting and implementing them, defendants failed to consider several important aspects of the issues before them, including, at a minimum, (1) plaintiffs' reliance interests in any announced research opportunities and awarded research grants; (2) whether those projects could be adjusted, rather than terminated, to comply with defendants' new "priorities" (assuming those new "priorities" and their application to existing funding opportunities and awards were otherwise lawful); (3) whether defendants could have adopted a measure other than across-the-board delay of the grant awards process and elimination of entire categories of programs to effectuate their new "priorities" (assuming those new "priorities" and their application to existing funding opportunities and awards were otherwise lawful); and (4) as to ongoing research projects, the harm that eliminating those projects would inflict on human test subjects participating in the studies.

232. The Challenged Directives are arbitrary and capricious for the additional reason that they rely on factors which Congress has not intended defendants to consider, including considerations in conflict with the PHSA's directives in favor of diversity, equity, and inclusion.

233. Accordingly, plaintiffs are entitled to an order and judgment, and to a preliminary and permanent injunction, holding unlawful and setting aside the Challenged Directives and enjoining any action taken to enforce or implement the Challenged Directives.

Count 4—Against All Defendants
U.S. Constitution, Separation of Powers

234. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

235. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326-27 (2015).

236. The Constitution "grants the power of the purse to Congress, not the President." *City & County of San Francisco v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018); *see* U.S. Const. art. I, §9, cl. 7 (Appropriations Clause); U.S. Const. art. I, §8, cl. 1 (Spending Clause). "Among Congress's most important authorities is its control of the purse." *Biden v. Nebraska*, 600 U.S. 477, 505 (2023). "The Appropriations Clause is thus a bulwark of the Constitution's separation of powers among the three branches of the National Government." *U.S. Dep't of Navy v. FLRA*, 665 F.3d 1339, 1347 (D.C. Cir. 2012) (Kavanaugh, J.). If not for the Appropriations Clause, "the executive would possess an unbounded power over the public purse of the nation." *Id*.

237. Congress also possesses exclusive power to legislate. Article I, Section 1 of the Constitution states that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and a House of Representatives." *See Clinton v.*

City of New York, 524 U.S. 417, 438 (1998) ("There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes.").

238. The Constitution further provides that the executive must "take Care that the Laws be faithfully executed." U.S. Const. Art. II, Sec. 3; *see Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 327 (2014) ("Under our system of government, Congress makes the laws and the President . . . faithfully executes them." (brackets and quotation marks omitted)).

239. The Executive Branch violates the Take Care Clause where it declines to execute or otherwise undermines statutes enacted by Congress and signed into law or duly promulgated regulations implementing such statutes. *See In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 551 (D.C. Cir. 1999) ("[T]he President is without authority to set aside congressional legislation by executive order . . . ."); *Kendall v. United States*, 37 U.S. 524, 613 (1838) (rejecting argument that by charging the President with faithful execution of the laws, the Take Care clause "implies a power to forbid their execution"); *see also Util. Air. Reg. Grp.*, 573 U.S. at 327 (noting that the President "act[s] at time through agencies").

240. The Executive's authority vis-à-vis Congress is particularly limited where, as here, no statutes authorize the Executive's action. Congress consistently has appropriated funds to NIH's ICs to further their statutory purposes of advancing and promoting medical research and has not authorized the Executive to decline to spend vast swaths of funds. Further, Congress has provided for a procedure by which the Executive may propose to Congress to either rescind or cancel funds. *See* Congressional Budget and Impoundment Control Act of 1974, 2 U.S.C. §§682 *et seq*. That statute likewise does not permit the Executive to take unilateral action, instead requiring the President must "propose[]" any rescission to Congress (which Congress must then affirmatively approve) and may not defer funding for the policy reasons defendants explicitly

invoke here. 2 U.S.C. §§683, 684(a). Accordingly, the Executive's authority is at its "lowest ebb." *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637-38 (1952) (Jackson, J., concurring).

241. Defendants' adoption, implementation, and enforcement of the Challenged Directives—including their pattern and policy of systematic delays and terminations—violates the foregoing separation-of-powers constraints. Through these actions, defendants have overridden the careful judgments of Congress by refusing to disburse duly appropriated funding.

