

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

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

Plaintiffs,

v.

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

Defendants.

Case No. 1:25-cv-10787-WGY

**REPLY IN SUPPORT OF PLAINTIFFS’
MOTION FOR A PRELIMINARY INJUNCTION**

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INTRODUCTION

Defendants have upended decades of precedent carefully designed to ensure scientific rigor in NIH grant processes. Even though this Court rejected Defendants’ jurisdictional argument in *Massachusetts v. Kennedy*, No. 1:25-cv-10814 (“States’ case”), Defendants recycle their arguments here to try to avoid judicial review of these indefensible changes. Defendants mischaracterize the legal framework governing NIH’s funding obligations and distort the record. They do so without even trying to define the forbidden research topics. Plaintiffs respectfully request that this Court grant their motion, ECF No. 37.

ARGUMENT

I. The Court has jurisdiction over Plaintiffs’ suit.

In the States’ case, which largely raises the same claims as here, this Court determined it has subject matter jurisdiction. Leaning heavily on a Supreme Court *per curiam* order, Defendants rehash essentially identical arguments, conspicuously ignoring this Court’s on-point order in the States’ case. (Case No. 1:25-cv-10814, ECF No. 105 (D. Mass. May 12, 2025)) (“SMJ Order”). For the same reasons explained in that order, the Court has subject matter jurisdiction here.

A. This Court has already rejected Defendants’ Tucker Act arguments.

Plaintiffs’ “claims are, at their core, assertions that [Defendants] acted in violation of federal law—not its contracts.” *California v. Dep’t of Educ.*, 132 F.4th 92, 97 (1st Cir. 2025) (“*California I*”); *see* ECF No. 41 at 13–17. As in the States’ case:

This is not an action for monetary damages against the United States for which the Court of Claims was created. Rather . . . it is an action to stop the Public Officials from violating the statutory grant-making architecture created by Congress, replacing Congress’s mandate with new policies that directly contradict that mandate, and exercising authority arbitrarily and capriciously, in violation of federal law and the Constitution.

SMJ Order at 23.

And as in the States’ case, and unlike in *California*, Plaintiffs seek broad equitable and prospective relief, including enjoining the Directives, and do not seek an order that “requires the Government to pay out past-due grant obligations.” *Dep’t of Educ. v. California*, 145 S. Ct. 966, 968 (2025) (*per curiam*) (“*California II*”). Thus, this Court remains the appropriate jurisdiction to hear Plaintiffs’ claims. *See* SMJ Order at 23.

The nature of the grants also forecloses application of the Tucker Act. These grants are *not* contracts—an argument unaddressed in *California*. Defendants inaccurately assert, ECF No. 66 at 16, that “[t]he standard contract conditions are all satisfied,” but omit the element of “intent to contract.” *Columbus Reg’l Hosp. v. United States*, 990 F.3d 1330, 1339 (Fed. Cir. 2021). Indeed, *NIH itself* has consistently maintained that grants are not contracts. *See* Ex. 43.¹

Similarly, agreements, like grants, that serve to advance public policy interests or provide a public benefit lack the requisite consideration to be a contract. *Am. Near E. Refugee Aid v. USAID*, 703 F. Supp. 3d 126, 132–33 (D.D.C. 2023); *see also St. Bernard Parish Gov’t v. United States*, 134 Fed. Cl. 730, 736 (2017). In *Thermalon Indus., Ltd. v. United States*, Defendants’ sole case on this point, the Government received “significant consideration” for an NSF award, in the form of “title to any equipment plaintiff . . . purchased with grant funds” and “a royalty-free license to the intellectual property resulting from the research.” 34 Fed. Cl. 415, 414 (1995). There is no such consideration here. The basic elements of a contract are thus absent.

Moreover, “[e]ven assuming that the other requisite elements of a contract are present[,]” statutory authority to enter a contract is necessary. *Pa. Dep’t of Pub. Welfare v. United States*, 48 Fed. Cl. 785, 791 (2001). Congress distinguishes between NIH authority to enter into “contracts” versus “grants.” *See* ECF No. 41 at 21. “[A]bsent some clear indication that the legislature intends

¹ Citations to “Ex. []” refer to the numbered exhibits attached to the Declaration of Shalini Goel Agarwal dated May 19, 2025.

to bind itself contractually, the presumption is that ‘a law is not intended to create private contractual or vested rights but merely declares a policy to be pursued until the legislature shall ordain otherwise.’” *Nat’l R.R. Passenger Corp. v. Atchison, Topeka & Santa Fe Ry. Co.*, 470 U.S. 451, 465–70 (1985) (citation omitted). Congress’s distinction between contracts and grants belies any clear indication of legislative intent to create contractual rights.

B. Plaintiffs do not seek specific performance of a contract.

Plaintiffs challenge agency action as a violation of federal law, not for specific performance of a contract. The D.C. Circuit has emphasized this distinction:

It is one thing to rely on the generally recognized rule that a plaintiff cannot maintain a contract action in either the district court or the Court of Claims seeking specific performance of a contract. It is quite another to claim, as the Government does in this case, that an agency action may not be enjoined, even if in clear violation of a specific statute, simply because that same action might also amount to a breach of contract.

Megapulse, Inc. v. Lewis, 672 F.2d 959, 970–71 (D.C. Cir. 1982).

