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

Leave to File Excess Pages Granted
April 9, 2025 (ECF No. 59)

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Congress created the National Institutes of Health (NIH) to support biomedical research that enhances health, lengthens life, and reduces illness and disability.[1] In the decades since its creation, NIH has done exactly that. The agency's work has powered life-changing scientific advances in public health, from the creation of the rubella vaccine to the development of treatments for HIV. NIH fuels these breakthroughs through financial support to external researchers; the agency awards billions of dollars in grants to research institutions around the country each year. The process of awarding these grants is governed by the apolitical, science-based assessment of proposed projects, as set forth in statutes, regulations, and decades of agency policy.

That longstanding process has been upended in a matter of weeks—and the agency's critical work is now in jeopardy. Since his inauguration, the President has issued a barrage of executive orders denouncing federal programs that advance diversity, equity, and inclusion (DEI) or support transgender health, among other things. Defendants, in turn, have adopted and implemented a series of directives that curtail NIH's support for previously advertised funding opportunities and previously awarded grants that relate to these and other blacklisted topics. The consequences of defendants' actions have been numerous and far-reaching. For example, defendants have abruptly slowed the entire process of reviewing grant applications and issuing research awards so they can weed out proposals with a perceived connection, however attenuated, to blacklisted subjects. They have also enforced their directives by terminating hundreds of ongoing projects *en masse*—without prior notice, in the middle of the academic year—on the ground that the cancelled research had some connection to the blacklisted topics. In short, defendants have disrupted the entire pipeline of federal support for public health research—

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

including proposed or ongoing projects at plaintiffs' public institutions.

The 15 plaintiffs who bring this motion (for ease of reference, "plaintiffs") seek the Court's intervention to prevent these immediate harms. As set forth below, plaintiffs satisfy each of the criteria for preliminary injunctive relief. First, they are likely to show that defendants broke the law in adopting and implementing the challenged directives: the directives violate basic tenets of the Administrative Procedure Act (APA), run afoul of constitutional guarantees, and exceed defendants' statutory authority. Second, plaintiffs will suffer irreparable harm if the directives remain in effect: the cessation of funding has already jeopardized research programs that cannot proceed without continued financial support. Third, the balance of equities and public interest strongly favor a preliminary injunction. Plaintiffs have a substantial interest in the continued operation their academic institutions' research programs, and the only "harm" a preliminary injunction will cause defendants is that they will have to continue supporting public health research—as Congress has directed them to do. For these reasons, the Court should preliminarily enjoin defendants' implementation and enforcement of the challenged directives.

BACKGROUND

I. Legal Framework Governing NIH's Support for Biomedical Research

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

NIH traces its origins to the 1887 establishment of a federal laboratory to study epidemic diseases. Housed within the Department of Health and Human Services (HHS), today's NIH is made up of 27 institutes and centers—"ICs," in NIH parlance—that specialize in discrete diseases or body systems or carry out distinct projects. These ICs carry out NIH's scientific mission through both in-house studies ("intramural" research) and financial support for projects conducted at outside institutions ("extramural" research). NIH's extramural grants make it the primary source of federal funding for biomedical and public health research in the United States: in Fiscal Year

2024 alone, NIH spent over $36 billion on these grants.[2] The awards are critical not only for the funded projects themselves, but also for the future of the biomedical-research enterprise: the grants support graduate students, postdoctoral fellows and early-career investigators, allowing the United States to educate and train the next generation of scientists. Ex. 37 ¶¶2, 4; *see, e.g.*, Ex. 12 ¶22.[3]

Congress authorized NIH's extramural research activities through a number of express statutory directives in the Public Health Service Act (PHSA). Under section 301 of act, the HHS Secretary, acting through the "Public Health Service" (an umbrella term that includes NIH), must "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." 42 U.S.C. §241(a). The same provision allows the Secretary to discharge this responsibility by awarding research grants to universities and other institutions. *Id.* §241(a)(3); *see also id.* §§284(b)(1)(A), 284(b)(2)(A) (similar, for individual IC directors).

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 "priorities" purportedly embodied in the directives at issue in this suit. For example, as described below (*see infra*, pp. 7–11), defendants have prohibited research projects with a perceived connection to "DEI." But the PHSA is replete with provisions that promote diversity, equity, and inclusion, including provisions requiring NIH to (1) increase "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); (2) "improve research related to the health of sexual and gender minority populations," *id.* §283p; (3)

[2] *See* United for Med. Rsch., *NIH's Role in Sustaining the U.S. Economy*, at 5 (March 2025), https://bit.ly/3Xz6Wry.

[3] "Ex." refers to exhibits to the Declaration of Chris Pappavaselio (ECF No. 77) being filed with this motion.

conduct research related to women's health and reproductive health, *id.* §285a-6; and (4) conduct certain research involving "African-American women and other women who are members of racial or ethnic minority groups," *id.* §285b-7a(c)(1). The PHSA also promotes diversity by establishing the National Institute on Minority Health and Health Disparities, which supports research and training "with respect to minority health conditions and other populations with health disparities," *id.* §285t(a),[4] and the Office of Research on Women's Health, which aims to increase women's representation among NIH grantees, *id.* §287d(e).

Congress has also established a public process through which NIH identifies its research priorities. Under the PHSA, 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," called the "National Institutes of Health Strategic Plan," to "provide direction to [NIH's] biomedical research investments." 42 U.S.C. §282(m)(1). Each of NIH's ICs similarly develops, with public input, a strategic plan that publicly articulates its research priorities. *Id.* §282(m)(3). NIH's most recent plan, developed in 2019–20 and adopted in 2021, states that NIH will 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, such as COVID-19, Ebola virus disease (EVD), and influenza (flu)."[5]

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

Most of NIH's funding comes from annual congressional appropriations, with discrete

[4] The statutory term "minority health conditions" means 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).

[5] NIH, *NIH-Wide Strategic Plan, Fiscal Years 2021–2025*, at 3, 8 (2021), https://bit.ly/NIHSP2125 (Strategic Plan).

amounts appropriated to each IC to carry out the purposes set forth in the authorizing statutory provisions described above. *See* Am. Compl. (ECF No. 75) ¶45 n. 15 (collecting appropriations acts). In recent years, these appropriations bills have specifically rejected efforts to cut NIH's funding. For example, in its 2017 budget proposal, the first Trump Administration sought to slash the "indirect cost rate" used to calculate certain payments to NIH grantees. The proposal drew bipartisan criticism, with the Senate Appropriations Committee reporting that the proposal would "abandon[] the Government's long-established responsibility" for research and "jeopardiz[e] 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.[6]

Consistent with past appropriations, in 2024 Congress appropriated to each of NIH's ICs specific amounts "for carrying out section 301 and title IV of the [PHSA]" with respect to each IC's respective statutory purposes. Further Consolidated Appropriations Act, 2024, Pub. L. 118-47, div. D, tit. II, 138 Stat. 460, 656–58; *see* Full-Year Continuing Appropriations and Extensions Act, 2025, Pub. L. 119-4, div. A, §1101(a)(8), 139 Stat. 9, 11 (maintaining same levels).