242. Accordingly, plaintiffs are entitled to a preliminary and permanent injunction holding unlawful and setting aside, and to a declaration pursuant to 28 U.S.C. §2201 declaring unlawful, the Challenged Directives and any action taken to enforce or implement the Challenged Directives.

Count 5—Against All Defendants
U.S. Constitution, Spending Clause

243. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

244. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong*, 575 U.S. at 326-27.

245. The Spending Clause of the U.S. Constitution, art. I, §8, cl. 1, provides that Congress—not the Executive—"shall have Power to lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States."

246. The Spending Clause requires States to have fair notice of the terms that apply to the disbursement of funds to them. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 25 (1981); *NFIB v. Sebelius*, 567 U.S. 519, 583-84 (2012). The funding conditions must be

set out "unambiguously." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). And the federal statute must be viewed "from the perspective of a state official who is engaged in the process of deciding whether the State should accept [federal statute] funds and the obligations that go with those funds." *Id*.

247. Defendants' adoption, implementation, and enforcement of the Challenged Directives—including their pattern and policy of systematic delays and retroactive terminations—has altered the terms upon which grants were obligated and disbursed to plaintiffs, contrary to Congressional authority. These alterations are coercive, retroactive, ambiguous, and unrelated to the purpose of the myriad grants affected.

248. Defendants' adoption, implementation, and enforcement of the Challenged Directives—including their pattern and policy of systematic delays and retroactive terminations—are also contrary to the principle that funding restrictions can only impose conditions that are reasonably related to the federal interest in the project and the project's objectives. *S. Dakota v. Dole*, 483 U.S. 203, 207, 208 (1987). Here, the delays and terminations are not related to the federal interest in NIH research—to support and encourage scientific research—and instead are related to policies and political factors. Indeed, the effect of these delays and terminations is to chill scientific research as they have subjected researchers and the administrators who support them to the fear that their ongoing research activities can and will be suspended based on shifting political objectives of the current Administration.

249. Accordingly, plaintiffs are entitled to a preliminary and permanent injunction holding unlawful and setting aside, and to a declaration pursuant to 28 U.S.C. §2201 declaring unlawful, the Challenged Directives and any action taken to enforce or implement the Challenged Directives.

Count 6—Against All Defendants
***Ultra Vires* Executive Action**

250. Plaintiffs incorporate by reference the foregoing paragraphs of this Amended Complaint as if set forth herein.

251. The actions challenged herein are contrary to law and outside of defendants' authority because defendants lacked statutory or constitutional authority to issue or implement the Challenged Directives and because defendants' actions are contrary to statutory requirements.

252. The Challenged Directives purport to restrict research on subjects that Congress has expressly required NIH to support. The PHSA requires NIH and its ICs to conduct research related to the health of women, racial and ethnic minorities, and sexual and gender minorities. 42 U.S.C. §§282(h), 283p, 285a-6, 285b-7a(c)(1). In declaring research related to DEI, gender identity, and transgender health off-limits, defendants' actions are contrary to congressional mandates.

253. The Challenged Directives defy statutory provisions requiring NIH to articulate its research priorities through a formal and public strategic plan. The PHSA contains detailed requirements governing this plan. The agency must develop and formalize the plan every six years. 42 U.S.C. §282(m)(1). It must consult with relevant stakeholders in doing so. *Id.* §282(m)(4). The plan must contain a host of information, including "strategic research priorities and objectives," "priorities and objectives to advance the treatment, cure, and prevention of health conditions," and "near-, mid-, and long-term scientific needs." *Id.* §282(m)(2)(A). And the agency must submit the plan to Congress and post it on its website. *Id.* §282(m)(1). Defendants' promulgation and implementation of the Challenged Directives—which have effected large-scale changes in agencies priorities without the development and consultation called by for the creation of a new Strategic Plan—are contrary to this congressionally mandated process.

