IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*, *Plaintiffs,* v. ROBERT F. KENNEDY, JR., *et al.*, *Defendants.*	No. 1:25-cv-10814-BEM

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

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INTRODUCTION

Congress created the National Institutes of Health to support biomedical research that enhances health, lengthens life, and reduces illness and disability. In the decades since its creation, NIH has done exactly that. The agency's work has powered life-changing scientific advancements in public health—from the discovery of fluoride to prevent tooth decay, to the creation of vaccines against hepatitis, to the use of lithium to manage bipolar disorder. NIH fuels these breakthroughs primarily through financial support to external researchers: last year, the agency awarded more than $36 billion through more than 60,000 grants to institutes of higher education around the country, including public colleges and universities in every plaintiff state.[1] The process of awarding these grants is governed by scientific principles and apolitical, merits-based assessments of proposed research programs, as set forth in comprehensive legislation, detailed regulations, and decades of policy guidance and development.

These norms have been upended in a matter of weeks—and the agency's critical work is now in jeopardy. Since his inauguration on January 20, the President has issued a series of executive orders denouncing federal programs that advance diversity, equity and inclusion (DEI); acknowledge the existence of transgender people; or facilitate gender-affirming care. Taking their cue from these orders, defendants have begun abruptly terminating NIH-funded research projects with a perceived connection—however attenuated—to diversity, minority populations, gender, or transgender individuals. And the list of politically disfavored topics has only grown, now expanded to include vaccine hesitancy and projects related to COVID-19. The consequence has been the

[1] The parties seeking relief in this motion are Massachusetts, California, Maryland, Washington, Arizona, Delaware, Hawai'i, Nevada, New Jersey, New York, Oregon, Rhode Island, and Wisconsin. Colorado, New Mexico, and Minnesota are also plaintiffs but are not parties to this motion. For ease of reference, this memorandum refers to the movant states as "plaintiffs." Plaintiffs seek emergency relief in this motion only with respect to NIH's decision to termination already-awarded grants—*i.e.*, Counts 4, 5, 6, and 8, and part of Count 7 of the Complaint.

early termination of hundreds of previously awarded grants, for research projects and clinical trials that are currently underway, including grants awarded to plaintiffs' public institutions.

These mass terminations are unlawful, and plaintiffs satisfy the criteria for temporary emergency relief. First, plaintiffs are likely to succeed on the merits of their claims. Defendants' decision to terminate plaintiffs' grants is arbitrary and capricious in multiple ways: among other things, defendants failed to adequately explain the basis for their decision and failed to engage in reasoned consideration of any recipients' projects (or the consequences of terminating them). The terminations are also contrary to law: they violate both the regulation that governs NIH's grant awards and the statutory scheme governing NIH research programs generally. And the terminations violate separation-of-powers principles: Congress appropriated funds for NIH research programs that the Executive Branch may not simply choose not to spend. Second, plaintiffs will suffer immediate and irreparable harm if these terminations remain in effect. Among other things, the cessation of funding will immediately jeopardize ongoing research programs that cannot proceed without continued financial support. Third, the balance of equities and the public interest weigh heavily in favor of a temporary restraining order. Plaintiffs have a substantial interest in the successful operation of their research programs and higher education institutions, and the only "harm" defendants will face from a TRO is that they will have to comply with the terms of grant awards that they themselves awarded. For these reasons, the Court should temporarily enjoin NIH's unlawful termination of grants to the plaintiffs and their instrumentalities and subdivisions.

BACKGROUND

I. Congressional Authorization and Appropriation for NIH Research

A. Congress creates NIH and authorizes it to fund biomedical research.

NIH traces its origins to the 1887 establishment of a laboratory to study epidemic diseases. Today, the agency is made up of 27 subsidiary institutes and centers—or "ICs," in NIH parlance—

each focusing on a different disease or body system. 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." *Mission and Goals*, NIH (Oct. 24, 2024), https://www.nih.gov/about-nih/what-we-do/mission-goals.

NIH carries out this mission through both in-house research ("intramural" research) and financial support for research conducted at outside institutions ("extramural" research). Twenty-five of the agency's ICs—all named as defendants—are involved in the process of awarding extramural research grants. Through these efforts, NIH is the primary source of federal funding for biomedical and public health research in the United States. In Fiscal Year 2024 alone, NIH spent over $29 billion on over 40,000 competitive research grants.[2] These awards are critical not only for the funded projects themselves, but also for the future of the biomedical-research enterprise. NIH's grants support postdoctoral fellows, graduate students, and early-career investigators whose work advances scientific discovery and innovation; the funds allow these individuals to access the mentorship, cutting-edge resources, collaborative environments, and professional networks that are essential for educating and training the next generation of scientists.

Congress authorized NIH's extramural research activities through a number of express statutory directives. For example, section 301 of the Public Health Service Act (PHSA) provides that, acting through the "Public Health Service" (an umbrella term that includes NIH), the Secretary of Health and Human Services shall "promote the coordination of[] research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis,

[2] *See Total NIH Budget Authority: FY 2024 Operating Plan*, NIH (Aug. 2024), https://report.nih.gov/nihdatabook/report/5 (outlining the operating plan for FY2024, including $26.5 billion in research program grants and $3.2 billion in other research grants); *NIH Awards by Location & Organization*, NIH, https://report.nih.gov/award/index.cfm (searchable results); *see also 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).

treatment, control, and prevention of physical and mental diseases and impairments." 42 U.S.C. §241(a). The same provision allows the Secretary to discharge this responsibility by awarding grants to universities and other institutions for research projects. *Id.* §241(a)(3). Subsequent PHSA provisions confer similar authority on the directors of NIH's individual ICs. *See id.* §§284(b)(1)(A), 284(b)(2)(A).

Other sections of the PHSA provide more specific directives to each IC, detailing their general purposes and establishing specific programs within each of them. Some of these provisions are directly at odds with the "policy priorities" defendants now invoke to terminate plaintiffs' NIH grants. For example, as described below (*see infra*, pp. 6–9), defendants have purported to terminate already-issued research grants based on their perceived connection to "DEI." This newly stated anti-DEI policy is inconsistent with several statutory directives. The PHSA states, for example, that the NIH director "shall, in conducting and supporting programs for research . . . provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities)," 42 U.S.C. §282(h), and "shall . . . encourage efforts to improve research related to the health of sexual and gender minority populations," *id.* §283p. The statute likewise requires NIH's ICs to conduct research related to women's health or reproductive health, *id.* §285a-6, including, for example, cardiovascular research involving "African-American women and other women who are members of racial or ethnic minority groups," *id.* §285b-7a(c)(1). Statutory directives have also established the 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),[3] and the Office of Research on Women's

[3] 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)-(2).