C. NIH follows a standard process to review extramural grant applications.

NIH generally awards extramural grants through a competitive process established by statutes and regulation. That process begins with a "notice of funding opportunity" (NOFO), in which the agency publicly declares its intention to fund a specific project and outlines the project's goals. *See* Ex. 11 §2.3.5, at I-51. Applications submitted in response to the NOFO then undergo

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

two layers of evaluation: an initial layer of review by a "scientific review group" (also known as a "study section"), followed by "advisory council" review. *See id.* §2.4.1-3, at I-71–76. Both bodies carry out their work at regularly scheduled meetings that must be noticed in advance in the Federal Register. *See* 5 U.S.C. §1009(a)(2); 42 U.S.C. §284a(e); 41 C.F.R. §102-3.150; 42 C.F.R. §52h.3.

Study sections review applications for their scientific merit and likely impact on the field of research. *Id.* §2.4.1.2, at I-72; Ex. 37 ¶¶21–22. NIH has hundreds of study sections, organized by specialty and consisting primarily of non-federal scientists with expertise in the relevant field. *See* 42 C.F.R. §52h.4. For each NOFO, the assigned study section reviews applications and issues each one a numerical "impact score" and a percentile rank comparing it to other applications for the same project. 42 C.F.R. §52h.8; *see also id*. §§52a.5, 52h.11. A favorable study-section recommendation is a prerequisite to a final award. *See* 42 U.S.C. §§284(b)(2)(B), 289a(a).

Each fiscal year, NIH's ICs publish guidance called "paylines" to help applicants interpret their study-section scores. Ex. 12 ¶24. 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. *Id.* In Fiscal Year 2025, for example, published guidance from the National Institute of Allergy and Infectious Diseases (NIAID) established a 12th-percentile payline for the category of "R01" awards with junior principal investigators.[7] In other words, an applicant in that category who received a score from the relevant study section within the 12th percentile—called a "fundable" score—could anticipate that NIAID would likely fund his or her project. Ex. 12 ¶24.

Applications recommended by study sections then proceed to the advisory-council stage. While study sections focus on scientific merit, the advisory councils—one for each IC—weigh programmatic issues, such as how an application aligns with the institute or center's priorities and

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

overall funding availability. Ex. 11 §2.4.3, at I-75–76; Ex. 37 ¶23. A favorable recommendation from the relevant advisory council is a prerequisite to final award of any grant over $50,000. 42 U.S.C. §284(b)(2); *see also id.* §284a(a)(3)(A)(ii). The advisory council's recommendations go to the IC's director, who makes the ultimate funding decision and issues a final "Notice of Award" to successful applicants. *See id.* §284(b)(3); Ex. 11 §5, at IIA-59.

Before the events giving rise to this lawsuit, NIH's application process followed a predictable timetable with three yearly application cycles published in advance. Per the agency's website, 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

See Standard Due Dates, NIH (last updated Aug. 23, 2024), https://grants.nih.gov/grants-process/submit/submission-policies/standard-due-dates.

II. Events Requiring a Preliminary Injunction

A. Defendants promulgate the Challenged Directives to prohibit research 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 around Inauguration Day. On January 20, President Trump signed an executive order entitled "Ending Radical Government DEI Programs and Preferencing" directing federal agencies to "terminate, to the maximum extent allowed by law," all "'equity-related' grants or contracts." Ex. 1, §2(b)(1). The same day, the President signed an executive order entitled

"Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" directing federal agencies to "take all necessary steps, as permitted by law," to strip federal funds from anyone promoting "gender ideology" and to "assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology." Ex. 2, §3(e), (g). The next day, the President signed an executive order entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity" requiring agencies to "include in every contract or grant award" a "term requiring" any "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).

Defendants have since formulated, adopted, and executed a series of directives that carry out and expand upon these executive orders at NIH by blacklisting entire categories of research that the Administration disfavors for political reasons.

First, on January 21, the Acting Secretary of Health and Human Services issued a memorandum to all HHS subcomponents entitled "Immediate Pause on Issuing Documents and Public Communications" (Notice Pause Directive). *See* Ex. 39. 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. *See* Ex. 39, at 1.

Second, on February 10, the Acting Secretary promulgated a "Secretarial Directive on DEI-Related Funding" (Secretarial Directive). The Secretarial Directive instructed NIH personnel to "briefly pause" all payments to grantees "related to DEI and similar programs" and advised that "grants may be terminated in accordance with federal law." Ex. 4, at 1.

Third, NIH's Deputy Director for Extramural Research, Michael Lauer, issued back-to-back memoranda regarding research priorities on February 12 and 13. The first, entitled "NIH Review of Agency Priorities Based on the New Administration's Goals" (Lauer Memorandum),

informed the agency's grants-management officers that "NIH is in the process of reevaluating the agency's priorities based on the goals on the new administration." Ex. 5. The second, styled "Supplemental Guidance" (Supplemental Lauer Memorandum), instructed grants-management officers that "[i]f the sole purpose of the grant . . . supports DEI activities, then the award must be fully restricted." Ex. 6. The Supplemental Lauer Memorandum also called for "hard funding restrictions" for initiatives that "discriminate" on the basis of race, sex, or other protected characteristics, without defining what constituted such discrimination. *Id.*

Fourth, on or about March 4, NIH issued a directive entitled "Award Assessments for Alignment with Agency Priorities—March 2025" (Priorities Directive). Ex. 8. The Priorities Directive stated that "NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI)" and instructed ICs to "completely excise all DEI activities." *Id.* at 1. The directive further instructed ICs to "review the specific aims" of any grant application and "assess whether the proposed project contains any DEI research activities or DEI language." *Id.* The appendices to the Priorities Directive made clear that the topics blacklisted by the current Administration had grown to include "China," "DEI," and "[t]ransgender issues," and provided NIH staff with specific language "to use when terminating awards" related to those topics. *Id.*, Appx. 2. Among other things, the directive explained, NIH staff were 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." *Id.*

Fifth, on March 13, NIH's Chief Grants Management Officer, Michelle Bulls, issued a directive entitled "Award Revision Guidance and List of Terminated Grants via letter on 3/12" (Award Revision Guidance). Ex. 9. The Award Revision Guidance expanded the list of blacklisted topics yet again—this time to include vaccine hesitancy—and instructed the ICs on how to

terminate grants related to the blacklisted topics. *See id.* According to Ms. Bulls' 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 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.*

Sixth, and most recently, 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). Ex. 10. The Revised Priorities Directive added yet another blacklisted topic—COVID-19—and identified the language to use when terminating grants with a perceived connection to any blacklisted topic:

- 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.