254. The adoption and enforcement of the Challenged Directives exceed defendants' statutory authority because they conflict with duly enacted congressional appropriations. Congress appropriated funds to NIH's ICs so that those funds would be spent in accordance with the statutory purposes and public priorities just discussed. Congress allocated certain sums of money to NIH so that the agency could use those sums during the fiscal year. In implementing the Challenged Directives, defendants have interrupted the flow of funding to existing projects and precluded the prompt awarding of new grants—with a dwindling opportunity to reallocate funds before they are no longer available at the end of the fiscal year. These actions are contrary to the purpose for which the funds were appropriated and Congress's longstanding and well-established framework of NIH funding. *See* 31 U.S.C. §1301(a) (funds "shall be applied only to the objects for which the appropriations were made except as otherwise provided by law"); *Gen. Land Office v. Biden*, 722 F. Supp. 3d 710, 732 (S.D. Tex. 2024) ("While agencies are afforded discretion for certain lump-sum appropriations decisions, their actions still must remain within the bounds of the statute." (citation omitted)); *California v. Trump*, 379 F. Supp. 3d 928, 953 (N.D. Cal. 2019), *aff'd*, 963 F.3d 926 (9th Cir. 2020) (judicial review is available under the APA where plaintiffs allege that funds are being used "in a statutorily *impermissible* manner"); *Lincoln v. Vigil*, 508 U.S. 182, 193 (1993) ("[A]n agency is not free simply to disregard statutory responsibilities: Congress may always circumscribe agency discretion to allocate resources by putting restrictions in the operative statutes . . . .")).

255. Defendants cannot take any action that exceeds the scope of their constitutional and statutory authority.

256. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong*, 575 U.S. at 326-27. Indeed, the

Supreme Court has repeatedly allowed equitable relief against federal officials who act "beyond th[e] limitations" imposed by federal statute. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

257. Accordingly, plaintiffs are entitled to preliminary and permanent injunctive relief barring the actions challenged herein. Pursuant to 28 U.S.C. §2201, plaintiffs are also entitled to a declaration that the actions challenged herein are contrary to law and outside of defendants' authority.

Count 7—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(1):
Unlawful Withholding and/or Unreasonable Delay of Agency Action

258. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

259. The APA authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. §706(1). Relief is warranted under this provision where an agency completely fails to take, or unreasonably delays in taking, "a discrete agency action that it is required to take." *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (emphasis omitted); *see id.* at 63 n. 1.

260. The APA provides that, "within a reasonable time, each agency *shall* proceed to conclude a matter presented to it." 5 U.S.C. §555(b) (emphasis added).

261. The PHSA provides that applications for NIH research grants shall undergo "technical and scientific peer review" by a study section, and that a favorable review is a prerequisite to a final award of any grant. 42 U.S.C. §§284(b)(2)(B), 289a(a). The PHSA further states that each NIH institute's advisory council "*shall* meet . . . at least three times each fiscal year," *id.* §284(e) (emphasis added), and that it "*shall* advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute" on areas within the council's

jurisdiction, *id.* §284(a)(1) (emphasis added). The PHSA also provides that sign-off from an advisory council is a prerequisite to a final award of any grant in excess of $50,000. *Id.* §284(b)(2); *see id.* §284a(a)(3)(A)(ii).

262. Under NIH regulations, "[a]ll applications" for NIH grants "*shall* be evaluated by the [HHS] Secretary [or his designee] through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council." 42 C.F.R. §52.5(a) (emphasis added); *see also id.* §52a.5 ("NIH grants may be awarded generally only after approval recommendations from both appropriate scientific peer review groups and national advisory councils or boards."). The regulations further provide for the creation of study groups and reiterate that "no awarding official shall award a grant . . . unless the application has been reviewed by a peer review group . . . and the group has made recommendations concerning the scientific merit of that application." *Id.* §52h.7; *see generally id.*, pt. 52h. Moreover, the regulations provide that, "subject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be required by law, the Secretary *will* (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part." *Id.* §52.5(b) (emphasis added).

263. For the foregoing reasons, the following are discrete agency actions that NIH is required to take: (a) the activities of NIH's advisory councils, including the holding of council meetings, the review of pending grant applications by the relevant council, and the making of a final recommendation on each application by the relevant council, (b) the activities of NIH's study sections, including the holding of section meetings, the review of pending grant applications by

the relevant study section, and the making of a final recommendation on each application by the relevant study section—are likewise discrete agency actions that NIH is required to take, and (c) the prompt review and issuance of a final decision on NIH grant applications and renewal requests.

264. As discussed, in implementing the Challenged Directives, defendants have cancelled and/or substantially delayed the above-described required activities of NIH's advisory councils and study sections—a significant and unprecedented departure from the NIH's published review process and the agency's past practice.