Health to increase women's representation among NIH institutes and grantees, *id.* §287d(e).

Congress has also established a public process to identify the research priorities of NIH and its ICs. Every six years, the NIH director must "develop and submit to the appropriate committees of Congress and post on [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 ICs similarly develops and promulgates a strategic plan that publicly articulates its research priorities. *Id.* §282(m)(3). Most recently, in 2020, NIH published an updated strategic plan stating, among other things, that 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," as well as rapid vaccine development "to mitigate emerging infectious disease outbreaks" like COVID-19, Ebola virus disease (EVD), and influenza (flu)." NIH, NIH-Wide Strategic Plan, Fiscal Years 2020–2025, at 3, 8 (2020), https://bit.ly/NIHSP2125 (Strategic Plan)

B. Congress appropriates funds for NIH's extramural research.

Most of NIH's funding comes from annual discretionary appropriations from Congress, with specific amounts appropriated to each of NIH's ICs to carry out the purposes set forth in the authorizing statutory provisions described above.[4]

[4] *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, 1573-1577; Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, div. A, tit. II, 133 Stat. 2534, 2562-2565; 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, 3074–76; 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, 131 Stat. 135, 524–27; *see also, e.g.*, Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, div. G, tit. II, 121 Stat. 1844, 2173–77.

In recent years, Congress has specifically rejected efforts to significantly cut NIH's funding. For example, in a budget proposal in 2017, the first Trump Administration sought to slash the "indirect cost rate" for NIH grants, capping researchers' individually negotiated rates 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, abandoning the Government's long-established responsibility" for research infrastructure and jeopardizing "biomedical research nationwide." S. Rep. No. 115-150, at 109 (2017). To avoid this, Congress enacted statutory language (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.

In fact, from Fiscal Years 2017 through 2023, Congress increased NIH funding annually.[5] Congress's 2024 appropriations to NIH were no different. Consistent with past appropriations, Congress appropriated to each of NIH's ICs specific amounts "for carrying out section 301 and title IV of the [PHSA]" with respect each IC's respective statutory purposes. Further Consolidated Appropriations Act, 2024, Pub. L. 118-47, div. D, tit. II, 138 Stat. 460, 656–58.[6]

II. Events Requiring a Temporary Restraining Order

A. NIH formulates a policy of denying funds to projects with a perceived connection to certain politically disfavored topics.

The present state of disruption traces its origin, at least in part, to a series of executive orders issued on or shortly after Inauguration Day. On January 20, President Trump signed

[5] *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341 (reflecting more than 20 years of stable, and generally increasing, NIH funding).

[6] Congress has not enacted a Consolidated Appropriations Act for Fiscal Year 2025, but its recent "continuing resolution" maintains the same level of funding as set forth in the 2024 CAA, through September 30, 2025. *See* Full-Year Continuing Appropriations and Extensions Act, 2025, Pub. L. 119-4, div. A, §1101(a)(8), 139 Stat. 9, 11.

Executive Order 14151, entitled "Ending Radical Government DEI Programs and Preferencing" (DEI Order), which directs federal agencies to "terminate, to the maximum extent allowed by law, . . . all . . . 'equity-related' grants or contracts." Ex. 1, §2(b)(1).[7] 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), which directs 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." Ex. 2, §3(e), (g). On January 21, the President signed Executive Order 14173, entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity" (Discrimination Order), which requires agencies to "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." Ex. 3, §3(b)(iv)(B).

In keeping with the President's directives, by the second week of February, defendants developed a policy that required the termination of grants that did not align with the Administration's priorities. The disfavored categories originally focused on "DEI-related" projects. On February 10, the Acting Secretary of Health and Human Services issued a "Secretarial Directive on DEI-Related Funding" instructing agencies to "briefly pause" all payments made to grantees "related to DEI and similar programs" and advising that "grants may be terminated in accordance with federal law." Ex. 4. The February 10 directive did not define the term "related to DEI and similar programs." *Id.* On February 12, Michael Lauer, then NIH's Deputy Director for Extramural Research, informed NIH's Chief Grants Management Officers that "NIH is in the

[7] Citations to "Ex. __" are to exhibits to the Declaration of Christopher Pappavaselio, unless otherwise indicated.

process of reevaluating the agency's priorities based on the goals on the new administration." Ex. 5. On February 13, Mr. Lauer instructed Chief Grants Management Officers that "[i]f the sole purpose of the grant . . . supports DEI activities, then the award must be fully restricted." Ex. 6. His memorandum 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. *Id.*

By the end of February, defendants' implementation of these directives through mass termination of NIH grants was underway. Defendants targeted not only "DEI," but other subjects identified in the executive orders, too. On February 28, for example, a post on the Department of Government Efficiency's official X account announced over $10 million in canceled grants related to gender-affirming care, sexual orientation, and race. Ex. 7. On or about March 4, NIH issued updated guidance to NIH staff, indicating the specific language NIH staff should use when terminating a grant because of its perceived relation to China, DEI, or "[t]ransgender issues." *Id.*, App. 2. The guidance also stated that "diversity supplements" would be canceled and not issued going forward.[8] By March 13, the list of scientific research disfavored by the Administration had grown yet again—this time to vaccine hesitancy—and NIH's termination of awarded grants grew drastically. That day, Michelle Bulls, NIH's Chief Grants Management Officer, instructed the ICs on how to issue termination letters, and on what bases. Ex. 9. According to her instructions, termination letters were to include the following language: "It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated." *Id.* (bracketed

[8] Diversity supplements are grants to increase diversity in the scientific profession by providing career development resources to individuals from underrepresented populations. NIH has 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 individuals with disabilities, individuals who experienced poverty, or individuals from rural areas. *See 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.

placeholder in original). The termination category language that Ms. Bulls provided included terminations for a program's relation to DEI, gender, and vaccine hesitancy. *Id.*

News outlets reported that on March 25, NIH again distributed updated guidance on grant terminations, yet again expanding the list of politically disfavored subject matters to include COVID-19. These subjects—and the termination language to be included in grant terminations relating to these subjects—were identified as:

- 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 fund these 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.