Defendants’ reliance on *Ingersoll-Rand Co. v. United States*, 780 F.2d 74 (D.C. Cir. 1985) is misplaced. ECF No. 66 at 17. That case involved claims by a private company over the termination of an Air Force procurement contract. 780 F.2d at 75. There was no grant, policy, or shift in agency priorities prompting the termination. The Air Force simply terminated the contract, the plaintiff sought “only the award of the contract,” and the court concluded the dispute was “entirely contained within the terms of the contract.” *Id.* at 77–80. By contrast, Plaintiffs challenge the Directives and resulting terminations, seek broad equitable relief, and do not seek to enforce any contractual terms. Several other courts have rejected similar challenges in cases seeking nearly identical relief.² This Court should do the same.

² See, e.g., *Climate United Fund v. Citibank, N.A.*, 2025 WL 1131412, at *10 (D.D.C. Apr. 16, 2025) (“Plaintiffs seek equitable relief vindicating their rights to access their grant funds and to enjoin EPA’s unlawful suspension and termination of their grants. Plaintiffs do not ask for specific performance, nor do they ask the court to interpret the

C. Plaintiffs’ suit is not a programmatic challenge.

This Court also already rejected Defendants’ assertion that a challenge to the Directives is an impermissible programmatic challenge. SMJ Order at 24. Plaintiffs challenge “discrete agency actions”—NIH’s Directives and terminations. *See id.* Defendants’ cited authority only highlights the distinction between the “wholesale” challenges in those cases and the discrete final agency actions here. *See Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 891 (1990); *Ala.-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 490 (5th Cir. 2014). As the Court noted in the States’ case, “[t]he fact that [the Defendants] have enforced these directives against hundreds of projects does not make this lawsuit programmatic even if it is large.” SMJ Order at 24; *New York v. Trump*, 133 F.4th 51, 68 (1st Cir. 2025); *AAUP v. Rubio*, No. 25-cv-10685, 2025 WL 1235084, at *21 (D. Mass. Apr. 29, 2025). The Court should likewise hold Plaintiffs’ suit is *not* a programmatic attack.

D. Defendants’ actions are not “committed to agency discretion.”

Defendants wrongly assert that Plaintiffs cannot pursue their claims because any “NIH actions to terminate existing grants or award future grants” are “committed to agency discretion by law.” *See* ECF No. 66 at 24 (citing 5 U.S.C. § 701(a)(2)). First, this APA limitation, to the extent applicable, does not govern Plaintiffs’ *constitutional* claims.

As to Plaintiffs’ APA claims, once again, this Court has rejected Defendants’ similar argument in the States’ case. *See* SMJ Order at 26–27. Plaintiffs do not challenge NIH’s “discretionary spending decisions.” ECF No. 66 at 25. Instead, as in the States’ case, Plaintiffs challenge specific Directives and terminations that defy limits set by Congress and Defendants themselves on that discretion. *See* Complaint at ¶¶ 195–249. Defendants cite *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993), to argue “allocation of funds” is committed solely to agency discretion. *See*

terms of any contract.”); *Pacito v. Trump*, 2025 U.S. Dist. WL 893530, at *13–14 (W.D. Wash. Mar. 24, 2025); *Rhode Island v. Trump*, 2025 U.S. Dist. WL 1303868, at *5–7 (D.R.I. May 6, 2025).

ECF No. 66 at 24–25. But as this Court observed, all *Lincoln* “stands for [is] the unremarkable proposition that review is precluded so long as the agency allocates funding from a lump-sum appropriation to meet permissible statutory objectives.” SMJ Order at 27. Thus, review is available where, as here, the Directives and terminations conflict with statutes and regulations.

Defendants cite 42 U.S.C. § 282(b)(3) to argue that, because Congress instructed the NIH director to “conduct[] priority-setting reviews,” the agency has discretion to bulk terminate hundreds of grants. ECF No. 66 at 25. Nothing in the statute supports Defendants’ reading, nor did Defendants raise it in the grant termination notices. Nor is there evidence that any priority-setting reviews were done “in consultation with the heads of the national research institutes and national centers.” Defendants also argue “NIH is not statutorily required to enter into *any* grant agreements.” ECF No. 66 at 25. But Defendants *have* awarded grants to Plaintiffs and Members that cannot be terminated in ways that violate the APA.

E. Plaintiffs’ claims are justiciable.

Defendants question the justiciability of Plaintiffs’ claims based on the nature of the challenged Directives, alleging that they are moot, unconnected to Plaintiffs’ harms, or not final agency action. *See* ECF No. 66 at 20–24.³ This Court already ruled on very similar arguments in the States’ case, and its reasoning applies with full force here. *See* SMJ Order at 25–26.

Defendants argue that some Directives are irrelevant because they were rescinded or did not cause Plaintiffs’ injuries. *See* ECF No. 66 at 20–21. But what “the current record shows is that [Plaintiffs] have experienced significant injury from a series of overlapping and interlocking blacklisting Directives that have caused unprecedented delays and disruptions.” SMJ Order at 25–26. While the haphazard nature of the Directives ““makes it hard to know which [ones] are

³ Defendants do not make this argument with respect to the grant terminations and thus have waived it.

effective at any given time . . . [a]t this stage, all inferences must be taken in favor of the [Plaintiffs].” SMJ Order at 26. Defendants also argue that Plaintiffs’ challenges to some Directives are moot because NIH is now reviewing paused applications. *See* ECF No. 66 at 20–21. For the reasons discussed further in Section II.B., *infra*, Plaintiffs’ applicant claims remain viable.