Id., Appx. 3. Sometime in mid-March, defendants also issued a directive adding research related to the health effects of climate change as a blacklisted topic (Climate Change Directive).[8]

In sum, defendants have adopted a series of directives that identify blacklisted topics and curtail NIH's support for previously advertised funding opportunities and previously awarded grants relating to those topics. For ease of reference, plaintiffs refer to those directives—including any nonpublic or undisclosed directives—as the "Challenged Directives."

B. Defendants enforce the Challenged Directives against previously advertised funding opportunities and previously awarded grants.

Defendants have taken swift action to enforce the Challenged Directives, with direct and deleterious consequences for both the pipeline of NIH applications and already-issued awards.

1. Enforcement of the Challenged Directives causes unprecedented delays in the review and disposition of plaintiffs' grant applications.

Defendants' quest to prevent NIH from supporting research for blacklisted topics has upended the process of reviewing grant applications and awarding extramural research grants, bringing it to a virtual halt. These delays have manifested themselves in two concrete ways.

First, defendants have impeded the study-section and advisory-council meetings that, as described above, are necessary to the review of grant applications under governing law. According to NIH's published calendar (*see supra*, p. 7), "Cycle II" grant applications—which were reviewed by study sections in fall 2024—should have undergone advisory-council review in January 2025. And indeed, meetings for the advisory councils had been duly noticed for January and February 2025 in the Federal Register.[9] But after Inauguration Day, any meetings that had not yet been held were abruptly canceled. Ex. 12 ¶32. Throughout February and March, various NIH institute

[8] *See* Waldman, *et al.*, *NIH Ends Future Funding to Study the Health Effects of Climate Change*, ProPublica (March 25, 2025), https://www.propublica.org/article/nih-funding-climate-change-public-health.

[9] *See, e.g.*, 90 Fed. Reg. 5920 (NHLBI) (Jan. 17, 2025); 90 Fed. Reg. 2710 (NHGRI) (Jan. 13, 2025); 89 Fed. Reg. 104,554 (NIDA) (Dec. 23, 2024).

websites 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." *E.g.*, Ex. 43. Study sections saw similar cancellations. Applications submitted to NIH last fall in "Cycle III" should have undergone study-section review in February and March of this year, but meetings that had been noticed for January and February were cancelled after Inauguration Day without warning. *See* Ex. 44, at 1. And between January 22 and March 3, defendants suspended the scheduling of future advisory-council or study-section meetings: no meeting notices appeared in the Federal Register during that time. Ex. 40 ¶9.

This is unprecedented. Historically, broad cancellations or changes to noticed meetings have been rare. *See* Ex. 37 ¶25 (former IC director explaining that "[b]efore this year, [he] ha[d] never observed nearly all study sections and advisory councils canceled for a funding cycle"); *see also* Ex. 12 ¶¶30–33. According to an analysis of Federal Register notices, an average of four cancellations 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 per year. Ex. 40 ¶8. While defendants have resumed scheduling some future meetings, they have not done so at a pace that will allow them to meet the timelines that NIH has published and consistently met in the past. The number of meetings scheduled for this fiscal year remains far below the number of such meetings in every fiscal year since 2010, and even further below a level that would make up for the meetings not held in January and February. Ex. 40 ¶13 & fig. 1.[10] And meetings are still being abruptly cancelled. *See, e.g.*, Ex. 45, ¶21.

The consequences of these delays for plaintiffs have been significant. For example, as of

[10] In addition to cancelling previously scheduled meetings, defendants have also taken the unprecedented step of withdrawing previously issued NOFOs. *See* Ex. 19 ¶44 (NOFO abruptly pulled day before application deadline, preventing University of Maryland from submitting renewal application for nearly decade-old program). Some NOFOs were withdrawn after researchers had already expended resources submitting applications. *E.g.*, Ex. 12 ¶56.

April 3, the University of Massachusetts (UMass) has 326 applications awaiting review either by a study section or advisory council. Ex. 12 ¶¶27–28. Of these, (a) 272 are awaiting study-section review; (b) 40 have received fundable scores from study-section review and are awaiting advisory-council review; and (c) 14 have received possibly fundable scores from study-section review and are awaiting advisory-council review. *Id.* For certain grant applications, reviews have been delayed multiple times. Ex. 62 ¶¶6–7. Other states have faced similar delays.[11]

Second, defendants have also systematically delayed and withheld final decisions on applications favorably reviewed by study sections and advisory councils. Again, the consequences for plaintiffs and their institutions are significant. For example, as of April 3, 2025, UMass has 18 applications pending—for $66,119,813 in requested funding—that have received fundable scores and have been reviewed an advisory council but have not been notified of a final determination on funding. Ex. 12 ¶27(c).[12] This withholding of awards has also affected award renewals. When NIH approves a project with a multi-year period, the agency typically awards the grant for the first year at the outset, with funding for subsequent "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

[11] *See* Ex. 14 ¶45 (34 proposals worth $16 million awaiting study section); Ex. 16 ¶24 (77 proposals worth $177 million); Ex. 17 ¶24 (65 proposals); Ex. 19 ¶23 (380 proposals worth $1.04 billion); Ex. 21 ¶23 (41 proposals worth $87.8 million); Ex. 27 ¶18 (more than 500 proposals); Ex. 34 ¶24 (280 proposals worth $731.6 million); Ex. 36 ¶14 (proposals worth $312 million in annualized value); Ex. 52 ¶26 (40 proposals worth 70 million); Ex. 53 ¶23 (13 proposals worth nearly $27 million); Ex. 58 ¶23 (two proposals worth $3 million); Ex. 18 ¶¶18, 20 (multiple study sections canceled and approximately 200 pending proposals worth $354 million); Ex. 62 ¶6; Ex. 63 ¶6.