265. As discussed, in implementing the Challenged Directives, defendants have refused to process the Delayed Applications, including those of the Delayed Applications that have already received a "fundable" score from the relevant study section and/or a favorable recommendation from the relevant advisory council.

266. As discussed, in implementing the Challenged Directives, defendants have failed to process the Delayed Renewals even though they meet the requirement for renewal.

267. The above-described meeting cancellations and delays in application review constitute unlawful withholding and/or unreasonable delay of agency action within the meaning of §706(1). *See, e.g.*, *Rezaii v. Kennedy*, No. 1:24-cv-10838, 2025 WL 750215, at *5 (D. Mass. Feb. 24, 2025) (holding that a plaintiff had pleaded unreasonable delay where, among other things, the agency's delay in processing plaintiff's application was "at the outer edge of HHS's typical time for processing"); *Raouf v. U.S. Dep't of State*, 702 F. Supp. 3d 19, 33 (D.N.H. 2023) (finding that a plaintiff had pleaded unreasonable delay where she alleged that the "delay [was] attributable to . . . an *ultra vires* internal policy for intentionally delaying issuance of visas").

268. As discussed above, the above-described meeting cancellations and delays in application review have caused, are causing, and imminently threaten to cause direct, concrete, and irreparable harm to plaintiffs.

269. For the foregoing reasons, plaintiffs are entitled to an order, and to a preliminary and permanent injunction, compelling defendants to undertake: (a) the required unreasonably delayed and unlawfully withheld activities of NIH's advisory councils and study sections, and (b) the required unreasonably delayed and unlawfully withheld prompt review and issuance of a final decision on the Delayed Applications and Delayed Renewals.

Count 8—All Defendants
Declaratory Judgment

270. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

271. An actual and substantial controversy exists between plaintiffs and defendants about whether 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) permit NIH to terminate awarded grants on the grounds that NIH identified "agency priorities" after the award of the grant which the grant does not effectuate.

272. This action is presently justiciable because defendants have asserted: (a) that §200.340 permits NIH, as a matter of law, to terminate awarded grants on the grounds that NIH's "agency priorities" have changed since the award of the grant; and (b) that this interpretation of §200.340 permits NIH to terminate plaintiffs' awarded grants on the grounds that they relate to research areas that are no longer "agency priorities."

273. Plaintiffs assert that while 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) permit the termination of a federal award if the award no longer effectuates agency priorities identified as of the time of the federal award, these provisions do not

independently permit or authorize such termination based on agency priorities identified after the time of the Federal award.

274. Declaratory relief will clarify the rights and obligations of the parties and, therefore, pursuant to 28 U.S.C. §2201, is appropriate to resolve this controversy.

PRAYER FOR RELIEF

Wherefore, plaintiffs pray that the Court:

I. Enter an order pursuant to 5 U.S.C. §706(2) holding unlawful and setting aside the Challenged Directives, and any action taken to enforce or implement the Challenged Directives, on the ground that they are (a) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and/or otherwise not in accordance with governing statutes; (b) not in accordance with governing regulations; and (c) arbitrary and capricious;

II. Declare pursuant to 28 U.S.C. §2201 that the Challenged Directives, and any action taken to enforce or implement the Challenged Directives, are unconstitutional because they violate (a) the separation of powers and (b) the Spending Clause;

III. Enter a preliminary and permanent injunction barring defendants from carrying out the Challenged Directives and any actions to enforce or implement the Challenged Directives, including, without limitation, by directing defendants to: (a) reissue Notices of Funding Opportunities (NOFOs) withdrawn based on the Challenged Directives and to refrain from withdrawing NOFOs based on the Challenged Directives; (b) refrain from denying grant applications or renewal applications based on the Challenged Directives; (c) release reimbursements and other funding for awards that defendants have refused to pay based on the Challenged Directives; (d) rescind the termination of the Terminated Grants and refrain from eliminating funding for awards based on the Challenged Directives; and (e) promptly reschedule

and conduct all necessary steps in the review and disposition of plaintiffs' grant applications, including the Delayed Applications and Delayed Renewals;

IV. Enter an order pursuant to 5 U.S.C. §706(1) compelling defendants to undertake: (a) the required unreasonably delayed and unlawfully withheld activities of NIH's advisory councils and study sections, and (b) the required unreasonably delayed and unlawfully withheld prompt review and issuance of a final decision on the Delayed Applications and Delayed Renewals;

V. Declare pursuant to 28 U.S.C. §2201 that 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) do not independently permit or authorize termination of awarded grants based on agency priorities identified after the time of the Federal award; and

VI. Award such additional relief as the interests of justice may require.

April 14, 2025

Respectfully submitted.

