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

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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.

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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

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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

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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 most 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 "nonpublic 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" 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. $45 \, \P \, 8$.

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). 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)).

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."). 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–

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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,

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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. 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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Respectfully submitted,

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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 Shalini Goel Agarwal

EXHIBIT 44

Directive on NIH Priorities

Agency: National Institutes of Health

Office of the Director

Action: Directive

FOR FURTHER INFORMATION CONTACT:

National Institutes of Health

Office of the Director

EFFECTIVE DATE: February 21, 2025

Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards

The National Institutes of Health (NIH) is the largest public funder of biomedical and behavioral research in the world. The public trusts NIH with substantial funds to foster creative discoveries that will improve health and prevent disease in this Country. Accordingly, NIH is committed to promoting only the highest level of scientific integrity, public accountability, and social responsibility in the programs it funds. And NIH promises to prioritize the funding of projects that will generate a high return on the public's investment, so that taxpayer dollars are not going to waste. Every dollar should be used to make Americans live longer, healthier lives.

This mission requires NIH to ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on diversity, equity, and inclusion (DEI) and gender identity. While this description of NIH's mission is consistent with recent Executive Orders issued by the President, I issue this directive based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders.

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, DEI studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Likewise, 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 either.

For these reasons and pursuant to, among other authorities, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.207, 75.210, 75.371-373), the Director of NIH hereby directs:

NIH personnel shall conduct an internal review of all contract solicitations and notices of funding opportunities; applications pending Type 1 and Type 2 awards; existing awards; cooperative agreements; and other transactions. Such review shall be aimed at ensuring NIH grants, contracts, cooperative agreements, and other transactions do not fund or support low-value and off-mission research activities or projects - including DEI and gender identity research activities and programs. NIH personnel should also ensure grants, contracts, cooperative agreements, and other transactions are free from fraud, abuse, and duplication, and are being implemented consistent with federal law.

This Directive shall be implemented by all relevant NIH personnel, including but not limited to those in the Office of Extramural Research, Office of Intramural Research, and the Division of Program Coordination, Planning, and Strategic Initiatives. Grants, contracts, cooperative agreements, and other transactions deemed inconsistent with NIH's mission may, where permitted by applicable law, be subject to funding restrictions, terminated or partially terminated, paused, and/or not continued or renewed, in compliance with all procedural requirements.

Notwithstanding this Directive, and consistent with any court orders that may apply, no open award disbursements may be paused in reliance upon Office of Management and Budget Memorandum M-25-13 or any Executive Order underlying that Memorandum. Previous instructions ordering the immediate release of such funds remain in effect. Also, consistent with any court orders that may apply, this Directive does not instruct personnel to condition or withhold federal funding pursuant to Section 4 of Executive Order 14,187 (Protecting Children from Chemical and Surgical Mutilation) based on the fact that a healthcare entity or health professional provides care or treatment.

Dated: February 21, 2025

Acting Director of NIH

¹ To be clear, these citations are illustrative, not exhaustive. Further explanation of the range of statutory and regulatory authorities that support actions taken pursuant to this Directive will be issued as appropriate.

EXHIBIT 45

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

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

NATIONAL INSTITUTES OF HEALTH, et al.,

Defendants.

SUPPLEMENTAL DECLARATION OF SCOTT W. DELANEY, ScD JD MPH

- I, Scott W. Delaney, pursuant to 28 U.S.C. § 1746, declare as follows:
- I am offering this Declaration in my individual capacity and not on behalf of my employer.
- 2. I previously set forth my professional background in my Declaration filed on April 25, 2025, in support of Plaintiffs' Motion for Summary Judgement ("April 25 Declaration;" ECF No. 38, Attachment 27). Briefly, I am an epidemiologist and Research Scientist at the Harvard T.H. Chan School of Public Health (HSPH). I hold a Doctor of Science from HSPH (ScD, 2020) and have conducted epidemiologic research at HSPH in various capacities for eleven years. Throughout my career in epidemiology, I have applied for and received multiple types of grants from NIH either individually or as part of teams. Moreover, my current research activities are supported almost entirely by NIH research grants. Based on these experiences, I am exceedingly familiar with a broad spectrum of grant mechanisms available from NIH.
- 3. I am also the co-founder of grant-watch.us, a website and series of databases that track terminated NIH grants. This effort began in early March 2025 when I started tracking details of

terminated NIH grants. Together with a colleague, Dr. Noam Ross of rOpenSci, we built the most comprehensive, up-to-date database of specific grants that NIH has prematurely terminated since February 28, 2025. Our database aggregates data from multiple sources, including reports from Principal Investigators (i.e., scientists) whose grants were terminated; news reports; social media; Doge.gov; NIH's X feed; NIH RePORTER; USASpending.gov; and the HHS TAGGS system. Using this database, I previously identified in my April 25 Declaration 755 grants that I believe were terminated for vague policy reasons.