[12] Other states have experienced similar delays. *See* Ex. 14 ¶46 (10 proposals with fundable scores worth $3.2 million awaiting advisory council); Ex. 16 ¶25 (13 proposals worth $59.8 million); Ex. 17 ¶25 (31 proposals); Ex. 19 ¶24 (32 proposals worth $21.4 million); Ex. 21 ¶24 (36 proposals worth $90 million); Ex. 27 ¶19 (54 proposals worth $138 million); Ex. 34 ¶25 (70 proposals worth $172.4 million); Ex. 36 ¶14 (proposals worth $251 million in annualized value); Ex. 52 ¶27 (four proposals worth $3.2 million); Ex. 53 ¶24 (six proposals worth $19.6 million); Ex. 58 ¶24 (three proposals worth over $2.2 million); Ex. 59 ¶18 (12 proposals worth over $36.5 million); Ex. 62 ¶¶5–7, Ex. 63 ¶6 (two advisory councils delayed, one for five-year grant); Ex. 18 ¶¶7, 18, 43 (grant applications have stalled at preliminary stages after receiving traditionally fundable scores).

complying with applicable policies and practices. *See* 42 C.F.R. §52a.6. Here, too, delays abound. For example, as of April 1, the University of Washington had 73 overdue renewals, totaling over $61 million. Ex. 27 ¶22; Ex. 14 ¶¶44, 48. These overdue renewals have caused significant disruption, jeopardizing ongoing research and forcing staffing reductions, furloughs, and terminations. *Id.* ¶¶24–32.

2. Enforcement of the Challenged Directives leads to the termination of grants at plaintiffs' public research institutions.

Defendants have also enforced the Challenged Directives by terminating hundreds of grants related to blacklisted subjects.[13] As part of those waves of terminations, plaintiffs' public universities and other instrumentalities have received numerous boilerplate letters ending grants in the middle of the academic year. The following March 21 letter to UMass is representative:

> 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.

[13] *HHS Grants Terminated*, HHS (Apr. 11, 2025), https://taggs.hhs.gov/Content/Data/HHS_Grants_Terminated.pdf.

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

Because the termination letters used the same boilerplate language—which came, in turn, from directives like the Priorities Directive, Award Revision Guidance, and Revised Priorities Directive—the letters contained no explanation of how the grant recipients' research programs are even connected to these predetermined categories. Nor did they explain the categories themselves. With respect to the "DEI" category, the termination letters did not explain what constituted "artificial and non-scientific categories" or what made an equity objective "amorphous."[14] For the gender-identity category, the termination letters did not explain how, for example, a project purportedly "based on gender identity" "ignore[s], rather than seriously examine[s], biological realities."[15] For vaccine hesitancy, the letters did not identify the source or content 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."[16] And for COVID-19, the letters did not identify what was meant by "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.[17]

The terminated grants themselves—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 plaintiffs can attest.

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[14] Exs. 12 (at Ex. H), 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).

[15] Exs. 12 (at Ex. D), 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); Ex. 65 ¶10.

[16] Ex.27 (at Ex. C); *see also* Ex. 65 ¶11 (terminating grant assessing effectiveness of shingles vaccine not individuals' vaccine hesitancy).

[17] Exs. 20 (at Ex. G) & 29 (at Ex. A).

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 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.* ¶18.

Meanwhile, in California, the universities of the California State University (CSU) system have received notices of termination for more than 17 NIH grants, initially totaling $ 7 million. Ex. 15 ¶¶22, 25. With additional terminations, losses have grown to over $20 million. Ex. 62 ¶5. The University of California, San Francisco has received notices of termination for 52 grants, totaling several million dollars. Ex. 65 ¶¶6, 10. The terminated grants include research into disease prevention and mental health disparities, including suicide prevention, HIV prevention and interventions, cardiovascular health, eating disorders, and smoking cessation. Ex. 15 ¶28; Ex. 14 ¶¶55, 56.

Maryland has likewise seen millions of dollars in grants terminated. The University of Maryland, Baltimore (UMB) has received termination notices for 14 awards, for a total of over $33 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.* ¶¶38–41, 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. 16 ¶¶27–31; Ex. 17 ¶29; Ex. 22 ¶30; Ex. 24 ¶31 & Ex. E; Ex. 64 ¶10); 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).

Even as this lawsuit has been underway, terminations based on the Challenged Directives have continued to roll in, compounding the uncertainty and instability for plaintiffs' institutions. *See, e.g.*, Ex. 45, ¶¶18-21.

3. Enforcement of the Challenged Directives leaves billions in congressionally appropriated funds unspent.

As a result of the delays and terminations described above, NIH has failed to award billions of dollars appropriated by Congress, with only a few months left of available funding. In

comparison to the $4.08 billion that the agency awarded to 8,071 projects in Weeks 4 to 11 of 2024, it awarded just $2.45 billion to 4,961 projects in the same time period this year. Ex. 61 ¶7. Focusing on a comparison of Weeks 6 to 11 in both years, the comparison is even more striking: $576 million to 1,342 projects last year compared to $180 million to 395 projects for this year—a reduction of approximately 69%. Ex. 61 ¶8.

ARGUMENT

To obtain 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 an injunction. *U.S. Ghost Adventures, LLC v. Miss Lizzie's Coffee LLC*, 121 F.4th 339, 347 (1st Cir. 2024). 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. This Court, not the Court of Federal Claims, has jurisdiction over plaintiffs' claims.

Defendants will likely argue, as the federal government has in other recent cases, that plaintiffs' claims belong in Court of Federal Claims under the Tucker Act as breach of contract claims. *See* 28 U.S.C. §1491(a)(1) (vesting jurisdiction in the Claims Court for actions based on an "express or implied contract with the United States"). That argument contravenes two elemental jurisdictional rules: that districts court have jurisdiction over claims that challenge unconstitutional and *ultra vires* conduct by federal officials, and that district courts have jurisdiction over challenges to final agency action under the APA, even when a remedial order may result in "the payment of money by the Federal Government." *Bowen v. Massachusetts*, 487 U.S. 879, 910 (1988); *see Linea Area Nacional de Chile S.A. v. Meissner*, 65 F.3d 1034, 1042–43 (2d Cir. 1995) (citing *Bowen* in holding that request for reimbursement under statutory entitlement not a claim for money damages and fell within APA's waiver of sovereign immunity); *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968–

70 (D.C. Cir. 1982) (holding that, even where plaintiff has a contract with the government, district courts have jurisdiction over claims not based on the contract). Applying those rules here, plaintiffs' constitutional, equitable, and APA claims are within the core of this Court's jurisdiction.