And Plaintiffs challenge final agency actions. Defendants acknowledge an action is final if it marks the consummation of the agency’s decision-making and carries legal consequences. *See* ECF No. 66 at 21. The action need not be formal and, as this Court recently explained, even an “unwritten” policy compelling agency officers to “consider” certain “factor[s]” can be reviewed under the APA. *AAUP*, 2025 WL 1235084, at *21. The Directives memorialize Defendants’ policy that certain research topics are off limits and detail the steps NIH officials must take to execute that policy. *See* Complaint at ¶¶ 85–104. The Directives obviously have legal consequences: Plaintiffs would not have been harmed but for their implementation.

Defendants argue the Directives are not final because they “merely ordered a *review* of the grants to determine whether they were consistent with the agency’s priorities,” and, like the manual in *Whitewater Draw Natural Resources Conservation District v. Mayorkas*, 5 F.4th 997, 1008 (9th Cir. 2021), did “not prescribe any particular option in any particular way.” ECF No. 66 at 22, 24. But that misrepresents the Directives’ text and effect—courts take a “pragmatic” approach to finality. *Army Corps of Eng’rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016). On their face and in practice, the Directives outline forbidden topics, based on which they direct review *and termination* of grants and prohibit new awards or funding requests. *See, e.g.*, ECF No. 38–13 at 2 (“ICs must take care to completely excise all DEI activities using the following categories.”); ECF No. 38–14 (same as to “non-priority activities”), 6 (stating that, upon receipt of list of “HHS Departmental Authority Terminations,” the “[Office of Policy for Extramural Research

Administration] will issue termination letters on behalf of the IC Chief Grants Management Officers.”); Ex. 44 at 2 (“Such review shall be aimed at ensuring NIH grants . . . do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs.”).⁴

F. Associational Plaintiffs have standing.

Defendants’ assertion that Plaintiffs APHA and UAW do not seek to protect interests germane to their purpose borders on frivolous. ECF No. 66 at 27. APHA’s mission is to “[b]uild public health capacity and promote effective policy and practice.” ECF No. 38–23 ¶ 2. Defendants’ decision to throw away billions of dollars of biomedical research mid-stream by terminating hundreds of grants to qualified researchers, including APHA members, certainly hinders APHA’s stated mission. Meanwhile, UAW represents approximately 75,000 workers who “depend on funding from the [NIH] for their jobs including salary, benefits, research costs . . . training and mentoring opportunities.” ECF No. 38–25 ¶ 5. Here, UAW seeks to protect the employment and training opportunities of the workers it represents, as funding terminations and delays put jobs and livelihoods at risk. *See* ECF No. 38–25 ¶ 15.

Second, Defendants argue that given “the sheer number of declarations” from associational Plaintiffs’ members, “[i]ndividual members must participate to show entitlement to injunctive relief[.]” ECF No. 66 at 26. Plaintiffs included numerous member declarations not for standing, since one member would suffice, *see United States v. AVX Corp.*, 962 F.2d 108, 116 (1st Cir.1992),

⁴ Plaintiffs learned of this Directive after filing their motion and include it as one of the previously “nonpublic or undisclosed directives” they challenge through this suit. *Massachusetts v. Kennedy*, No. 1:25-cv-10814 (D. Mass.), Dkt. 76-1 at 3. The delayed reveal of this Directive underscores the need to include in Plaintiffs’ claims any “non-public or undisclosed directives that curtail NIH support for previously advertised funding opportunities and previously awarded grants, on the grounds that the opportunities or grants relate to one or more of the [] topics identified as inconsistent with defendants’ priorities after the opportunities or grants were issued[.]” *See id.* Defendants’ complaints fall flat, ECF No. 66 at 19 n.10, as this description gives notice of the set of challenged Directives—a set uniquely known by Defendants. That Plaintiffs are still learning of additional Directives also counsels in favor of at least limited discovery into the full set of Directives.

but to demonstrate the breadth of devastation that Defendants’ actions are causing the medical community and public health, *see, e.g.*, ECF No. 41 at 40–43, and the boilerplate “reasoning” given to each member for the termination of their grants, *see, e.g.*, ECF No. 41 at 15. Moreover, Defendants provide no citation for the idea that a plaintiff asserting associational standing cannot seek injunctive relief. *See* Section III, *infra*. And the First Circuit has long held the opposite. *See Camel Hair & Cashmere Inst. of Am., Inc. v. Associated Dry Goods Corp.*, 799 F.2d 6, 12 (1st Cir. 1986) (“Actions for declaratory, injunctive and other forms of prospective relief have generally been held particularly suited to group representation.”).

II. Plaintiffs are likely to succeed on the merits.

A. Plaintiffs are likely to succeed on their Section 706(2) APA claims.

1. Defendants’ actions are contrary to law.

a. Defendants flouted congressional mandates.

As Plaintiffs have detailed, the Directives and terminations contradict congressional mandates regarding health disparities and underrepresentation in the biomedical field of racial minorities, women, and those from economically disadvantaged backgrounds. ECF No. 41 at 24–27, 32. Defendants do not and cannot dispute they are subject to these mandates.