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** application for *pro hac vice* admission forthcoming

EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary
Washington, D.C. 20201

TO: Heads of Operating Divisions Head
Heads of Staff Divisions

THROUGH: Wilma M. Robinson, Ph.D., Deputy Executive Secretary

FROM: Dorothy A. Fink, MD, Acting Secretary

DATE: January 21, 2025

SUBJECT: Immediate Pause on Issuing Documents and Public Communications – ACTION

As the new Administration considers its plan for managing the federal policy and public communications processes, it is important that the President's appointees and designees have the opportunity to review and approve any regulations, guidance documents, and other public documents and communications (including social media). Therefore, at the direction of the new Administration and consistent with precedent, I am directing that you immediately take the following steps through February 1, 2025:

1. Refrain from sending any document intended for publication to the Office of the Federal Register until it has been reviewed and approved by a Presidential appointee. Please note that the Office of the Executive Secretary (Exec Sec) withdrew from OFR all documents that had not been published in the Federal Register to allow for such review and approval.
2. Refrain from publicly issuing any document (e.g., regulation, guidance, notice, grant announcement) or communication (e.g., social media, websites, press releases, and communication using listservs) until it has been reviewed and approved by a Presidential appointee.
3. Refrain from participating in any public speaking engagement until the event and material have been reviewed and approved by a Presidential appointee.
4. Coordinate with Presidential appointees prior to issuing official correspondence to public officials (e.g., members of Congress, governors) or containing interpretations or statements of Department regulations or policy. Nothing in this guidance is intended to limit an employee's personal correspondence with members of Congress or other third parties, including an employee's whistleblower protected communications.
5. Notify Exec Sec promptly of any documents or communications that you believe should not be subject to the directives in paragraphs 1-4 because they are required by statute or litigation; affect critical health, safety, environmental, financial, or national security functions of the Department; or for some other reason. Please provide the title, a brief summary, the target release date, and the rationale for expedited release to your Exec Sec Policy Coordinator.

The President's appointees intend to review documents and communications expeditiously and return to a more regular process as soon as possible.

If you identify any actions taken inconsistent with these requests, please know they shall not be considered impliedly ratified. These items should be immediately withdrawn or rescinded to deem them as void and without effect.

Thank you for your assistance in ensuring a smooth transition consistent with our nation's democratic principles.

Dorothy A. Fink, MD, Acting Secretary

EXHIBIT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

EXHIBIT 3

National Institutes of Health
Office of Extramural Research

Date: February 12, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

From: Michael S. Lauer, MD Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.12 09:26:33 -05'00'
Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S Date: 2025.02.12 09:40:52 -05'00'
NIH Chief Grants Management Officer

Subject: NIH Review of Agency Priorities Based on the New Administration's Goals

NIH is in the process of reevaluating the agency's priorities based on the goals of the new administration. NIH will effectuate the administration's goals over time, but given recent court orders, this cannot be a factor in IC funding decisions at this time. In consultation with NIH leadership and with the Office of General Counsel (OGC), we recognize that NIH programs fall under recently issued Temporary Restraining Orders (*New York et al. v. U.S. Office of Management and Budget* and *Commonwealth of Massachusetts et al. v. National Institutes of Health et al* see attached). Therefore, with this memo, IC CGMOs are authorized, along with their respective grants management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements (previously cleared through Office of Extramural Research) grants. Until further notice, as awards are issued, ICs must follow their existing FY25 IC funding policies and use the previously approved negotiated indirect cost rates. Additional details on future funding actions related to the agency's goals will be provided under a separate memo.