Start with plaintiffs' constitutional and equitable claims. It is well-established that plaintiffs may challenge unconstitutional and *ultra vires* conduct by federal officials in district court. *See* 28 U.S.C. §1331 (conferring "original jurisdiction of all civil actions arising under the Constitution"); *see, e.g.*, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326–27 (2015) (recognizing federal courts' power to enjoin federal officials from exceeding the bounds of their constitutional and statutory authority). It is equally well-established that the Tucker Act does not cover such claims for prospective, equitable relief. To be "cognizable under the Tucker Act," a claim "must be one for money damages against the United States," and "the claimant must demonstrate that the source of substantive law he relies upon can fairly be interpreted as mandating compensation by the Federal Government for the damages sustained." *United States v. Mitchell*, 463 U.S. 206, 216–17 (1983) (quotation marks omitted). That description plainly does not apply to plaintiffs' constitutional causes of action and *ultra vires* claims.

Nor does it apply to plaintiffs' APA claims. Section 702 of the APA waives the United States' sovereign immunity for claims requesting judicial review of agency actions and "seeking relief other than money damages." 5 U.S.C. §702. Here, plaintiffs ask the Court to set aside the Challenged Directives, including actions taken to implement them, and they seek an order requiring defendants to undertake actions unlawfully withheld or unreasonably delayed. Those requests are textbook examples of APA claims—not the stuff of a contractual-damages claim. That is true even though a decision in plaintiffs' favor might have financial consequences: as the Supreme Court has made clear, an "action for specific relief" under the APA does not become an

action for money damages merely because setting aside the challenged agency action could "require the payment of money by the federal government." *Bowen*, 487 U.S. at 893–94.

The Supreme Court's decision in *Bowen* sheds light on this distinction between claims for money damages (which belong in the Claims Court) and APA claims for specific relief (which belong in district court). There, Massachusetts challenged the Secretary of Health and Human Services' disallowance of certain federal Medicaid reimbursements; the Commonwealth asked the district court to set aside the Secretary's decision and enjoin the agency from "failing or refusing to reimburse the Commonwealth" the "federal share of expenditures" it was due. *Id.* at 882, 887 n. 10; *see id.* at 893–84. In response, the Secretary sought to characterize the Commonwealth's claim as one for "money damages" and argued that the Claims Court had exclusive jurisdiction under the Tucker Act. *See id.* at 890. But the Supreme Court sided with Massachusetts. As the Court explained, "[t]he fact that a judicial remedy may require one party to pay money to another is not a sufficient reason to characterize the relief as 'money damages.'" *Id.* at 893. Instead, "money damages" means "a sum of money used as compensatory relief . . . to *substitute* for a suffered loss." *Id.* at 895. And Massachusetts' was not a suit for money damages because the Commonwealth sought a form of "specific relief" to "enforce the statutory mandate itself, which happens to be one for the payment of money." *Id.* at 900. In other words, Massachusetts sought "the very thing to which [it] was entitled," *id.* at 895, rather than "money in *compensation* for the damage sustained by the failure of the Federal Government to pay as mandated." *Id*. at 900. And so the claim fell within the scope of §702's sovereign immunity waiver. *See id.* at 893, 910.

This case is like *Bowen*. Here, plaintiffs here do not seek money "in *compensation* for the damage sustained by the failure of the Federal Government to pay as mandated." *Id.* at 900. Rather, as in *Bowen*, they "challenge[] the Federal Defendants' compliance with the APA, alleging

the Federal Defendants failed to follow the proper procedure[s]." *Maine v. U.S. Dep't of Agriculture.*, No. 1:25-cv-131, 2025 WL 1088946, at *19 (D. Me. Apr. 11, 2025). In other words, plaintiffs seek "the very thing to which [they are] entitled," *Bowen*, 487 U.S. at 895—specific relief that sets aside the Challenged Directives, voids actions taken to implement the Challenged Directives, and compels defendants to undertake actions they have unlawfully withheld. "Although, as in *Bowen*, a decision in [plaintiffs'] favor" could "result in 'the payment of money by the Federal Government to the State,' 'this outcome is a mere by-product of [the Court's] primary function of reviewing [defendants'] interpretation of federal law." *Maine*, 2025 WL 1088946, at *19 (quoting *Bowen*, 487 U.S. at 909–10). Thus, this Court has "jurisdiction under §702 to review" the Challenged Directives and to grant plaintiffs "the complete relief authorized by [the APA]." *Bowen*, 487 U.S. at 910–11; *see also, e.g.*, *Randall v. United States*, 95 F.3d 339, 347 (4th Cir. 1996) (reviewing relationship between APA and Tucker Act and concluding that plaintiff's claims "were primarily for equitable relief"); *Maine*, 2025 WL 1088946, at *19 (D. Me. Apr. 11, 2025) (holding that APA claims challenging improper freezing of federal funding belonged in district court even though injunction would "likely result" in "the payment of money").

The Supreme Court's recent motion order in *California v. Department of Education*, No. 24A910, 2025 WL 1008354 (Apr. 4, 2025), does not compel a different result. As an initial matter, that order was not a decision on the merits. It issued from the Court's "emergency docket, without full briefing or hearing, and its precedential value is thus limited." *Maine*, 2025 WL 1088946, at *19 n. 8 (citations omitted); *see also Merrill v. Milligan*, 142 S. Ct. 879, 879 (2022) (Kavanaugh, J., concurring) ("The Court's stay order is not a decision on the merits"); Order at 6, *Sustainability Inst. v. Trump*, No. 2:25-cv-2152 (D.S.C.) (Apr. 9, 2025) (ECF No. 52) ("The Supreme Court's brief treatment of *Bowen* and *Great-West Life* in *California* and the cursory mention of potential

jurisdictional issues do not appear to settle all jurisdictional questions in this case."). Even on its own terms, however, the Court's stay order in *California* does not suggest that this case belongs in the claims court, for at least two reasons.

First, the order cited *Bowen* as controlling law and rested on the Court's reasoning that the TRO in that case might "enforce a contractual obligation to pay money." *California*, 2025 WL 1008354, at *1. As already explained, however, *Bowen* points to a different outcome in this case, because plaintiffs do not ask this Court to enforce contractual obligations or award retrospective money damages. Instead, as in *Bowen*, plaintiffs ask the Court to set aside unlawful agency decisions—*i.e.*, "ongoing polic[ies] that ha[ve] significant prospective effect." *Bowen*, 487 U.S. at 889. The APA empowers this Courts to review those policies. *See id.* at 909–10.