Ex. 10. To date, NIH has terminated hundreds of grants because those grants allegedly no longer effectuate the agency's priorities. *See* HHS Grants Terminated, HHS, https://taggs.hhs.gov/Content/Data/HHS_Grants_Terminated.pdf.

B. Defendants terminate grants at plaintiffs' public research institutions.

As a result of the foregoing policy directives, plaintiffs' public universities have received numerous letters terminating already-in-progress grants using the boilerplate language Ms. Bulls provided to the ICs. Each termination letter has followed essentially the same form, referring to the research no longer effecting "agency priorities." For instance, the University of Massachusetts (UMass) Amherst received the following on March 21:

> Effective with the date of this letter, funding for Project Number 5R34MH129279-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. §200.340(a)(2). This letter constitutes a notice of termination.
>
> The 2024 Policy Statement applies to your project because NIH approved your grant on 8/16/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."
>
> The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards." According to the Policy Statement, "NIH may . . . terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time your grant was issued, 2 C.F.R. §200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."
>
> This award no longer effectuates agency priorities. 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.

Ex. 12 (at Ex. B) (internal footnotes omitted).

Because the termination letters used the same boilerplate language—which in turn was taken from the NIH staff guidance documents provided to the ICs in February and March 2025—the letters contained no explanation of how the grant recipients' research programs fell within these predetermined categories. Nor did they explain the categories themselves. With respect to the "DEI" category, for example, the termination letters did not define what constituted "artificial

and non-scientific categories"; how to determine whether a research program had an "equity objective"; what made an equity objective "amorphous"; or how NIH determined that the research program involved any such categories or objectives.[9] Similarly, for the gender-identity category, the termination letters did not explain how the research project was "based on gender identity," did not explain the ways in which studies "ignore, rather than seriously examine, biological realities," and did not identify whether (and if so, how) the terminated research program was among such studies.[10] For vaccine hesitancy, the letters did not identify the source or expression of NIH's "policy" not to prioritize research activities that focus on "why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment," or how the research project falls within that category.[11] And for COVID-19, the letters did not identify what they meant by "COVID-related grant funds"; whether the research program received such "COVID-related grant funds"; or the basis for NIH's assertion that such funds had the "limited purpose" of "ameliorat[ing] the effects of the pandemic," rather than the myriad other purposes of scientific research relating to the pandemic—including prevention of the next pandemic.[12]

The terminated grants—which defendants awarded after a thorough review process for scientific merit and consistency with agency priorities—supported a wide range of scientific inquiry, as each of the plaintiff states can attest.

In Massachusetts, for example, UMass has had four active grants terminated, as well as two passthrough awards. Ex. 12 ¶¶14, 18. UMass's terminated grants had funded three studies

[9] Exs. 12 (at Exs. F, H), 14 (at Exs. 2, 3, 5, 6, 7, 8), 15 (at Exs. 22, 32, 34, 38, 44, 45), 18 (at Ex. 6), 19 (at Exs. 2, 3, 8, 9, 10), 20 (at Exs. C, E), 23 (at Exs. A, C), 26 (at Exs. A, B), 27 (at Exs. A, B, D, E, G) & 28 (at Exs. G, H, I).

[10] Exs. 12 (at Ex. D), Exs. 14 (at Exs. 1, 4, 8, 10), 15 (at Ex. 23), 18 (at Exs. 2, 3, 7, 11), 19 (at Exs. 1, 7), 20 (at Ex. A), 27 (at Ex. F), 29 (at Exs. C, D) & 30 (at Ex. B).

[11] Exs. 14 (at Ex. 12) & 27 (at Ex. C).

[12] Exs. 15 (at Ex. 24), 20 (at Ex. G) & 29 (at Ex. A).

aimed at understanding and reducing the spread of HIV among different vulnerable populations and one study on the effects of the quality of behavioral health care on children. *Id.* ¶14. The passthrough awards had funded studies testing COVID treatment in African American communities and improving training for long-term services and dementia care providers treating sexual and gender minority residents. *Id.* ¶17.

Meanwhile, in California, the universities of the California State University (CSU) system have received notices of termination for 17 NIH grants, for a total of nearly $7 million in lost funding to CSU. Ex. 15 ¶¶22, 25. The terminated grants include research into disease prevention and mental health, including suicide prevention. *Id*. ¶28. San Diego State University (SDSU) has received notices of termination for 12 grants for a total of approximately $6.5 million in lost funding to SDSU. Ex. 14 ¶¶50, 52. The terminated grants include research into mental health disparities and rates of suicide as between sexual minority individuals and heterosexual individuals; HIV prevention and interventions; cardiovascular health; eating disorders; and smoking cessation. *Id.* ¶¶55, 56.

Maryland has likewise seen millions of dollars in grants terminated. The University of Maryland, Baltimore (UMB) has received termination notices for 11 awards and one passthrough award, for a total of over $15 million in research funding. Ex. 19 ¶¶27–32. The terminated grants include research into alleviating chronic pain conditions; how the wealth gap impacts health outcomes across different groups; and, in conjunction with three other institutions, training for the next generation of global health scholars. *Id.* ¶32. The University of Maryland, College Park (UMCP), for its part, has received notices of termination for nine NIH grants, for a total of approximately $1 million in research funding lost. Ex. 18 ¶¶22–28. The terminated grants include research into alcohol use and misuse across sexual orientation and gender identity, alcohol and

drug use among sexual minority youth of color, and the diagnosis of autism. *Id.* ¶¶27, 28.

Similarly, the University of Washington (UW) has received notices of termination for at least twelve grants where UW was the primary grantee and multiple grants where a UW researcher is a subgrantee. The terminations will result in the loss of over $2.9 million in research funding to UW. Ex. 27 ¶¶33–37. The terminated grants include research into the impact of anti-LGBTQ policies on sexual minority health; prophylactic treatment of Chlamydia; and a Diversity Supplement for treating lupus. *Id.* ¶¶38–39, 40–41, 44.