Attachments

1. Temporary Restraining Order, *New York et al. v. U.S. Office of Management and Budget* (Jan. 31, 2025)
2. Court Order Questions – HHS OGC Responses (February 4, 2025)
3. Temporary Restraining Order, *Commonwealth of Massachusetts et al. v. National Institutes of Health et al.*, (February 10, 2025)
4. Order Enforcing TRO, *New York et al. v. U.S. Office of Management and Budget* (February 10, 2025)
5. Office of General Counsel Note, *New York et al. v. U.S. Office of Management and Budget* (February 10, 2025)

EXHIBIT 4

National Institutes of Health
Office of Extramural Research

Date: February 13, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

From: Michael S. Lauer, MD Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.13 15:06:52 -05'00'
Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S Date: 2025.02.13 15:11:19 -05'00'
NIH Chief Grants Management Officer

Subject: Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals

The Office of Extramural Research is issuing supplemental guidance to the memo, dated February 12, 2025, to Institute and Center (IC) Chief Grants Management Officers (CGMOs) and their respective staff to issue hard funding restrictions on awards and within the Payment Management System (PMS)/Program Support Center (PSC) on awards where the program promotes or takes part in diversity, equity, and includsion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristics. The restriction requirement applies to new and continuation awards made on or after February 14, 2025. If the sole purpose of the grant, cooperative agreement, other transaction award (including modifications), or supplement supports DEI activities, then the award must be fully restricted. The restrictions will remain in place until the agency conducts an internal review for payment integrity. Such review shall include, but not be limited to a review for fraud, waste, abuse, of all grants, cooperative agreements, and Other Transactions that determines the funding of the activities/program are in the best interest of the government and consistent with current policy priorities.

Attachments

1. Memo NIH Review of Agency Priorities Based on the New Administration's Goals, February 12, 2025

2. UPDATE - Temporary Restraining Order in State of New York et al. v. Trump et al., 1:25-cv-00039 (D.R.I.), February 12, 2025

3. Secretarial Directive on DEI Related Funding, February 10, 2025

EXHIBIT 5

Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

Category 1: The sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above.

- Action: ICs must not issue the award.

Category 2: Project partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
    - **Note:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not all-inclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

- Issue a revised NOA.
    - Change the budget and project period end dates to match the date of the termination letter.
    - Check PMS, determine amount of funds remaining, and deobligate the amount reflected in PMS when revising the NOA. Note: This applies to Multi-Year Funded Awards, as well. Work with FFR-C if you have questions regarding deobligating funds to avoid placing the recipient in debt collection.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
    - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR)) within 120 days of the end of this grant to avoid unilateral closeout.
    - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
        - Sample language for use: "Funds in the amount of $xxxxxxx [insert $ amount total cost] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered."
- Appeals language must be used (prior to October 1, 2025):
    - NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This letter represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli.

      Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.
- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From:	Memoli, Matthew (NIH/OD) [E]
To:	Bundesen, Liza (NIH/OD) [E]
Cc:	Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject:	Re: Clean Version of DEI Restriction Term - Final
Date:	Friday, February 28, 2025 2:54:19 PM

approved

Matt

Get Outlook for iOS

From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

EXHIBIT 6

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Thursday, March 13, 2025 4:04 PM
To: Chief GMOs <ChiefGMOs@mail.nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov>
Subject: Award Revision Guidance and List of Terminated Grants via letter on 3/12

Chiefs,

Attached are two items: 1) updated categories for you to use when issuing NOAs to officially terminate the awards where letters were issued, and 2) the list of termination letters that were issued yesterday. Please revise your NOAs related to the attached list by next **Wednesday, March 13, 2025, cob**. It is extremely important that issue the revised awards timely. If there are delays, please let me know and we can try to help somehow/some way. I appreciate you all.

Please save this guidance until we can clear the updated staff guidance, and you will need this to issue revised awards. Note: If your IC is not listed on the attached spreadsheet – no action is required, at this time.

Guidance for IC staff to use when terminating awards identified by HHS or the IC due to DEI or other agency priorities.

- Issue a revised NOA.
    1. Change the budget and project period end dates to match the date of the termination letter.
    2. OPERA will place a hard funds restriction on all documents within the excel spreadsheet. Do not deobigate any funds when you issue the revised award to terminate the projects. If there are no animals and humans, FFR-C will deobligate the awards after the Final FFRs are submitted. No deoblgiation actions required from the ICs.
    3. Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated.
    4. Termination Term to be used **DELETE THE OLD TERM RELATED TO DOLLAR AMOUNTS FOR HARD FUNDS RESTRICTIONS – IT IS NO LONGER APPLICABLE**.