Second, the Court in *California* questioned whether the plaintiffs there could establish irreparable harm, because it accepted the defendants' contention that the plaintiffs had "the financial wherewithal to keep their programs running." 2025 WL 1008354, at *1. But that is decidedly not the case for plaintiffs here; their educational institutions do not have the means to indefinitely support researchers while awaiting action on grant applications or to supply millions of dollars of funding for programs that have been terminated in the middle of the academic year, with no prior notice. *See infra*, pp. 37–38 (discussing irreparable harms to plaintiffs).[18] Nor can plaintiffs avoid ongoing and irreparable nonmonetary harms, like budgeting uncertainty and harm to recruiting efforts. *See id.* As *Bowen* made clear, challenging agency actions that cause such

[18] Some—but not all—of plaintiffs' institutions have been able to supply emergency funding to temporarily blunt the impact of these harms, but this emergency funding cannot avoid irreparable harm to plaintiffs' institutions absent prompt relief from this court. *See, e.g.*, Ex. 18 ¶¶32, 35, 41 (in Maryland, no financial resources available for stopgap funding); Ex. 25 ¶23 (in New York, stopgap funding limited to two weeks); Ex. 17 ¶37 (in Hawai'i, $18,000 in stopgap funding can cover student payroll only through year-end); Ex. 34 ¶¶6, 45 (stopgap funding drawn from limited funds); Ex. 49 ¶¶5, 7–11 (no alternative sources of funding available at CSU); Ex. 65 ¶¶7, 10–11 (UC preparing to lay off grant specific staff, including clinical monitoring staff and monetary relief unable to replace expertise of staff or repair lack of scientific validity from incomplete study data).

harms does not amount to a request for "money damages"—even if "a judicial remedy may require one party to pay money to another." 487 U.S. at 893.

For all these reasons, this Court has jurisdiction to hear plaintiffs' claims.

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

A. Plaintiffs are likely to establish that defendants violated APA §706(2).

The APA requires a Court to "hold unlawful and set aside agency action" that is "arbitrary [or] capricious," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "otherwise not in accordance with law." 5 U.S.C. §706(2)(A), (C). Plaintiffs are likely to succeed in this action because, in adopting and enforcing the Challenged Directives, defendants violated these fundamental tenets of administrative law.[19]

1. The Challenged Directives conflict with duly enacted statutes.

The Challenged Directives first violate §706(2) because they violate Congress's statutory prescriptions in three concrete ways. *See* 5 U.S.C. §706(2)(A), (C).

First, the Challenged Directives purport to restrict research on subjects that Congress has expressly required NIH to *support*. Take the issues of "DEI," gender identity, and transgender health. As described above, the PHSA *requires* NIH to conduct research related to the health of women and racial, ethnic, sexual, and gender minorities. *See supra*, pp. 3–4 (citing 42 U.S.C. §§282(h), 283p, 285a-6, 285b-7a(c)(1)). Indeed, Congress has established an entire institute—the National Institute on Minority Health and Health Disparities—to advance the health of individuals in racial or ethnic minority groups. *See* 42 U.S.C. §285t(a). In declaring research related to DEI,

[19] The Challenged Directives are final agency actions subject to the APA. Final agency actions (1) "mark the consummation of the agency's decisionmaking process" and (2) determine "rights or obligations" or trigger "legal consequences." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597 (2016) (quotation marks omitted). The Challenged Directives do both: they (1) set forth NIH's position and instructions relating to the blacklisted research categories and (2) contain action items (for example, "ICs must not issue the award") which immediately affected NIH's obligations toward grantees and grant applicants. *See Biden v. Texas*, 597 U.S. 785, 808–09, 2545 (2022) (holding that agency memoranda were final agency action where they "bound [agency] staff").

gender identity, and transgender health off-limits, the defendants have improperly "substitute[d] their policy judgments for those of Congress." *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000). The APA does not allow an agency to thumb its nose at Congress in this way. *See, e.g.*, *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994) (explaining that a court may not accept "the agency's policy judgments . . . if they conflict with the policy judgments that undergird the statutory scheme").

Second, the Challenged Directives are inconsistent with statutory provisions requiring NIH to articulate its research priorities through a formal and public strategic plan. As discussed above, 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). Although new administrations are certainly permitted to shift priorities in NIH research, the scale at which defendants have disrupted previously issued opportunities and awards is irreconcilable with Congress's intention that strategic priorities be developed and formalized publicly and in advance of an awards process. In the face of §282(m)'s calibrated procedure for establishing the agency's strategic vision, defendants cannot alter that vision overnight.

Third, and finally, the adoption and enforcement of the Challenged Directives exceed defendants' statutory authority because they conflict with duly enacted congressional appropriations. Congress allocated certain sums of money to NIH so that the agency could use those sums during the fiscal year. *See supra*, pp. 4–5 & n. 6; *see also* Am. Compl. (ECF No. 75)

¶45 n. 15 (collecting authorities). 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. The upshot: a substantial portion of Congress's appropriation will remain unspent, contrary to the purpose for which the funds were appropriated and Congress's longstanding and well-established framework of NIH funding. That is unlawful. *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"); *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"). Because enforcement of the Challenged Directives effectively "impounds" appropriated funds, defendants are flouting their statutory responsibilities, and the adoption and enforcement of the Challenged Directives is contrary to duly enacted statutes.

2. The Challenged Directives conflict with governing regulations.

Plaintiffs are next likely to show that the Challenged Directives violate §706(2) because they are not in accordance with controlling regulations. 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 adopting and enforcing the Challenged Directives, defendants invoke 2 C.F.R. §200.340 (2020), which contemplates termination of federal grants in certain circumstances if "an award no longer effectuates the program goals or agency priorities." But defendants' reliance on that provision is misplaced for two reasons.

First, defendants err in invoking 2 C.F.R. §200.340 (2020) because it does not apply to—much less control—NIH grant terminations. Section 200.340 appears in a set of OMB regulations (2 C.F.R., subtitle A) that, by its own terms, consists only of nonbinding "guidance" designed to

streamline procedures across agencies. *See* 2 C.F.R. §1.105(b) (2020) ("Publication of the OMB guidance in the CFR does not change its nature—it is guidance and not regulation."). The NIH grant-award process is instead governed by HHS's own bespoke implementing regulations in C.F.R. title 45. *See* 89 Fed. Reg. 80,055, 80,055 (Oct. 2, 2024) ("[H]istorically, [HHS] has had its own set of implementing regulations . . . ."). HHS adopted these HHS-specific regulations "prior to OMB's initial streamlining efforts," *id.*, and has maintained them ever since.

Crucially, the HHS-specific regulations in title 45 have *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. 78,590, 78,638 (Dec. 26, 2013). In 2014, HHS codified a version of this nonbinding OMB provision in 45 C.F.R. §75.372. *See* 79 Fed. Reg. 75,871, 75,919 (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.*; 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 a failure to effectuate "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. 49,506, 49,507, 49,559 (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. 72,899, 72,911, 72,903 (Nov. 16, 2020). Defendants' current position—that the 2020 version of §200.340 allows them to enforce the Challenged Directives by terminating existing grants—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—contra the canon against surplusage. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 668–69 (2007).[20] Thus, the Challenged Directives' reliance on §200.340 is contrary to law. *See Nat'l Env't Dev. Assn's Clean Air Project v. EPA*, 752 F.3d 999, 1003 (D.C. Cir. 2014) (setting aside an EPA "directive" that was "plainly contrary to EPA's own regulations").