This story has played out across the other plaintiff states, as well, as their public universities received the same form letters and immediately lost funding for wide-ranging research projects. These terminations include research for debilitating diseases such as Alzheimer's Disease (*e.g.*, Ex. 24 ¶31 & Ex. E; Ex. 16 ¶¶27–31; Ex. 22 ¶30, Ex. 17 ¶29 (subawardee termination)) and cardiovascular disease (Ex. 24 ¶32); HIV prevention and intervention (Ex. 20 ¶¶35–40; Ex. 26 ¶18); mental and behavioral health conditions, including suicidality (Ex. 32 ¶26); alcohol and substance use and misuse (Ex. 24 ¶30); encouraging Native American students to achieve four-year bachelor's degrees (Ex. 13 ¶5); and training grants designed to encourage historically underrepresented groups to pursue scientific research (Ex. 17 ¶32; Ex. 26 ¶19).

Defendants' terminations based on these the aforementioned politically disfavored categories are ongoing, compounding the uncertainty and instability for plaintiffs' institutions. On April 2, 2025, some plaintiffs received yet another set of funding terminations, for grants that fall within the scope of various programs that promote career development training and other opportunities for professionals from diverse backgrounds. Ex. 12 ¶20.

ARGUMENT

The standard for a TRO is "the same as for a preliminary injunction": the moving party must demonstrate that it is likely to succeed on the merits, that it will suffer irreparable harm absent

emergency relief, and that the equities and public interest favor a TRO. *Orkin v. Albert*, 557 F. Supp. 3d 252, 256 (D. Mass. 2021). Plaintiffs have made those showings here: defendants' unprecedented grant terminations violate the law in multiple ways, and swift judicial intervention is needed to avoid immediate and irreparable harm to ongoing research at plaintiffs' institutions.

I. Plaintiffs have standing to bring their claims.

As a threshold matter, plaintiffs have suffered a textbook Article III injury. "To establish standing, a plaintiff must show an injury in fact caused by the defendant and redressable by a court order." *Webb v. Injured Workers Pharmacy, LLC*, 72 F.4th 365, 372 (1st Cir. 2023). The claims in this case easily satisfy that standard: defendants' terminations directly deprived plaintiffs of federal funding, and an order from this Court will redress that harm. *See id.* (noting that "[t]raditional tangible harms," like "monetary harms," are "obviously concrete" for purposes of showing injury).[13]

II. Plaintiffs are likely to succeed on several independently sufficient grounds.

A. Defendants' decision to terminate plaintiffs' grants violates the APA because it is arbitrary and capricious.

Plaintiffs are first likely to prevail in this litigation because defendants' decision[14] to terminate their grants (and the criteria defendants adopted to select grants for termination) is arbitrary and capricious. 5 U.S.C. §706(2)(A). This "arbitrary-and-capricious standard requires

[13] There can there be no doubt that plaintiffs assert their *own* interests, rather than those of third parties. And some plaintiffs' public research institutions are instrumentalities of the plaintiff States, which have standing to bring suit on their behalf. *See Biden v. Nebraska*, 600 U.S. 477, 488–94 (2023) (noting that harm to a public instrumentality of the State constitutes harm to the State); *Tennessee v. Dep't of Education*, 104 F.4th 577, 588, 590 (6th Cir. 2024) ("[F]or 70 years a state has been able to assert Article III standing via injuries to a state university—the state's agency in the educational field." (quotation marks omitted)).

[14] The decision to terminate plaintiffs' grants is a final agency action subject to the APA. Final agency actions "mark the consummation of the agency's decisionmaking process" and are those "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quotation marks omitted). The terminations here meet both prongs: they announce NIH's definitive decision to end each award, and they immediately suspend funding.

that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). An agency decision flunks this test where, among other things, "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 [made a decision that] 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). Defendants' terminations violate a number of these bedrock APA principles.

First, defendants fail to acknowledge—much less justify—the fact that their termination decisions rest on a *change* in the agency's long-held priorities. While an agency may modify its policies from time to time, the APA "ordinarily demand[s] that [the agency] display awareness that it *is* changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Defendants have done neither of these things. NIH's boilerplate termination letters say simply that plaintiffs' awards "no longer effectuate[] agency priorities." *See supra*, pp. 10–11. That curt statement fails to acknowledge that *the agency itself* has changed its priorities. *See Fox*, 566 U.S. at 515 ("An agency may not . . . depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."). And even if defendants had acknowledged their changes, they have not even tried to "show that there are good reasons" for them. Take defendants' newfound opposition to "DEI." Defendants have terminated hundreds of awards with perceived connections to DEI on the ground that "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." *See supra*, n. 9 (collecting letters). But defendants have offered nothing to back

up those conclusory proclamations—instead, award recipients are left guessing how defendants reached those conclusions and why they applied those conclusions to these specific grants. *Contra SEC v. Chenery Corp.*, 332 U.S. 194, 196–97 (1947) ("It will not do for a court to be compelled to guess at the theory underlying the agency's action; nor can a court be expected to chisel that which must be precise from what the agency has left vague and indecisive.").

Second, defendants have not engaged in reasoned consideration of any *individual* project before terminating a grant. The boilerplate nature of defendants' termination letters makes that clear: there is absolutely no attempt to draw a connection between defendants' new "priorities" and any specific terminated project. Taking the DEI example from the previous paragraph, the termination letters do not explain why a *particular grant* is "unscientific" or fails to "enhance health." The circumstances giving rise to the terminations also suggest that defendants are making termination decisions without the career NIH scientists with knowledge of the projects who usually manage grants. In short, any suggestion that defendants made a reasoned and individualized decision is "incongruent with what the record reveals about the agency's . . . decisionmaking process." *Dep't of Commerce v. New York*, 588 U.S. 752, 785 (2019); *see also Policy & Research, LLC v. HHS*, 313 F. Supp. 3d 62, 83 (D.D.C. 2018) (agency violated APA in failing to "undertake the kind of reasoned analysis of potential causes [for cutting project short] that the APA and its own regulations require").