Instead, Defendants hide behind a distorted account of their actions. First, Defendants allege that they *are* “preserving grants [researching] health disparities” by pointing to “at least 25” such grants that survived their purge of hundreds and asserting they terminated “DEI grants that [NIH] determined did not promote health.”⁵ ECF No. 66 at 32. Yet Defendants fail to define “DEI grants” or how, for example, a grant that addresses specific challenges related to kidney health faced by racial minorities constitutes “DEI.” Ex. 45 ¶ 6. Even if the survival of a smattering of

⁵ All twenty-five grants that Defendants cite were awarded by a single IC, the National Institute on Minority Health and Health Disparities, whereas Congress has mandated that ICs collectively foster collaboration between their various clinical research projects and encourage them to “utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities[.]” 42 U.S.C. § 282(b)(8)(D)(ii).

disparities and minority health research grants could satisfy Congress’s will that NIH prioritize such research, Defendants’ table is misleading. First, of the 25 grants listed, at least 3 were terminated, 2 ended *before* the Lorsch Declaration was signed,⁶ and 4 more projects will end this calendar year. Ex. 46 ¶ 3. By July of 2026, only 4 of the 25 grants will remain. *Id.* It is telling that NIH musters such scant evidence to attempt to show it is meeting Congress’s mandate to consider “social and other determinants of health that contribute to health disparities” in identifying “strategic research priorities.” ECF No. 66 at 40–41.

Defendants’ claim that they are “supporting . . . the recruitment of researchers from disadvantaged backgrounds” is also belied by the evidence. Defendants assert they continue to fund Kirschstein-NRSA grants, ECF No. 66 at 32–33, listing over 5,170 “active NRSA grants”⁷ and pointing to four with “diverse” in the title. This too is wholly misleading. While many NRSA opportunities remain, Defendants have categorically terminated those NRSA programs specifically intended to fulfill Congress’ mandates to increase recruitment of underrepresented groups. ECF No. 41 at 26; Ex. 45 ¶¶ 9, 10 (of the 11 broadest NRSA training programs, the 5 that specifically recruit from underrepresented communities have been terminated); *id.* at Ex. B (demonstrating similar terminations of non-NRSA programs focused on increasing diversity). NIH has stripped all mention of workforce diversity from the newly posted T32 and T35 NRSA opportunities it highlights (ECF No. 66 at 32–33; No. 38–27 ¶19; Decl. of Shalini Agarwal ¶ 9), revised instructions for institutional training grant applications to state that Recruitment Plans to

⁶ Compare ECF No. 38-27 at 33 (showing termination on Mar. 28, 2025 of “The ADELANTE Trial: Testing a multi-level approach for improving household food insecurity and glycemic control among Latinos with Diabetes”) with ECF No. 66-2 at 3 (listing the same grant as a “NIH Minority-Related Health Project[] that [Was] Not Terminated.”) Compare Ex. 45 at Ex. A (showing termination on May 5, 2025 of “Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach of metabolomics, lifestyles, and social determinants”) with ECF No. 66-2 at 2 (listing the same grant as a “NIH Minority-Related Health Project[] that [Was] Not Terminated”).

⁷ At least ten of these grants have already been terminated. Ex. 45 ¶ 8.

Enhance Diversity will no longer be required or considered, Ex. 49 at 3, and revised “peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities.” Ex. 50 at 5.

Defendants’ actions are also contrary to law because they run directly counter to the priorities Defendants set in their NIH and IC strategic plans. While Defendants argue these plans are not meant to be “a six-year straight jacket [sic],” ECF No. 66 at 33, Congress mandated that NIH “shall ensure” funding is “sufficiently allocated for research projects identified in strategic plans,” *see* 42 U.S.C. § 282(b)(6), providing researchers and institutions with the stability and predictability needed for the pursuit of scientific endeavors. *See, e.g.*, Proposed Brief of Amici Curiae Association of American Medical Colleges et al, ECF No. 47-01 at 8–11.

b. Defendants violated HHS regulations.

Defendants make two arguments that the terminations are legal despite their violation of HHS regulations. ECF No. 66 at 31–33. Both are inapposite. First, Defendants argue that 45 C.F.R. § 75.372(a) (specifying two grounds for termination: “for cause” or “fail[ure] to comply with the terms and conditions of the award”) sets out non-exclusive bases for termination because of its use of the word “may.” ECF No. 66 at 28. But this is refuted by the regulation’s structure and text, which set forth provisions for “termination” in its “Remedies for Noncompliance” section and prefaces its list of termination grounds by stating that “the Federal award may be terminated . . . *as follows.*” (emphasis added).⁸ The more natural reading of 45 C.F.R. § 75.372(a) is that “may” connotes that termination is not *required* for noncompliance. This is consistent with 45 C.F.R. § 75.371, which includes termination as *one among many* actions that HHS “may take” for

⁸ Notably, in placing so much weight on the appearance of the word “may” in the regulation, Defendants ignore the holding of the very case they cite, *see* ECF No. 66 at 28, that an interpretation of the word “may” as connoting permissiveness “can be defeated by . . . obvious inferences from the structure and purpose of the statute.” *United States v. Rodgers*, 461 U.S. 677, 706–07 (1983).

noncompliance. Courts have interpreted the list of termination grounds in 45 C.F.R. § 75.372(a) as the “only” basis on which HHS regulations allow for termination. *See, e.g., Policy & Rsch. LLC v. HHS*, 313 F.Supp. 3d 62, 76 (D.D.C. 2018); *Healthy Teen Network v. Azar*, 322 F. Supp. 3d 647, 651 (D. Md. 2018). 45 C.F.R. § 75.372(a) simply does not give Defendants authority to terminate grants where the “award no longer effectuates agency priorities.” *HHS declined to adopt that language* until an effective date of October 2025. If Defendants’ reading were correct there would have been no reason for HHS’s revision.