- 4. Since I compiled the list of terminated grants for my April 25 Declaration, I have learned of more grant terminations. Accordingly, I have updated my count of terminated NIH grants using the same methods outlined in my April 25 Declaration.
- 5. As of Friday, May 16, 2025, at 10:00 p.m. Eastern Daylight Time, I have identified 813 total grants (i.e., fifty-eight more than the previously reported 755 grants) that NIH has terminated based on vague "policy" assertions. A true and correct list of these fifty-eight additional grants is attached to this Declaration as Exhibit A.
- 6. Among these additional terminations was Grant Number U24DK137631, which was awarded to researchers at Duke University. The grant, entitled *Interventions that Address* Structural Racism to Reduce Kidney Health Disparities Research Coordinating Center, was part of six-institution (and thus six-grant) consortium organized by the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK) that focused on addressing specific challenges related to kidney health faced by racial minority communities. Other consortium members included researchers at the University of Colorado at Denver (U01DK137272), the University of North Carolina at Chapel Hill (U01DK137262), Northwestern University at Chicago (U01DK137258),

Icahn School of Medicine at Mount Sinai (U01DK137259), and Emory University (U01DK137269). All six of these grants were terminated on April 30, 2025.

- 7. In addition to investigating these additional fifty-eight grants, I also read carefully the Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, as well as the Declaration of Jon Lorsch ("Lorsch Declaration"), both of which were filed with the Court on May 12, 2025. The Lorsch Declaration included Exhibit B, which purported to list active National Research Service Award (NRSA) grants. In reference to Exhibit B, Dr. Lorsch declared that "[n]one of these grants were terminated." (Lorsch Declaration, Paragraph 34).
- 8. I reviewed all grants listed in Exhibit B of the Lorsch Declaration and compared them to evidence I previously collected of terminated grants. Based on my analysis, at least ten NRSA grants listed in the Lorsch Declaration have been and remain terminated, contrary to Dr. Lorsch's assertion. They include, F31AI186480, F31GM155995, F31GM151846, F31HG013889, F31MD018931, T32HL007854, T32GM154636, T32HL105323, T34GM145539, T34GM149430. Eight of these ten NRSA grants were part of programs specifically meant to recruit and train diverse future scientists from underrepresented backgrounds. I believe two other NRSA awards listed in Dr. Lorsch's exhibit—F30AG074618 and F31AG090071—may have been terminated and subsequently reinstated for unknown reasons.
- 9. More broadly, Defendants contend that, despite terminating some NRSA awards and programs, "NIH is supporting . . . the recruitment of researchers from disadvantaged backgrounds." Defendant's Opposition, ECF No. 66 at 33. To explore this contention, I identified the primary NRSA grant programs from the past year. I focused my analysis on programs in which multiple institutes or centers (ICs) participated. I categorized these programs based on whether they are (1) currently available, such that applicants can apply to them, or (2)

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no longer available and or recently terminated. I further categorized them based on whether they are (or were) meant to support either (1) students and early career researchers from all backgrounds or (2) students and early career researchers exclusively from diverse and / or disadvantaged backgrounds. Unlike the former category, the latter category included programs explicitly designed to diversify the scientific workforce because such programs were only available to applicants from diverse backgrounds. I repeated this process for non-NRSA training awards as well. I have included a true and correct table listing and categorizing these programs as Exhibit B to this Declaration.

10. In sum, I identified eleven NRSA programs from the past year in which multiple ICs participated. Six of these programs are open to all applicants and, thus, are not explicitly designed to support students from diverse backgrounds. All six of these programs are still currently available or forecasted to be available within the next two months. In contrast, five of the eleven programs were explicitly designed to diversify the workforce by targeting only applicants from underrepresented backgrounds. None of these five is currently available or forecasted to be available. Thus, NIH has ended every NRSA program explicitly designed to recruit and support diverse students.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 1 day of May, 2025.