Third, defendants have "entirely failed to consider" important issues. *State Farm*, 463 U.S. at 43. Most notably, despite taking the unprecedented step of terminating hundreds of grants in the middle of an award year, defendants gave *no* consideration to plaintiffs' reliance interests. That decision to pull the rug out from under grant recipients is inexplicable. When NIH awards a grant, plaintiffs' public research institutions organize their affairs around the expectation that they will

receive continuous funding for at least the full award year (if not the full project term). *See, e.g.*, Ex. 12 ¶22. They hire staff, extend offers of admission to students, purchase equipment, recruit study participants, enter contracts with vendors, and more. *See, e.g.*, Exs. 18 ¶¶45-52; Ex. 27 ¶¶47-53; Ex. 36 ¶¶19-24. The APA required defendants to at least *consider* those reliance interests—and to explain why mid-year termination was nevertheless warranted. *See FDA v. Wages & White Lion Invs., LLC*, No. 23-1038, 2025 WL 978101, at *14 (U.S. Apr. 2, 2025) (explaining that, in changing positions, an agency "must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." (quotation marks omitted)); *see also Nat'l Council of Nonprofits v. OMB*, No. 25-cv-239, 2025 WL 368852, at *11 (D.D.C. Feb. 3, 2025) (concluding that a freeze on federal funds implicates reliance interests that "are all too real").[15]

Fourth, defendants have "relied on factors which Congress has not intended [them] to consider," *State Farm*, 463 U.S. at 43, and that are inconsistent with the relevant authorizing and appropriations statutes. In authorizing NIH to fund biomedical research, the PHSA contains a number of express directives in *favor* of diversity, equity, and inclusion across agency's institutes and in clinical research. *See, e.g.*, 42 U.S.C. §§282(h), 283p; 285b-7a(c)(1), §285t(a), 287d(e), 288(a)(4); *see also supra*, p. 4. It is arbitrary and capricious for defendants to fault projects for a perceived connection to goals that Congress explicitly directed the agency to support.

For all these reasons, plaintiffs are likely to establish that defendants' decision to terminate their grants is arbitrary and capricious.

[15] Reliance interests are just one of a number of important issues that defendants "entirely failed to consider." *State Farm*, 463 U.S. at 43. They also failed to weigh whether plaintiffs' projects could be adjusted, rather than terminated, to comply with defendants' new "priorities"; whether they could have adopted a measure other than across-the-board termination of entire categories of grants to effectuate their new "priorities"; and whether the terminations will harm human test subjects participating in studies terminated mid-stream. All of these failures are fatal under the APA.

B. Defendants' decision to terminate plaintiffs' grants violates the APA because it is contrary to the regulation governing HHS's awards.

Plaintiffs are also likely to succeed in this action because NIH's grant terminations are "not in accordance with law" and were undertaken "without observance of procedure required by law." 5 U.S.C. §706(2)(A); *see Robert E. Derecktor of R.I., Inc. v. Goldschmidt*, 506 F. Supp. 1059, 1063 (D.R.I. 1980) ("Agency action not in accord with regulations is not in accord with law."). In terminating plaintiffs' grants, defendants rely on the 2020 version of 2 C.F.R. §200.340, which contemplates termination in certain circumstances if "an award no longer effectuates the program goals or agency priorities." 2 C.F.R. §200.340(a)(2) (2020). Defendants' boilerplate termination letters maintain that this regulation "permit[s] termination" here because plaintiffs' awards "no longer effectuate[] agency priorities." *See supra*, nn. 9–12. But defendants' reliance on §200.340 is misplaced: that nonbinding guidance does not apply to NIH grants at all, and even if it did, it does not justify defendants' decision to terminate in this case.

1. The governing regulation, 45 C.F.R. §75.372, does not permit termination based on a failure to effectuate "agency priorities."

As an initial matter, defendants err in invoking 2 C.F.R. §200.340 because that nonbinding OMB guidance does not govern NIH grant terminations. And the NIH-specific regulation that *does* govern such terminations does not allow the agency to cancel a grant based on its "priorities."

Section 200.340 appears in a set of OMB regulations that, by its own terms, consists only of nonbinding "guidance" designed to streamline grant procedures across agencies. *See* 2 C.F.R. Subpart A; 2 C.F.R. §1.105(b) (2000) ("Publication of the OMB guidance in the CFR does not change its nature—it is guidance and not regulation."). Instead, what governs the terms and conditions of NIH's grants is HHS's own bespoke implementing regulations in title 45 of the Code of Federal Regulations. *See* 89 Fed. Reg. 80055, 80055 (Oct. 2, 2024) ("[H]istorically, [HHS] has had its own set of implementing regulations . . . ."). HHS first adopted these HHS-specific

regulations "prior to OMB's initial streamlining efforts," *id.*, and has maintained them ever since.

And here is the crucial point: the HHS-specific analogue of §200.340—45 C.F.R. §75.372—has *never* allowed termination based on "agency priorities." In 2013, when OMB initially promulgated the predecessor to §200.340 (then codified at §200.339), the regulation contemplated only three grounds for an agency to terminate an award: (1) if the award recipient "fail[ed] to comply with the [award's] terms and conditions," (2) "for cause," or (3) "with the consent" of the award recipient. 78 Fed. Reg. 78590, 78638 (Dec. 26, 2013). In 2014, HHS codified a version of this nonbinding OMB provision in §75.372. *See* 79 Fed. Reg. 75871, 75919 (Dec. 19, 2014). In doing so, HHS maintained the same three reasons for termination—*i.e.*, it did not adopt an additional ground for failure to effectuate "agency priorities." *See id.*; *see* 81 Fed. Reg. 3004, 3017 (Jan. 20, 2016) (subsequent revision to §75.372 maintaining these same basic grounds).

Indeed, when later presented with an opportunity to modify §75.372 to include "agency priorities" as a possible basis for terminating grants, HHS declined to do so. In 2020, OMB amended §200.340 to remove the clause allowing termination "for cause," replacing it with the language on which defendants now rely, which permits termination "to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities." 85 Fed. Reg. 49506, 49507, 49559 (Aug. 13, 2020). Importantly, however, when HHS subsequently amended §75.372 in November 2020, it did *not* codify these OMB changes into its own termination provision. Instead, §75.372 continued to allow—and to this day still allows—termination only under the three limited circumstances for noncompliance or cause or with consent. 85 Fed. Reg. 72899, 72911, 72903 (Nov. 16, 2020). In sum, defendants' current position—that the 2020 version of §200.340 justifies their terminations—directly conflicts with the above regulatory text and historical backdrop. If defendants could terminate an award directly under §200.340, then §75.372

would be superfluous—in direct contravention of the canon against surplusage in administrative law. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 668 (2007).[16] For that reason, their reliance on §200.340 is contrary to law.

2. Section 200.340 does not allow defendants to terminate grants based on unilateral, post-award changes in "agency priorities."