Second, Defendants argue their actions are lawful because Notices of Award incorporate the NIH Grants Policy Statement 8.5.2, which incorporates 2 CFR § 200.340. ECF No. 66 at 27–29. But Plaintiffs’ case does not turn on award terms and conditions. Defendants’ failure to follow HHS’s regulations resolves this case. *See Policy & Rsch.*, 313 F.Supp.3d at 82 (holding that irrespective of what the Grants Policy Statement “might be read to authorize, its authority does not, and cannot, trump the agency’s formal regulations”). Nevertheless, Defendants are wrong that 8.5.2 incorporates 2 C.F.R. § 200.340 to allow for unilateral termination without noncompliance. Defendants make much of the fact that termination is in a separate sentence from other enforcement actions and uses the word “also,” ECF No. 66 at 28–29, but ignore the context, that it is in a section titled “8.5.2 Remedies for Non-Compliance or Enforcement Actions: Suspension, Termination, and Withholding of Support.” (emphasis added). Further, the Grants Policy Statement makes clear it is “intended to be compliant with . . . 2 C.F.R. § 200, *as modified by previously approved waivers and deviations*” and that the regulations control if there is a conflict (emphasis added). ECF No. 38–5 at 12. HHS modified 2 C.F.R. § 200 by declining to adopt termination provisions “if an award no longer effectuates the program goals or agency priorities.” In fact, another NIH document describing its terms and conditions underscores this. Ex. 51 at 2

(“NIH *does not adopt* 2 CFR § 200.240(a)(2) [sic], stating that the Federal awarding agency may terminate a Federal award if the award no longer effectuates the program goals or agency priorities.”(emphasis added)).⁹

2. Defendants’ actions are arbitrary and capricious.

Defendants stress that they “provided the reasons for” grant terminations and “explained why” NIH would not prioritize the research. ECF. No. 66 at 31. But they cannot articulate how the boilerplate language in the Directives and termination letters based on undefined terms like “DEI” constitutes a “reasoned explanation for its action.” *DHS v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1916 (2020); *see also*, Section II.D, *infra*. Nor could they: “conclusory statements will not do; an ‘agency’s statement must be one of *reasoning*.’” *Massachusetts v. NIH*, No. 25-CV-10338, 2025 WL 702163, at *17 (D. Mass. Mar. 5, 2025) (citation omitted).

As courts have stressed, the use of “template or boilerplate” language “issued to all Grant Recipients further strengthens Plaintiffs’ argument that [an agency] did not consider individual, or any, data or information.” *Am. Ass’n of Colleges for Tchr. Educ. v. McMahon*, No. 1:25-CV-00702, 2025 WL 833917, at *21 (D. Md. Mar. 17, 2025); *see also Massachusetts*, 2025 WL 702163, at *18 (absence of reasoning renders directives “arbitrary and capricious.”).¹⁰ The lack of engagement with data underlying or resulting from the research supported by the terminated grants highlights that failure here. *DHS*, 140 S. Ct. at 1896, 1913 (agency “entirely failed to consider []

⁹ The Lorsch Declaration misleadingly claims that NIH adopted OMB’s 2020 revisions to the Uniform Guidance in a November 17, 2020 notice, *see* ECF No. 66-1 ¶ 9 (citing Ex. 51), yet wholly ignores that NIH specifically declined to adopt the disputed provision pertaining to termination “if an award no longer effectuates the program goals or agency priorities.” Ex. 51 at 2.

¹⁰ In asserting that they satisfy the arbitrary and capricious standard, Defendants also emphasize that the Directives and termination letters provided “the authority under which [NIH] was terminating [the] grants” and “the grantee’s appeal rights.” ECF No. 66 at 30. But neither constitutes any agency *reasoning* for its decision. And for the reasons discussed below and in Plaintiffs’ opening brief, Defendants lacked authority under regulation, statute, and the U.S. Constitution for their actions. *See, e.g.*, ECF No. 41 at 23–27; *see* Section II.A.1, *supra*.

important aspect of the problem” because “rescission memorandum contains no discussion” of that aspect); *McMahon*, 2025 WL 833917, at *21.

Further, as stated, terminating NIH grants studying health disparities and diversifying the workforce runs afoul of congressional and other mandates. *See, e.g.*, ECF No. 41 at 23–27. Doing so reflects that Defendants “relied on factors which Congress has not intended it to consider.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Defendants cannot credibly argue that they “provide[d] a reasoned explanation for [their] change” in policy.¹¹ *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016); *Massachusetts*, 2025 WL 702163, at *20. The Directives and termination letters “fail[ed] to address,” among other things, “how [the] research will be conducted absent” government funding, a concern of particular importance “considering the number of [researchers] and associations that have made clear that research will have to be cut, as other funding sources will not be able to make up the shortfall.” *Massachusetts*, 2025 WL 702163, at *17; *see also id.* at *20; *AIDS Vaccine Advoc. Coal. v. Dep’t of State*, No. CV 25-00400, 2025 WL 485324, at *5 (D.D.C. Feb. 13, 2025); *DHS*, 140 S. Ct. at 1896 (failure to “address whether there was ‘legitimate reliance’ on the DACA Memorandum” rendered agency action arbitrary and capricious).