EXHIBIT A

Award Number	Project Title	Awardee Organization	Termination Date
R21HD107311	An intervention to promote healthy relationships among transgender and gender expansive youth	Seattle Children's Hospital	2025-02-28
R01Al186142	A seek, test, and treat intervention to reduce Chlamydia trachomatis	Tulona University of Louisiana	2025-03-20
	disparities in Black youth living in the deep South Kabawil: Adapting an Intervention to Reduce Intersectional Stigmas among Indigenous Sexual Minority Men and Traditional Healers in	Tulane University of Louisiana	
R01TW012904	Mesoamerica	University of Washington	2025-03-20
P30Al050409-26S1 R01HL168489	Center for AIDS Research at Emory University A daily diary examination of the influence of intersectional stigma on blood pressure	Emory University Columbia University Health Sciences	2025-03-21
R01MD017588-03S1	Promoting Health and Reducing Risk among Hispanic Sexual Minority Youth and their Families	University of Miami Coral Gables	2025-03-21
	Harnessing the power of peer navigation and mHealth to reduce	Wake Forest University Health	
R01NR019512	health disparities in Appalachia	Sciences	2025-03-21
U54MD012523-05S1	Center for Health Equity Research (CHER) OTA-21-015A Post-Acute Sequelae of SARS-CoV-2 Infection Initiative: NYU Langone Health Clinical Science Core, Data Resource Core,	University of Illinois at Chicago New York University School of	2025-03-21
OT2HL161847-01S1	and PASC Biorepository Core	Medicine	2025-03-24
P01AI158571-01A1S1	Design and Development of a Pan-betacoronavirus Vaccine	Duke University	2025-03-24
S06GM127983-04S1	Cherokee Nation Native AmericanResearch Center for Health	Cherokee Nation	2025-03-24
S06GM127983-03S1	RAD-X UP NARCH Supplement: A Cherokee Nation Community- Driven Program for Testing and Contact Tracing (Cherokee PROTECT)	Cherokee Nation	2025-03-24
U01Al167892-03S2	HIPC Data Coordinating Center	La Jolla Institute for Immunology	2025-03-24
U19Al171399	Al-driven Structure-enabled Antiviral Platform (ASAP)	Sloan-Kettering Inst Can Research	2025-03-24
010/41//1000	, a divolution of a state of the state of th	University of California, San	
U19Al171110	QCRG Pandemic Response Program RAPIDLY EMERGING ANTIVIRAL DRUG DEVELOPMENT INITIATIVE-	Francisco	2025-03-24
U19Al171292	AVIDD CENTER (READDI-AC)	Univ of North Carolina Chapel Hill Hackensack University Medical	2025-03-24
U19Al171401	Metropolitan AntiViral Drug Accelerator	Center	2025-03-24
U19Al171443	Center for Antiviral Medicines & Pandemic Preparedness (CAMPP) Development of outpatient antiviral cocktails against SARS-CoV-2	Scripps Research Institute, The	2025-03-24
U19Al171421	and other potential pandemic RNA viruses.	Stanford University	2025-03-24
U24TR001608-06S1	ACTIV-6	Duke University	2025-03-24
U24TR001608-07S1	ACTIV-6	Duke University	2025-03-24
U54EB015408-08S2	Point of Care Technology Research Center in Primary Care CoVPN 3008 Multi-Center, Randomized, Efficacy Study of Early vs Deferred Vaccination with COVID-19 mRNA Vaccine in Regions with	Massachusetts General Hospital	2025-03-24
UM1AI068618-18S1	SARS-CoV-2 Variants of Concern - LC Repository	Fred Hutchinson Cancer Center University of Puerto Rico Med	2025-03-24
T32GM148406	G-RISE at the University of Puerto Rico Medical Sciences Campus	Sciences	2025-04-02
T32GM144924	G-RISE at The University of Mississippi Initiative to Maximize Student Diversity at the University of New	University of Mississippi University of New Mexico Health Scis	2025-04-02
T32GM144834 K12GM068524	Mexico Health Sciences Center 2021 San Diego IRACDA Scholars Program	Ctr University of California at San Diego	2025-04-02 2025-04-02
T32GM148394	G-RISE at NMSU	New Mexico State University	2025-04-02
F31GM156104	Elucidating the Neuropeptidome Implicated in Crustacean Feeding Processes through Multiplexed Data-Independent Acquisition Mass Spectrometry	University of Wisconsin-Madison	2025-04-02
OT2OD035605	Partnership to Optimize Equity in Maternal and Infant Health	Delta Health Alliance, Inc.	2025-04-07
R01NS123115-02S1	Computational roles of inhibition in human action control Characterization of adaptive cis-regulatory variation across global	University of Oregon	2025-04-11
F31HG013889	populations UCSC Research Mentoring Internship Program: An Initiative to	Yale University	2025-04-15
R25HG006836	Increase Diversity and Inclusion in Genomics Research Bacterial and Molecular Determinants of Mycobacterial	University of California Santa Cruz	2025-04-15
R01Al179080	Impermeability Early resource scarcity effects on addiction-related behavior: a novel	University of Virginia	2025-04-18
K99DA060266	role for retrotransposons. Role of intestinal microfold (M) cells in creating a hotspot	Georgia State University	2025-04-21
R01Al184122	environment for HIV reservoir persistence and reactivation Promoting Sustained Viral Suppression Through Implementation of an Adapted Evidence-Informed Low-Barrier Care Model in a System	University of Washington	2025-04-23
R01MH132149-03S1	of HIV Primary Care Clinics	Northwestern University at Chicago	2025-04-23
R01MH129357-02S1	Anxiety and Interoception Risk for Eating Disorders in Childhood	University of Louisville	2025-04-24
R01EB033916	Robust, Contrast-Free Functional Renal MRI	University of Texas at Austin	2025-04-25