> It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research

Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Thanks,
Michelle

Termination Categories

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

EXHIBIT 7

NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities- March 2025

Issue Date: March 25, 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or other research activities that are not an NIH/HHS priority/ authority. To avoid issuing awards, in error, that support these activities ICs must take care to completely excise all non-priority activities using the following categories.

ICs should review the current application/RPPR under consideration, only. ICs should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted. Categories 1-3 are IC determinations not those ordered by HHS.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/ authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. This applies to all projects, including phased awards, etc.

- **Action:** ICs must not issue the award (competing or non-competing).
- For ongoing projects where NIH will not issue the next Type 5 (IC determination not HHS list), the IC must:
  - Issue a revised award to remove all outyears.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (access limited to CGMOs).
  - Include the following term in the revised NOA:

Term of Award:

It is the policy of NIH not to prioritize research programs related to [insert category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to

submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Check PMS to determine amount of funds remaining, and if funds are available request a hard funds restriction of all funds except $1 in PMS.

- **No cost extension requests:** For second and third NCE's, ICs must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS priority/authority and, if so, issue an award to end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, IC staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly closeout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

  - ICs may use the following term of award when approving/disapproving NCEs:
    - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support orderly closeout of the project, only. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
    - **Term of Award (disapproved extension)**: The no cost extension request for this project has been denied. Please proceed with orderly closeout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award in Section IV of

the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC. OPERA is consulting with eRA on options to collect these application updates in a structured format.
  - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa.] [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section [XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.
- **Action 2:** Once the IC and the applicant/recipient have reached an agreement, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

Term of Award (Approved 2/28/2025 – Refer to Appendix 4 for the approval from Dr. Memoli):

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of

conference (e.g., South Africa, etc.) or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

- **Unable to remove activities that are not an NIH/HHS priority/authority:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Category 4.
- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICs must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the DEI Term and Condition of Award in Section IV of the NOA of the parent grant. The IC must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the IC must revise the prior year award to remove references to those outyear commitments.
- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific topics that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the IC must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the IC must terminate the award following the process in Category 4.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICs receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICs must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authorities

Prospective reviews by GM where the DEI language in certain sections of the application has to be removed even though the project itself is not focused on DEI but may have language or have been awarded from a DEI NOFO that is expired/taken down for revision to go back up once the language is appropriately excised.

Examples below, and in these cases, IC should consider using the Category 2 term of award but remove the negotiation language from the term:

- Resource Section
- Biosketch
- RPPRs

Category 2C:

Subprojects terminated by HHS.

- OPERA will restrict the funds associated with the project. No action required from the IC.

Category 3: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

Category 4/HHS Departmental Authority Terminations:

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the IC must:
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final

FFRs are submitted. There is no deobligation action required from the ICs.

- Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
- Include the following Termination Term in the revised NOA:

  It is the policy of NIH not to prioritize [insert termination category language from Appendix 3, verbatim]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

  NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Note: Appeals language must be included **prior to** October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per 2 CFR 200.340, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).

- eRA provides OPERA with daily reports on NOAs issued, so ICs do not need to report to OPERA on each action completed.