Plaintiffs and Members whose applications have been delayed also have reliance interests NIH must consider: among other things, delays endanger the career progression of researchers who would diversify the field (a goal mandated by statute and regulation), *see* ECF No. 41 at 38–

¹¹ Defendants attempt to undercut the evidence suggesting that members of the so-called Department of Government Efficiency (“DOGE”) played a role in issuing the Directives and terminations. ECF No. 66 at 31 n.15. But this is contradicted by deposition testimony by the former director of NIH’s extramural research office indicating that DOGE members played a *significant* role in those efforts. ECF No. 38-9 at 38:3–20 (“Q: How did you first learn that grants were going to be terminated on February 28th? A: . . . [Rachel Riley] introduced herself as being part of DOGE, who was working with HHS. And she informed me that a number of grants will need to be terminated and that Matt Memoli will be sending me . . . a list of grants in an email shortly thereafter.”).

39, and they are unable to move forward with parallel funding opportunities, *see* ECF No. 41 at 42–43. There is no evidence that NIH considered these reliance interests.

Defendants attempt to refute NIH’s failure to consider reliance interests by asserting, without citation, that it “necessarily understood and considered that it was terminating funding on which the grantee relied to conduct research when it terminated the grant for that research.” ECF No. 66 at 31. Defendants’ sole declarant is silent as to this “fact” and no evidence supports the assertion. Instead, Defendants invite the Court to *assume* that NIH considered reliance interests. But “[a]n agency must defend its actions based on the reasons it gave when it acted,” and Defendants cannot “rely upon reasons absent from [their] original decision[s].” *DHS*, 140 S. Ct. at 1909–10. Accordingly, Defendants may not now turn to *post hoc* justifications.

Finally, given “the seriousness of the . . . deficiencies” of the Directives and terminations, remand is inappropriate. *Env’t Def. Fund v. FERC*, 2 F.4th 953, 976 (D.C. Cir. 2021).

3. Defendants’ actions are contrary to constitutional right.

For reasons Plaintiffs have explained, at Section II.C–D, *infra*; ECF No. 41 at 23–27, 35–37, Defendants’ actions also violate separation of powers principles and the Due Process Clause, and are thus “contrary to constitutional right, power, privilege, or immunity” under the APA. Defendants do not counter that constitutional violations give rise to a separate APA claim.

B. Plaintiffs are likely to succeed on their Section 706(1) APA claim.

Defendants incorrectly argue that Plaintiffs’ applicant claims are moot because delayed and suspended study sections and advisory councils allegedly are *generally* on track again. ECF No. 66 at 32–34. But Defendants fail to address the essential question raised by this claim: whether Plaintiffs’ and their Members’ applications are being reviewed. The evidence suggests they are not. Since Plaintiffs filed this motion, Defendants have begun to “administratively withdraw” applications for some programs purged as a result of the Directives, Ex. 52 ¶ 3, Ex. B, and others,

based on counsel’s continued contact with declarants, appear to remain suspended, Ex. 46 ¶¶ 6–7.¹² These discrete agency actions violate laws and regulations requiring that all applications “shall be evaluated,” that the evaluation proceed through the peer review process, and that NIH “will” reach a disposition on their applications. 42 C.F.R. § 52.5; 42 U.S.C. §§ 289a, 284a; ECF No. 66 at 37.

Defendants’ claim that they have discretion to defer applications under 42 C.F.R. § 52.5(b) and “[n]o statute or regulation mandates a decision,” ECF No. 66 at 37, misstates the law. Under 42 C.F.R. § 52.5(b), Defendants may only defer disposition “because of either lack of funds or a need for further evaluation[.]” Defendants ignore these limits on their discretion.

Defendants fail to counter additional bases for Plaintiffs’ applicant claims, as Defendants’ actions also violate separation of powers principles, are arbitrary and capricious, and are contrary to law and constitutional right under Section 706(2). ECF No. 66 at 36–37.

C. Defendants violate separation of powers principles.

Along with the arguments discussed above in Section II.A.1, Defendants also claim they do not violate separation of powers principles because the Public Health Act “explicitly” confers broad discretion in the management and operation of NIH programs and activities. ECF No. 66 at 39–40. Yet they ignore both that this general discretionary authority is limited to fulfilling the overall purpose of the Public Health Act, and that other congressional mandates limit their authority by *requiring* research into health disparities and steps to address underrepresentation of certain groups in the medical profession. *See PFLAG, Inc. v. Trump*, No. CV 25-337, 2025 WL 685124 at *14–18 (D. Md. March 4, 2025) (“Defendants’ attempt to transform statutory language providing agencies some limited discretion in determining research priorities into specific authorization for the action at issue here, which goes well beyond determining research priorities,

¹² Indeed, while NIH could easily have removed F31 diversity statements and considered F31 applicants for the parent grant, NIH is refusing to do so, severely disadvantaging those previously encouraged to self-report their identities.