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	Computational Methods for Precise Holographic Control and		0-05 -4 00
K99NS135649	Mapping of Neural Circuits	Columbia Univ New York Morningside	2025-04-28
D04M142C040 02C4	Efficacy of digital cognitive behavior therapy for insomnia for the	University of California, San	2025 04 20
R01MH126040-03S1 F31DK141249	prevention of perinatal depression Investigating the roles and dynamics of the endoplasmic reticulum	Francisco Baylor College of Medicine	2025-04-28 2025-04-28
F31DK141249	during paligenosis and metaplasia formation	Baytor College of Medicine	2025-04-26
	Hardship and Survival: The Impact of Migration-Related Trauma,		
	Communal Coping, and Social Stressors on the Suicide and Mental		
F31MD018931	Health Outcomes of Latina Immigrant Women	Johns Hopkins University	2025-04-29
131110010931	Innovations in Personalizing Treatment for Eating Disorders Using	Johns Hopkins Onlycraity	2023-04-23
	Idiographic Methods and the Impact of Personalization on		
DP2MH136495-01S1	Psychological, Physical, and Sociodemographic Outcomes	University of Louisville	2025-04-30
	Assessing mechanistic relationships of central amygdala neuron	Chinosolty of Louisville	2020 0.00
F31DK138767	activity and glucagon-like peptide-1 receptor agonism	University of Alabama at Birmingham	2025-04-30
	CyberGut: towards personalized human-microbiome metabolic		
R01DK133468-03S1	modeling for precision health and nutrition	Institute for Systems Biology	2025-04-30
	Mitigating the Effects of Structural Racism on Chronic Kidney		
U01DK137269	Disease Disparities among African Americans	Emory University	2025-04-30
	Renal transplant Equity through Partnership and Structural	Icahn School of Medicine at Mount	
U01DK137259	Transformation (REPAST)	Sinai	2025-04-30
50000000000000000000000000000000000000	Improving access to renal transplantation for Underserved Black	971 TO 900 TO 6290	
U01DK137258	Communities	Northwestern University at Chicago	2025-04-30
	CommunityRx – Chronic Kidney Disease (CRx-CKD)" An EMR-		
	integrated community resources referral intervention to address	Hairrain of Namb Oardina Obaral	
U01DK137262	structural racism and kidney health disparities in rural North Carolina	University of North Carolina Chapel Hill	2025-04-30
UU1DK13/202	NAVIGATE Kidney: A Multi-Level Intervention to Reduce Kidney	пш	2025-04-30
U01DK137272	Health Disparities	University of Colorado Denver	2025-04-30
001DK137272	Interventions that Address Structural Racism to Reduce Kidney	Oniversity of Cotorado Denver	2023-04-30
U24DK137631	Health Disparities Research Coordinating Center	Duke University	2025-04-30
K99AI173544	to the Man are as the second of the second o	mente etco esta de termo de la composita de la	2025-05-02
	Improving phage-based medicine with immunoengineering	University of Pittsburgh at Pittsburgh	Technological Committee of the Committee
R01AG058066-04S1	Protective Genetic Varients for Alzheimer Disease in the Amish	Case Western Reserve University	2025-05-05
R01MD018459	Elucidating the high and heterogeneous risk of gestational diabetes	University of California at Los	2025-05-05
	among Asian Americans: an integrative approach of metabolomics,	Angeles	
	lifestyles, and social determinants		
F31AI186480	From exposure to infection: defining factors modulating the efficiency of influenza A virus infection	Emory University	2025-05-07
131A1100400	Identifying and manipulating behavioral and neural correlates of	Littory University	2023-03-07
K99MH135062	contextual learning	Northwestern University at Chicago	2025-05-08
NOOT-II I I OOUUZ	Building Accessible and Inclusive Paths for Students in Biomedical	Northwestern Oniversity at Officago	2023-03-00
R25LM014208	Informatics and Data Science	University of Pittsburgh at Pittsburgh	2025-05-28
		Time Time Time Time Time Time Time Time	