Defendants also err in invoking §200.340 because, even if did apply to NIH grants, it does not justify termination on the grounds asserted here. The language of that guidance provision does not refer to any "change" in agency priorities as a basis for termination—instead, it says only that termination is possible "if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. §200.340(a)(2) (2020). The most natural reading of that language, in context, is that it covers failures stemming *from the grant recipient—i.e.*, where the recipient can no longer effectuate the goals and priorities that motivated the award in the first place. Defendants' contrary interpretation—that NIH can terminate any award, at any time, for any reason, so long as it incants the words "agency priorities"—would render superfluous a whole host of OMB and HHS regulations dealing with grant terminations. That is not a sensible construction: the notion that the second subclause of a nonbinding provision tucked away in OMB guidance gives defendants this unchecked termination authority is simply not plausible. *See Ryder v. Union Pac. R.R. Co.*, 945 F.3d 194, 203 (5th Cir. 2019) ("[W]e presume that [agencies], no less than Congress, do not hide elephants in mouseholes." (quotation marks omitted)).

Even if the text and structure of OMB's guidance permitted defendants' interpretation, moreover, history forecloses it. When OMB first suggested adding the no-longer-effectuates

[16] HHS has since published an interim final rule that will "fully adopt 2 C.F.R. part 200" effective October 1, 2025, 89 Fed. Reg. 80055, 80056 (Oct. 2, 2024), thereby incorporating "agency priorities" as a ground for termination in HHS's own regulations. But that just further proves the point: if §200.340 already provided HHS all the authority it needed to terminate based on "agency priorities," these amendments would be superfluous.

language to §200.340, commenters "expressed a concern that the proposed language w[ould] provide Federal agencies too much leverage to arbitrarily terminate awards without sufficient cause." 85 Fed. Reg. at 49509. OMB responded that the language did not present that risk because, "as written," the language did not allow agencies "to terminate grants arbitrarily." The agency went on to reassure the public that the changes were designed to ensure that agencies "prioritize *ongoing support* to Federal awards that *meet program goals*." *Id.* at 49507 (emphasis added). Defendants' current interpretation of §200.340(a)(2) is impossible to square with those responses.

3. Plaintiffs' grants did not contain a provision allowing terminations based on "agency priorities," as §200.340 requires.

Finally, defendants may not rely on §200.340 to terminate plaintiffs grants because that guidance requires any "priorities"-related grounds for termination to be included the terms of the grant award. Here, the notices of award for plaintiffs' terminated grants contained no such term. *See, e.g.*, Ex. 12 (at Ex. A at 3-5).

In the 2020 version of its guidance, OMB stated that "[f]ederal awarding agencies *must* make recipients aware, *in a clear and unambiguous manner*, of the termination provisions in §200.340." 2 C.F.R. §200.211(c)(v) (2020) (emphasis added). OMB reiterated this condition in §200.340 itself: "A Federal awarding agency should *clearly and unambiguously* specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section." 2 C.F.R. §200.340(b) (2020) (emphasis added). Taken together, these provisions bar an agency from invoking §200.340(a)(2) unless that provision was fairly, transparently, and unambiguously stated in the grant award.

OMB's 2024 guidance confirms this reading. That guidance combined two provisions from the 2020 guidance—former §200.340(a)(2), permitting termination "if an award no longer effectuates the program goals or agency priorities," and former §200.340(a)(5), permitting

termination "pursuant to termination provisions included in the Federal award"—because one encompassed the other. *See* 89 Fed. Reg. 30046, 30089 (Apr. 22, 2024); 2 C.F.R. §200.340(a)(4) (2024). Thus, the 2024 guidance was intended to clarify what was already true of the 2020 guidance—namely, that a federal agency may terminate a federal grant based on a provision in §200.340 only if that provision was included in the terms and conditions of the award.

Here, rather than a clear statement, the notices of award for plaintiffs' grants contain no reference, clear or otherwise, to the termination provision in §200.340(a)(2). *See, e.g.*, Ex. 12 (at Ex. A at 3-5). That is conclusive: NIH considers those notices to be "the legally binding document" that notifies the grantee that an award has been made. Ex. 11, at I-34. In NIH's own words, the notice "contains or references *all* the terms and conditions of the grant." *Id.* (emphasis added).

In the grant termination letters, defendants maintained that the grant awards incorporated by reference the NIH Grants Policy Statement, which in turn incorporated the provision of §200.340. *See id.* at IIA-155.[17] That argument is unavailing. A derivative incorporation of §200.340, through the award's incorporation of the NIH Grants Policy Statement, does not "make recipients aware, in a clear and unambiguous manner," of the applicability of that provision. 2 C.F.R. §200.211(c)(v) (2020). The NIH Grants Policy Statement is a 400-page document, in which references to §200.340 appear in one paragraph. Where express clarity is required in order to incorporate a particular regulatory provision into a grant award, the Policy Statement's generalized reference to "requirements" is insufficient.

Even on its own terms, the Policy Statement's reference to §200.340 would have indicated that grounds for terminations under that provision were limited to a grant recipient's failure to comply with the award's terms—not that it included a change in "agency priorities." The reference

[17] The complete NIH Grants Policy Statement can be found at https://grants.nih.gov/policy-and-compliance/nihgps.

to §200.340 appears in a section entitled "Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support." Ex. 11, at IIA-155. That section states that grant termination is only authorized "[i]f a recipient has failed to comply with the terms and conditions of award." *Id.* Here, NIH's termination letters made no attempt to claim that the recipients had failed to comply with the awards' terms.

Defendants' interpretation is further refuted by two separate canons of interpretation. First, NIH's assertion in its termination letters regarding §200.340 runs counter to the canon that generally disfavors wholesale incorporation of an entire regulatory scheme. *See St. Christopher Assocs., L.P. v. United States*, 511 F.3d 1376, 1384 (Fed. Cir. 2008). Second, the reference to §200.340 in the NIH Grants Policy Statement had a confined application—to the recipients' failure to comply with the awards' terms—which in turn suggests that only that confined application of the guidance was incorporated by reference into the Grants Policy Statement. *See Montoya v. CRST Expedited, Inc.*, 88 F.4th 309, 323 (1st Cir. 2023) ("Ordinarily, where a specific provision conflicts with a general one, the specific governs.").

For these reasons, too, defendants' actions in terminating plaintiffs' grants are contrary to the regulation governing NIH grant awards (and, to the extent it applies, OMB's guidance)

C. Defendants' decision to terminate plaintiffs' grants violates the APA because it is contrary to the statutes authorizing and appropriating funds to NIH and is in excess of statutory authority.