Second, even if §200.340 did apply to NIH grants, it does not independently authorize defendants to terminate grants based on unilateral, post-award changes in "agency priorities." The language of §200.340 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' apparent interpretation—that "agency priorities" includes agency priorities identified *after* the grant is awarded—would not only produce the absurd result of permitting NIH to terminate any award by simply changing its mind, but would also render superfluous a whole host of OMB and HHS regulations dealing with grant terminations. That is not a sensible

[20] 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. 80,055, 80,056 (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.

construction: the notion that the second subclause of a nonbinding provision tucked away in OMB guidance gives defendants this sweeping power is not credible. *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 proposed the language on which defendants now rely, commenters objected "that the proposed language w[ould] provide Federal agencies too much leverage to arbitrarily terminate awards." 85 Fed. Reg. at 49,509. OMB disagreed: "as written," the agency explained, the language did not allow agencies "to terminate grants arbitrarily" and was designed to ensure that agencies "prioritize ongoing support to Federal awards that meet program goals." *Id.* at 49,507. Defendants' current interpretation of §200.340(a)(2) is impossible to square with those responses. *See Kisor v. Wilkie*, 588 U.S. 558, 579 (2019) (courts should not defer to an agency's new interpretation of a regulation if it creates unfair surprise or upsets reliance interests).

3. The Challenged Directives are arbitrary and capricious.

Finally, plaintiffs are likely to show that the Challenged Directives violate §706(2) because they are arbitrary and capricious. The "arbitrary-and-capricious standard requires 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 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 [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' Challenged Directives violate each of these principles.

First, defendants fail to acknowledge—much less justify—the fact that the Challenged

Directives 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 not done so. Take their newfound opposition to "DEI." The Challenged Directives claim that support for DEI is "inconsistent with the Department's policy of improving the health and well-being of all Americans." Ex. 4. Such cursory statements fail to acknowledge that the agency itself has *changed* its priorities. *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."). A review of the NIH's operative Strategic Plan confirms that defendants have effected a *sub silentio* change in agency priorities. As discussed above, NIH's most recent Strategic Plan, developed during the first Trump Administration, stated that NIH would prioritize women's and minority health and the development of vaccines to prevent infectious-disease outbreaks. Strategic Plan, *supra*, n. 5, at 3. It is impossible to square the Challenged Directives' blacklisted topics with those goals.

And even if defendants had acknowledged their changes, they have not even tried to "show that there are good reasons" for them. *Fox*, 566 U.S. at 515. Again consider defendants' opposition to "DEI." Following instructions in the Challenged Directives, defendants have terminated hundreds of awards with perceived connections to DEI *en masse* 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. 14. 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 them to 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 . . . .").

Second, the Challenged Directives are arbitrary and capricious because they contain little to no reasoning as to why the blacklisted topics were chosen, nor do they allow any reasoned consideration of individual projects in their implementation. Instead, they flatly require that any grants relating to the blacklisted categories be terminated (if previously awarded) or not funded (if applied for). The boilerplate nature of defendants' termination letters makes that clear. The language is drawn verbatim from "language provided to NIH by HHS" in Appendix 3 of the Priorities Directive and Revised Priorities Directive; there is absolutely no attempt to draw a connection between defendants' new "priorities" and any specific project. In short, any suggestion that defendants' directives are reasoned and individualized decisions 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 Pol'y & Rsch., 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, in issuing and implementing the Challenged Directives—including by delaying the scheduling of study sections and advisory councils, unpublishing NOFOs to which grant applications had already been submitted, and mandating the unprecedented termination of 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 applicants and grant recipients is inexcusable. When NIH issues NOFOs, plaintiffs' public research institutions invest resources in applying for those opportunities in reliance on the established rules and procedures governing

the application process. *See, e.g.*, Exs. 12 ¶¶60, 61; Ex. 18 ¶34. And 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; Ex. 49 ¶9. 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 their sudden change of course 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 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 federal-funding freeze implicated "all too real" reliance interests).[21]

For all these reasons, plaintiffs are likely to establish that defendants' Challenged Directives are arbitrary and capricious.

B. Plaintiffs are likely to establish that defendants violated separation-of-powers principles, the Spending Clause, and the equitable prohibition against *ultra vires* action.

Plaintiffs are also likely to succeed on the merits because defendants' adoption and enforcement of the Challenged Directives runs 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*,

[21] 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 not funded altogether, to comply with defendants' new "priorities"; whether they could have adopted a measure other than across-the-board de-funding of entire categories of grants to effectuate their new "priorities"; and whether the de-funding will harm human or animal test subjects participating in studies suspended or ended mid-stream. All of these failures are fatal under the APA.

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 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. *See Youngstown*, 343 U.S. at 637 (R. Jackson, J., concurring).

First, the Constitution does not authorize defendants' actions. 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 & County 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 exhaustively 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. *San Francisco*, 897 F.3d at 1232 (quoting *In re Aiken County*, 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, to amend, or to repeal statutes.").

Second, no statute authorizes defendants' actions. As set forth above, Congress consistently has appropriated billions of dollars each year for NIH and its ICs to further their missions by awarding grants. Defendants may not unilaterally refuse to spend this duly appropriated funding by indefinitely delaying funding decisions and 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 of appropriated funding or deferral of obligation of such funding. 2 U.S.C. §§683, 684(b). Far from 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. Accordingly, no statute authorizes the Executive to delay decisionmaking on pending grant applications or to mass-terminate existing grants, with the effect of preventing the expenditure of vast swaths of appropriated funding.

Because defendants' adoption and implementation of the Challenged Directives are not authorized by the Constitution or statute, the President's authority is at "its lowest ebb." *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, the Spending Clause, the equitable prohibition against *ultra vires* action, and are impermissible. *See id.* at 1234–35.

C. Plaintiffs are likely to establish that defendants violated APA §706(1) by unlawfully withholding and unreasonably delaying required agency action.

For the reasons discussed in Parts I-A and I-B above, plaintiffs are likely to show that the

Court should set aside the Challenged Directives in their entirety and enjoin any action to enforce or implement them. At the very least, however, plaintiffs are entitled to an order under 5 U.S.C. §706(1) compelling defendants to undertake the actions they have withheld or delayed as a result of the directives. To prevail on a claim under §706(1), a plaintiff must show that (1) the action in question is "a discrete agency action that it is required to take," and (2) the agency failed to take, or unreasonably delayed in taking, that action. *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). Both criteria are satisfied here.