‘stretch[es] the statutory language beyond hope of recognition.’”) (citing *City of Providence v. Barr*, 954 F.3d 23, 32 (1st Cir. 2020)).

D. Defendants’ Directives and terminations are unconstitutionally vague.

Defendants cannot refute that the Directives and termination notices lack definitions for terms like “DEI,” “gender identity,” “transgender issues,” “amorphous equity objectives,” and “COVID-related research.” *See* ECF No. 41 at 35–37. Nor can they explain away high-level NIH officials’ testimony attesting to the vagueness of these terms. *See id.* at 36; *see also* ECF No. 38-9 at 44:6–17, 48:8–14, 50:9–17, 51:16–24, 63:21–64:12. Recent news exposes the resulting arbitrary enforcement. *See* Ex. 53 ¶ 3 (“NIH staff members have been given lists of terms . . . to be used as reasons to reject proposals or flag grants for investigation. They include ‘inequity,’ ‘racism,’ ‘underserved,’ ‘SDOH,’ which stands for social determinants of health.”). Courts have held similar directives unconstitutionally vague, echoing this Court’s concern about these undefined terms in the States’ case. *See NEA v. Dep’t of Educ.*, No. 25-CV-091, 2025 WL 1188160, at *18 (D.N.H. Apr. 24, 2025) (collecting cases) (“The Letter does not make clear . . . what the Department believes constitutes a DEI program” and “does not even define what a ‘DEI program’ is.”); *NAACP v. Dep’t of Educ.*, No. 25-CV-1120, 2025 WL 1196212, at *6 (D.D.C. Apr. 24, 2025). Where a law or policy “regulates conduct based on ‘wholly subjective judgments without statutory definitions, narrowing context, or settled legal meanings,’ it is likely to be void for vagueness.” *NEA*, 2025 WL 1188160, at *18.

Defendants try to distract the Court from these infirmities. For instance, Defendants assert that “the Directives do not regulate [the] conduct” of Plaintiffs and Members “but instead direct the agency to conduct a review.” ECF No. 66 at 34. But the Directives regulate which grants are precluded from funding—and therefore govern Plaintiffs’ and Members’ own work and research. *See NEA*, 2025 WL 1188160, at *19 (“The Supreme Court has repeatedly struck down legal

prohibitions that sweep in a wide swath of conduct while leaving individual enforcement decisions to the subjective determinations of enforcement authorities.”) (collecting cases).

Defendants’ assertion that a facial challenge is improper likewise lacks merit. Courts in this Circuit enjoined agency directives based on facial void-for-vagueness challenges. *See NEA*, 2025 WL 1188160, at *23; *Loc. 8027, AFT-N.H., AFL-CIO v. Edelblut*, 651 F. Supp. 3d 444, 454 (D.N.H. 2023); *see also NAACP*, 2025 WL 1196212, at *23. Regardless, Plaintiffs and Members have “identif[ied] specific [research] activities that they plan to engage in but are arguably barred” by the Directives, making a sufficient showing for an as-applied challenge. *See Edelblut*, 651 F. Supp. 3d at 454; *see also* ECF Nos. 38-21 ¶ 18–22; 38-38 ¶ 13–14, 38-32 ¶ 21–22.

Contrary to Defendants’ argument, grants can constitute a property interest protected by the Due Process Clause. *See Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 576–77 (1972) (collecting cases); *see also NEA*, 2025 WL 1188160, at *21–23. Because the Directives are inherently vague and “encourage[] an arbitrary and discriminatory enforcement,” they are unconstitutional. *See Papachristou v. City of Jacksonville*, 405 U.S. 156, 170 (1972).

III. Plaintiffs and their members will suffer irreparable harm.

Defendants attempt to divert the Court’s attention from Plaintiffs’ substantial irreparable harm by demanding, without support, individualized showings of harm for each member. But associational standing exists precisely for this situation and only requires “specific allegations establishing that *at least one* identified member had suffered or would suffer harm.” *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) (emphasis added).

Recent cases in this District follow this approach. In *Doe v. Trump*, the court found that two associational plaintiffs demonstrated irreparable harm through “numerous” declarations that describe “one or more members facing the same type of injury.” No. CV 25-10135, 2025 WL 485070 at *6, *13 (D. Mass. Feb. 13, 2025). Similarly, in a recent case challenging the slashing

and capping of indirect cost rates on NIH grant awards, the court analyzed irreparable harm without demanding evidence from every institution in the plaintiff states. *Massachusetts*, 2025 WL 702163, at *58–68. Defendants’ reliance on *Adams v. Freedom Forge Corporation* is misplaced. There, the court sought individual showings from 136 *individual* plaintiffs—bearing no resemblance to the *associational* plaintiffs here. 204 F.3d 475, 485-86 (3d Cir. 2000). Here, each *Plaintiff* has demonstrated irreparable harm. *See* ECF No. 41 at 39–43.