Plaintiffs are also likely to succeed on the merits of their claims that defendants' grant terminations are contrary to law and beyond statutory authority. *See* 5 U.S.C. §706(2)(A), (C). In terminating plaintiffs' grants, defendants defied Congress's statutory directives to NIH to support research according to publicly promulgated priorities (including those explicitly directed toward now-forbidden DEI), and defied Congress's appropriation of funds to NIH's ICs with the expectation that those funds would be spent in accordance with those statutory purposes and public

priorities.

As described above, duly enacted statutes require NIH and its ICs to encourage and support research, authorizing NIH and its ICs to discharge that responsibility by awarding extramural grants. 42 U.S.C. §284(b)(1) (A), (b)(2)(A). Congress also requires 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. In addition to these general statutory directives, Congress also requires NIH to articulate its priorities via the NIH Strategic Plan, which NIH must develop, submit to the appropriate congressional committees, and post online. *Id.* §282(m)(1). NIH's most recent Strategic Plan, promulgated during the first Trump Administration, stated that 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," as well as vaccine development. Strategic Plan, *supra*, at 3.[18] Consistent with these statutes, Congress consistently has appropriated funds to NIH's ICs with the expectation that defendants will spend the funds in accordance with Congressional directives and NIH's publicly adopted priorities.

This Administration—the first ever to do so—has terminated grants *en masse* based on those grants' perceived connection to "DEI" or other disfavored policies. This action is contrary to law in two ways. First, it plainly violates NIH's own priorities, adopted pursuant to statutory directive, including to promote diversity and address disadvantaged populations. Second, by terminating so many grants with a dwindling opportunity to reallocate funds before they are no longer available, a substantial portion of Congress's appropriation will remain unspent, contrary

[18] Congress has also created institutions and programs within NIH that run afoul of the Administration's anti-DEI priorities like the National Institute on Minority Health and Health Disparities, the Office of Research on Women's Health, and various awards to facilitate the recruitment of women and minorities into biomedical and behavioral research. *See supra*, pp. 4–5.

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."). "While agencies are afforded discretion for certain lump-sum appropriations decisions, their actions still must remain within the bounds of the statute." *Gen. Land Office v. Biden*, 722 F. Supp. 3d 710, 732 (S.D. Tex. 2024) (citation omitted); *see 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 . . . .")).[19] Where, as here, defendants' mass grant terminations effectively dismantle NIH's funding activities without any meaningful likelihood that they can be restored, NIH is flouting its statutory responsibilities. The terminations therefore are contrary to the statutes authorizing and appropriating funds for NIH research and beyond defendants' statutory authority.

D. Defendants' decision to terminate plaintiffs' grants violates separation-of-powers principles.

Finally, plaintiffs are likely to succeed on the merits because defendants' mass grant terminations run afoul of separation-of-powers principles. Under those bedrock principles, the President's authority to act, "[n]o matter the context," "necessarily 'stem[s] either from an act of Congress or from the Constitution itself." *Trump v. United States*, 603 U.S. 593, 607 (2024) (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952)). Here, under the three-part framework set out in Justice Robert Jackson's concurring opinion in *Youngstown*, the

[19] For similar reasons, these actions are judicially reviewable under the APA. Because NIH almost certainly will not use the funds to fulfill permissible statutory purposes (or any purpose at all), NIH is using them in "a statutorily *impermissible* manner," which courts may review. *See California v. Trump*, 379 F. Supp. 3d 928, 953 (N.D. Cal. 2019), *aff'd*, 963 F.3d 926 (9th Cir. 2020) (citation omitted); *see also Lincoln*, 508 U.S. at 193 (holding allocation of lump-sum appropriation was unreviewable "*as long as the agency allocates funds*" to "meet permissible statutory objectives" (emphasis added)).

Executive's authority is at its "lowest ebb," because no constitutional or statutory provision authorizes the Executive to terminate a vast swath of authorized funding simply because it relates to politically disfavored topics, particularly when there will be no meaningful opportunity to reallocate that funding to other permissible purposes.

First, the Constitution does not authorize the Executive's conduct here. The Constitution makes clear that, "[a]bsent congressional authorization, the Administration may not redistribute or withhold properly appropriated funds in order to effectuate its own policy goals." *City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1235 (9th Cir. 2018). That principle follows from Congress's authority over spending: the Constitution "grants the power of the purse to Congress, not the President," and "vests exclusive power to Congress to impose conditions on federal grants." *Id.* at 1231; *see* U.S. Const. art. I, §9, cl. 7 (Appropriations Clause); U.S. Const. art. I, §8, cl. 1 (Spending Clause). The Constitution also grants the legislative power to Congress, limiting the President's role in lawmaking to proposing laws he thinks wise and vetoing those he thinks unwise. *INS v. Chadha*, 462 U.S. 919, 951 (1983) (describing "single, finely wrought and exclusively considered[] procedure" for enacting legislation); U.S. Const. art. I, §7, cls. 2, 3. Indeed, rather than allow the Executive to modify duly enacted laws, the Constitution imposes on the President a duty "to take care that the laws be faithfully executed." U.S. Const. art. II, §3. In all these ways, the Constitution declines to grant the Executive "unilateral authority to refuse to spend" vast swaths of duly authorized and appropriated funding. *See San Francisco*, 897 F.3d at 1231 (quoting *In re Aiken Cnty.*, 725 F.3d 225, 261 n.1 (D.C. Cir. 2013); *see also 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, amend, or to repeal statutes.").

Second, no statute authorizes the Executive's actions here. As set forth above, Congress

consistently has appropriated specific funds to each of NIH's ICs to further the purposes set forth in the PHSA—*i.e.*, to advance and promote medical research, which for years has included billions of dollars of grant awards in furtherance of that purpose. This NIH funding accordingly was duly authorized and appropriated by Congress, and defendants may not unilaterally refuse to spend it by mass-terminating grants. Indeed, Congress has established a comprehensive statutory regime that governs when and how the Executive Branch can decline to spend duly appropriated funds through the Congressional Budget and Impoundment Control Act of 1974, 2 U.S.C. §§681 *et seq.* (ICA). The ICA sets forth the procedure by which the Executive may propose either rescission (*i.e.*, cancellation) of appropriated funding or deferral (*i.e.*, delay) of obligation of such funding. 2 U.S.C. §§683, 684(b). Rather than enabling unilateral Executive action, the ICA requires that 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, no statute authorizes the Executive to mass-terminate these grants, with the effect of preventing the expenditure of vast swaths of appropriated funding.