1. Defendants are required to hold study-section and advisory-council meetings and to issue final decisions on grant applications.

As described above, defendants have cancelled and declined to schedule study-section and advisory-council meetings, and they have refused to issue final decisions on pending grant applications and renewals. *See supra*, pp. 11–14. These are all "discrete agency action[s]" that NIH is "required to take." *S. Utah Wilderness All.*, 542 U.S. at 64.

First, by statute and regulation, 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 discrete agency actions that NIH is required to take. As discussed above, the PHSA provides that applications for NIH research grants *must* undergo "technical and scientific peer review." 42 U.S.C. §§284(b)(2)(B), 289a(a). Regulations, in turn, 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." 42 C.F.R. §52h.7.

For similar reasons, the activities of NIH's advisory councils are discrete agency actions that NIH is required to take. The PHSA states that each NIH institute's advisory council "*shall*

meet . . . at least three times each fiscal year," 42 U.S.C. §284a(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.* §284a(a)(1) (emphasis added). The PHSA also makes sign-off from an advisory council 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). Likewise, 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.

Finally, the issuance of a timely, up-or-down decision on grant applications is a discrete and required agency action. Under NIH regulations, "[a]ll applications" for grants "*shall* be evaluated by the [HHS] Secretary [or his designee] through [qualified] officers and employees." *Id.* §52.5(a) (emphasis added). "[S]ubject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be required by law," those regulations state, "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). And, more generally, 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).[22]

2. Defendants unreasonably delayed the foregoing actions.

To determine whether an agency has unreasonably delayed a discrete and required action,

[22] Crucially, the fact that defendants may exercise discretion in deciding whether to grant or deny a particular application does not mean they have the discretion to refuse to issue a decision on the applications at all. *See Tang v. Chertoff*, 493 F. Supp. 2d 148, 154 (D. Mass. 2007) ("[W]hile it is undisputed that the substance of the Attorney General's decision is discretionary, he does not have discretion to decide not to adjudicate at all.").

courts ordinarily look to the six so-called "*TRAC* factors." *Town of Wellesley v. FERC*, 829 F.2d 275, 277 (1st Cir. 1987) (applying *Telecomms. Rsch. & Action Ctr. v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) (*TRAC*)).[23] Here, those factors clearly show that defendants' delays are unreasonable.

Most notably, defendants' cancellation of study-section and advisory-council meetings and withholding of final decisions on applications and renewals fails to comport with any "rule of reason." *See In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008) (listing this as the "first and most important factor"). As described above, the backlog of meetings and decisions flouts defendants' *own published timetables*, which sets a predictable, triannual schedule for review and disposition of applications. *See supra*, pp. 7, 11–12; *Ashtari v. Pompeo*, 496 F. Supp. 3d 462, 470 (D.D.C. 2020) (evaluating rule of reason based in part on internal policy guidance). Indeed, as discussed, the current delays in NIH's grantmaking process are unprecedented. *See supra*, p. 12. That is a telltale sign of unreasonable delay. *See, e.g.*, *Rezaii v. Kennedy*, No. 1:24-cv-10838, 2025 WL 750215, at *5 (D. Mass. Feb. 24, 2025) (holding that plaintiff had pleaded unreasonable delay where, among other things, agency's delay in processing plaintiff's application was "at the outer edge of HHS's typical time for processing").

Other factors demonstrate the unreasonableness of defendants' delay, too. For example, "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." *TRAC*, 750 F.2d at 80. Here, plaintiffs have presented compelling examples of how NIH-funded research has contributed and continues to contribute to

[23] The *TRAC* Court explained that: "(1) the time agencies take to make decisions must be governed by a 'rule of reason'; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'" 750 F.2d at 80 (citations omitted). Not all factors need be present. *See Wellesley*, 829 F.2d at 277 (discussing factors "in pertinent part").

significant breakthroughs in bettering human health. *See*, *e.g.*, Ex. 37 ¶32; Ex. 27 ¶¶23–32. Similarly, the *TRAC* factors take into account the effect of delayed action on the plaintiff, the agency, and the public. *See* 750 F.2d at 80. As described in the next sections, those factors point decisively in plaintiffs' favor.

For all of the above reasons, defendants have violated §706(1).

III. Plaintiffs face irreparable harm absent immediate injunctive relief.

In adopting and enforcing the challenged directives, defendants have 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).

Plaintiffs first face irreparable harm in the form of immediate and imminent 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 defendants' actions, 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. March 5, 2025) (recognizing irreparable harm from loss of NIH funding).

Further, the Challenged Directives have caused—and will continue to cause—operational burdens for plaintiffs' institutions. *See City & County 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). The swift and inexplicable termination of research grants has 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 Challenged Directives—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. For example, because researchers at University of Maryland (College Park) plan their lab budgets and hiring nine months to one year in advance, the delays and uncertainty have led to a 50% reduction in graduate admissions, and decisions to terminate or not to renew employment of researchers and trainees. Ex. 18 ¶¶38–41. As another 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 preliminary injunction.

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' adoption and enforcement of the Challenged Directives violate 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. Me. 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 abandons the prescribed schedule for the grant awards process, and abruptly eliminates funding opportunities and funding awards without notice or opportunity to account for the loss. The accompanying declarations detail the ongoing devastating consequences of the enforcement of the Challenged Directives and the many ways that the unreasonable delays in the grant awards process, the disruption to funding for announced funding opportunities, and the elimination of awarded grants will affect plaintiffs' institutions and communities. Moreover, the terminations of grant awards 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 disruption takes away federal funding for providing subjects with those test results. Ex. 19 ¶52.

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)). Because the terminations are unlawful, defendants have no cognizable interest in their enforcement. Moreover, in the unlikely event that defendants' actions were ultimately upheld, defendants have mechanisms to recover funds improperly paid to grantees. *See* Ex. 11 §8.5.4, at IIA-157.[24]

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

CONCLUSION

The Court should grant plaintiffs' motion for a preliminary injunction.

[24] Rule 65(c) provides that "[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." But the Court has the discretion whether to require a bond. *Pineda v. Skinner Servs., Inc.*, 22 F.4th 47, 57 (1st Cir. 2021); *Int'l Ass'n of Machinists & Aerospace Workers v. E. Airlines, Inc.*, 925 F.2d 6, 9 (1st Cir. 1991). The Court should exercise its discretion not to require a bond here.

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