Category 5: Awards to Entities in certain foreign countries

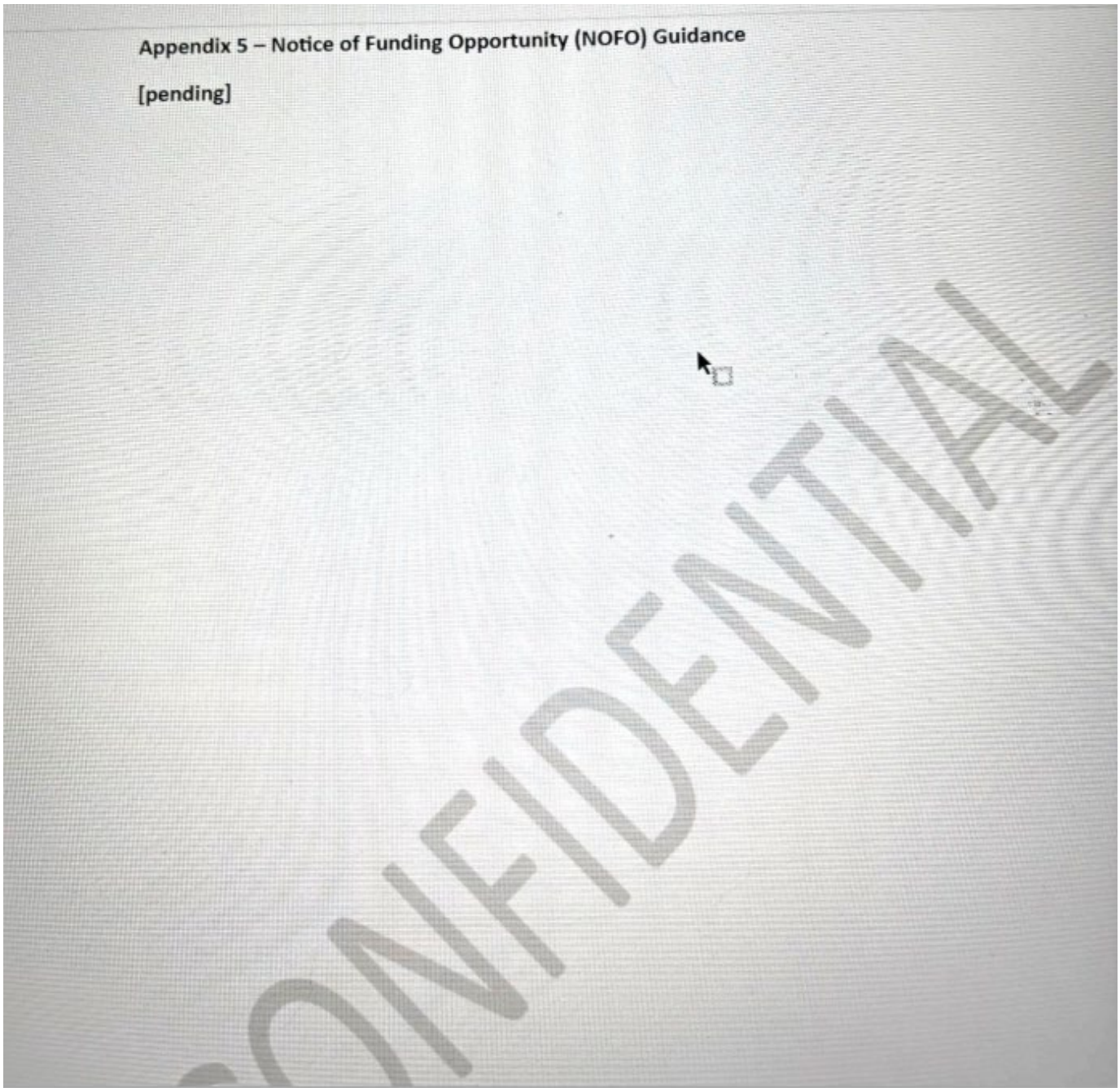
- Additional guidance on awards to foreign entities is forthcoming. At this time, ICs should hold all awards to entities located in South Africa or countries identified on any of the following lists.
  - State Department Countries of Particular Concern
  - State Sponsors of Terrorism
  - Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern
  - Office of Foreign Assets Control Sanctions List

Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
- **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated.
- **Linked (or equivalent) Awards**: If one linked award is terminated, the IC is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the IC and act as appropriate on the remaining awards.
- **Diversity Tables** – Ignore and issue the grant using the term provided above.
- **Diversity Plans** – Ignore and issue the award using the term provided above.

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports. Use this language for HHS terminations only.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination since race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.
- COVID: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.


Appendix 5 – Notice of Funding Opportunity (NOFO) Guidance
[pending]
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Appendix 6 – Frequently Asked Questions

1. **When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICs review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICs do not need to review Other Support for alignment with NIH/HHS priorities/authority.

2. **For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the IC notify the recipient that the Type 4 will not be issued?**

   OPERA is following up on this question, and will provide additional guidance, when available.

3. **When revising awards to terminate a project, how should the IC respond to red bars in SEAR?**

   The IC should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICs can clear the SEAR flag with a comment that the project is being terminated.

4. **If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the IC issue a subsequent Type 2 award?**

   No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

5. **For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?**

   OER is reviewing this policy and will provide additional guidance, when available.

6. **When ICs issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?**

   Yes, ICs must use the exact language provided in Appendix 3, with no edits.