Because the NIH grant terminations are not authorized by the Constitution or by statute, the President's authority is at "its lowest ebb." *See San Francisco*, 897 F.3d at 1233 (quoting *Youngstown*, 343 U.S. at 637 (R. Jackson, J., concurring)). These terminations accordingly violate separation-of-powers principles and are impermissible. *See id.* at 1234–35.

III. Plaintiffs face irreparable harm absent immediate injunctive relief.

Defendants' decision to terminate plaintiffs' grants has irreparably harmed plaintiffs—and will continue to do so absent immediate injunctive relief. *See, e.g.*, *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005) (explaining that "irreparable harm" exists where injuries "cannot adequately be compensated for either by a later-issued permanent injunction, after a full adjudication on the merits, or by a later-issued damages remedy").

Plaintiffs first face irreparable harm in the form of immediate loss of federal funding to their public institutions. On the evidence before the Court, that injury is irreparable because, even if plaintiffs could someday recover the funds that defendants are now unlawfully withholding, that monetary recovery would not make plaintiffs whole for the harms being done *today*. For example, because of limited institutional resources to fill the gaps left by terminations, some of plaintiffs' public institutions are being forced to "stop activities, reduce project personnel, and shutdown programs." Ex. 15 ¶41. Other terminations, meanwhile, have led to "diminished access to healthcare" for at-risk populations, Ex. 19 ¶¶38–39, or even the euthanization of animal subjects used in testing, *id*. ¶53. *See Massachusetts v. NIH*, No. 25-cv-10338, 2025 WL 702163, at *28 (D. Mass. Mar. 5, 2025) (recognizing irreparable harm from loss of NIH funding).

Further, the abrupt termination of NIH grants has caused—and will continue to cause—operational burdens for plaintiffs' institutions. *See City & Cnty. of San Francisco v. USCIS*, 408 F. Supp. 3d 1057, 1123 (N.D. Cal. 2019) (recognizing "burdens on . . . ongoing operations" and administrative costs imposed on public entities constitute irreparable harm); *Tennessee v. Dep't of Education*, 104 F.4th 577, 613 (6th Cir. 2024) ("unrecoverable compliance costs" constitute irreparable harm). These swift and inexplicable terminations have resulted in chaos and confusion across plaintiffs' institutions, particularly for recipients who found out their grants were terminated the very day the termination became effective. *See, e.g.*, Ex. 12 ¶ 62; Ex. 19 ¶¶45-47; Ex. 27 ¶¶47-53; Ex. 36 ¶¶19-24. Programmatic planning occurs years in advance. The sudden and unexpected nature of the terminations—in the middle of the academic year and budget cycle—has upended months, if not years, of the work of research institutions focused on research program preparation. Plaintiffs have to immediately assess the impact of the loss of funding on their budgets for staff, lab facilities, partner organizations, students; communicate programmatic changes to all identified

and affected parties; and redesign projects when possible or determine whether to end entire projects—and they have to do all of this with urgency, because funding has been shut off without any notice. For example, a San Diego State University project addressing significant suicide risk in young adults was one of the NIH grants terminated. Ex. 14 ¶78. This clinical trial involved over 85 active participants, all of whom have a history of one or more suicide attempts and current suicidal ideation. *Id.* ¶79. These participants were promised six months of clinical care and regular risk assessments as part of their participation; however, the termination of the grant would "cease the provision of essential suicide prevention care" putting these vulnerable patients at risk. *Id.* ¶¶ 80–81. The immediate termination has left no leeway for SDSU to safely transition these participants to alternative resources, if any exist. *Id.* ¶81.

IV. The balance of the equities and public interest favor a temporary restraining order.

The equities and public interest also compel preliminary relief. *See, e.g.*, *Does 1-6 v. Mills*, 16 F.4th 20, 37 (1st Cir. 2021) (noting the balance of equities and the public interest "merge when the [g]overnment is the opposing party") (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

As discussed above, plaintiffs have established a likelihood of success on the merits and irreparable harm to their research institutions. That "extremely high likelihood of success on the merits" shows that preliminary relief "would serve the public interest." *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). After all, "the public has an important interest in making sure government agencies follow the law." *Neighborhood Ass'n of the Back Bay, Inc. v. FTA*, 407 F. Supp. 2d 323, 343 (D. Mass. 2005); *see also Newby*, 838 F.3d at 12 (same). And "[t]here is generally no public interest in the perpetuation of unlawful agency action." *Planned Parenthood of N.Y.C., Inc. v. HHS*, 337 F. Supp. 3d 308, 343 (S.D.N.Y. 2018) (quoting *Newby*, 838 F.3d at 12). Here, plaintiffs have shown that defendants' grant terminations violated the APA and Constitution in myriad ways. There is a strong public interest in restraining defendants' unlawful

actions. *See, e.g.*, *Me. Forest Prods. Council v. Cormier*, 586 F. Supp. 3d 22, 64 (D. Maine 2022). Put simply, the public has an important interest in federal agencies playing by the rules.

Plaintiffs also have a substantial interest in the successful operation of their public health research programs. *See, e.g*., Exs. 19, 21 36. Both plaintiffs and the public suffer significant harm when the Executive terminates swaths of federal funding without any notice or opportunity to account for the loss. The accompanying declarations detail the devastating consequences of the grant terminations and the many ways that the terminations will affect plaintiffs' institutions and communities. The terminations also immediately harm third parties. For example, one terminated grant funded a study at UMB involving more than one thousand 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. Ex. 19 ¶148.

On the other side of the ledger, the federal government faces no "harm from an injunction that merely ends an unlawful practice or reads a statute as required." *R.I.L-R v. Johnson*, 80 F. Supp. 3d 164, 191 (D.D.C. 2015) (quoting *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013)); *see also Newby*, 337 F. Supp. 3d at 343. Because the terminations are unlawful, defendants have no cognizable interest in their enforcement.

The public interest and the equities clearly favor plaintiffs. A temporary restraining order is necessary to protect a vital source of funding for essential government functions.

CONCLUSION

For these reasons, the Court should enter a temporary restraining order.

April 4, 2025

Respectfully submitted.

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CERTIFICATE OF SERVICE

I, Gerard J. Cedrone, certify that on April 4, 2025, I provided a copy of the foregoing document to the following attorneys at the U.S. Department of Justice by electronic mail:

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