Defendants also incorrectly assert that “the primary claimed injury is the delayed payment of money.” ECF No. 66 at 42. The declarations address harms far beyond that. *See* ECF No. 41 at 39–43. Plaintiffs and Members have been forced to suspend critical scientific research, risking the usability of data, the credibility and outcomes of the research, and the well-being of research study participants. ECF Nos. 38-30 ¶¶ 25–27; 38-31 ¶ 32; 38-34 ¶ 30. Some study participants will have treatment or intervention interrupted. ECF Nos. 38-30 ¶¶ 27–28; 38-20 ¶ 37. Staff members have been or will be laid off. ECF Nos. 38-33 ¶ 23; 38-34 ¶ 25; 38-37 ¶ 21. These injuries amount to irreparable harm. *See Massachusetts*, 2025 WL 702163, at *31.

Defendants likewise wrongly assert that harm is speculative, cherry-picking statements from declarations. ECF No. 66 at 42–43. But the record conclusively demonstrates concrete, immediate harm from the Directives, terminations, *and* delays. *See, e.g.*, ECF Nos. 38-28 ¶ 23; 38-31 ¶ 24; 38-20 ¶ 37; 38-21 ¶ 16. Since the motion, these harms have continued, compounding the harm to public health research, institutional capacity, and scientific progress. *See, e.g.*, Ex. 52 ¶¶ 2–3 (previously pending application now “withdrawn”); Ex. 54 ¶ 3 (putting study on hold and additional reductions of team members’ hours).

IV. The balance of equities weighs in favor of an injunction.

Defendants argue *solely* that “[t]he government has a strong interest in safeguarding the public fisc.” ECF No. 66 at 43. But as multiple courts considering similar issues have recently noted, in the case of an injunction, “Federal Defendants ‘merely would have to disburse funds that Congress has appropriated’” for grants. *Maine v. USDA*, No. 1:25-CV-00131, 2025 WL 1088946, at *29 (D. Me. Apr. 11, 2025) (quoting *New York v. Trump*, No. 25-CV-39, 2025 WL 357368, at *4, *17 (D.R.I. Jan. 31, 2025)). Meanwhile, absent an injunction, Plaintiffs will suffer irreparable injury to their careers, valuable research will cease, and Defendants’ unlawful actions will continue. *See id.* at *13. The balance of equities favors granting preliminary relief.

V. Plaintiffs seek an injunction on behalf of themselves and their members.

Contra Defendants, Plaintiffs do not seek a “nationwide injunction,” but rather an injunction on behalf of Plaintiffs and their members.¹³ Where an association has standing, an injunction as to all members is appropriate, even where “not every member may derive any immediate benefit from the injunction.” *Playboy Enters. v. Public Serv. Comm’n*, 906 F.2d 25, 35 (1st Cir. 1990); *see also NEA*, 2025 WL 1188160, at *30–31 (holding proper scope of relief was on behalf of plaintiff association, its members, and institutions that employ them).

Defendants argue to limit relief, contending that “irreparable harm resulting from one grant termination” does not “warrant a preliminary injunction for all other terminations.” ECF No. 66 at 44. Yet Defendants offer no support for the idea that injunctions for associational Plaintiffs should

¹³ While not relevant to the pending motion, it is worth noting Plaintiffs’ position that a nationwide injunction is unnecessary, as similarly broad relief should follow were the Court to issue a ruling setting aside the Directives as arbitrary and capricious. Section 706(2) of the APA empowers courts to “hold unlawful and set aside” final agency actions. Courts have repeatedly ruled that this requires vacatur of the unlawful agency action in its entirety. *See, e.g., E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 681 (9th Cir. 2021) (“When a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.”); *Nat’l Min. Ass’n v. Army Corps of Eng’rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1988); *Career Colleges & Sch. of Texas v. Dep’t of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024).

be limited to members who show some heightened individual harm. *Cf., City of Evanston v. Barr*, 412 F. Supp. 3d 873, 888 (N.D. Ill. 2019) (“[A]n association that establishes standing and prevails is entitled to obtain relief for all of its impacted members.”). This Court should enter an injunction that provides relief to all Plaintiffs and their members.

VI. The court should not require a bond and should not stay any injunction.

Courts do not require bonds in “suits to enforce important federal rights or ‘public interests.’” *Crowley v. Loc. No. 82, Furniture & Piano Moving, Furniture Store Drivers, Helpers, Warehousemen, & Packers*, 679 F.2d 978, 1000 (1st Cir. 1982), *rev’d on other grounds*, 467 U.S. 526 (1984). Plaintiffs seek to vindicate public interests by enjoining the Directives and terminations. *See* ECF No. 37-1. Where the federal government has withheld previously-awarded funding and defendants face no individual monetary harm, a bond would “hold Plaintiffs hostage for the resulting harm.” *See, e.g., Nat’l Council of Nonprofits v. OMB*, No. 25-cv-239, 2025 WL 597959, at *19 (D.D.C. Feb. 25, 2025). Additionally, no stay should accompany preliminary relief, as Plaintiffs’ irreparable harms are ongoing. Defendants are unlikely to succeed on appeal, Plaintiffs would suffer substantial injury, and a stay would not serve the public interest. *See New York v. Trump*, 133 F.4th at 65 (citation omitted)

CONCLUSION

For the reasons discussed here and in Plaintiffs’ opening brief, ECF No. 41, Plaintiffs respectfully request that the Court grant their motion for preliminary injunction, ECF No. 37.

Dated: May 19, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2025 a true and correct copy of the above document was filed via the Court's CM/ECF system and that a copy will be sent automatically to all counsel of record.

May 19, 2025

/s/ Shalini Goel Agarwal
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