EXHIBIT B

Program¹	NRSA ²	Name	Explicitly meant to diversify workforce?	Currently available?3
Parent F30	Yes	Ruth L. Kirschstein National Research Service Award Individual Fellowship for Students at Institutions with NIH-Funded Institutional Predoctoral Dual-Degree Training Programs	No	Yes
Parent F30	Yes	Ruth L. Kirschstein National Research Service Award Individual Fellowship for Students at Institutions Without NIH-Funded Institutional Predoctoral Dual-Degree Training Programs	No	Yes
Parent F31	Yes	Ruth L. Kirschstein National Research Service Award Individual Predoctoral Fellowship	No	Yes
Parent F32	Yes	Ruth L. Kirschstein National Research Service Award Individual Postdoctoral Fellowship	No	Yes
Parent T32	Yes	Ruth L. Kirschstein National Research Service Award Institutional Research Training Grant	No	Yes
Parent T35	Yes	Ruth L. Kirschstein National Research Service Award Short- Term Institutional Research Training Grant	No	Yes
Diversity F31	Yes	Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research	Yes	No
MARC T34	Yes	Maximizing Access to Research Careers	Yes	No
U-RISE T34	Yes	Undergraduate Research Training Initiative for Student Enhancement	Yes	No
G-RISE T32	Yes	Graduate Research Training Initiative for Student Enhancement	Yes	No
IMSD T32	Yes	Initiative for Maximizing Student Development	Yes	No
Parent K01	No	Mentored Research Scientist Development Award	No	Yes
Parent K08	No	Mentored Clinical Scientist Research Career Development Award	No	Yes
Parent K23	No	Mentored Patient-Oriented Research Career Development Award	No	Yes
Parent K25	No	Mentored Quantitative Research Development Award	No	Yes
Parent K99/R00	No	NIH Pathway to Independence Award	No	Yes
ARC F99/K00	No	Advancing Research Careers Predoctoral to Postdoctoral Transition Award to Promote Diversity	Yes	No
MOSAIC K99/R00	No	Maximizing Opportunities for Scientific and Academic Independent Careers Postdoctoral Career Transition Award to Promote Diversity	Yes	No
MOSAIC UE5	No	Maximizing Opportunities for Scientific and Academic Independent Careers Organizational Research Education Award to Promote Diversity	Yes	No
IRACDA K12	No	Institutional Research and Academic Career Development Awards	Yes	No

¹ For brevity, programs listed above are only those (1) for extramural scientists; (2) focused on student or early career scientist training; and (3) in which multiple institutes or centers (ICs) currently or previously participated. For some programs not listed, only one IC participated. These include NIGMS' Bridges to the Baccalaureate and Bridges to the Doctorate programs, as well as programs in which only NIA or NICHD participated. This table also excludes a wide array of R25 Research Education Programs, many of which were (1) recently terminated or not renewed and (2) meant to support students from underrepresented backgrounds.

 $^{^{\}rm 2}$ NRSA refers to the Ruth L. Kirschstein National Research Service Award program.

³ Grant mechanisms are listed as "currently available" if either (1) a Program Announcement for the mechanism is active or (2) a Program Announcement for the mechanism is "forecasted" on Grants.gov to be posted as active on or before July 2025.

EXHIBIT 46

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

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

NATIONAL INSTITUES OF HEALTH, et al.,

Defendants.

SUPPLEMENTAL DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

- 1. I provide this supplemental declaration in support of Plaintiffs' Motion for Preliminary Injunction (ECF No. 37) and in response to Defendants' Opposition (ECF No. 66), including the Declaration of Jon Lorsch (ECF No. 66-1).
- 2. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I was Director of NIGMS from 2003-2011. To my knowledge, no terminations of any grants awarded by NIGMS occurred during my time as Director.
- 3. In his declaration (¶15), Jon Lorsch attaches and explains Exhibit A: a list of grants "related to health disparities in minority populations" which he represents NIH does not presently have any intent to terminate. However, searches of NIH Reporter revealed that MD013352 ("Impact of Navajo Nation Tax on Junk Food") ended in fiscal year 2021 and that MD018641 ("Understanding cancer and comorbidities among American Indian and Alaska Native people") was a two-year R21 award that ended on 4/30/25. In addition, two other awards (MD017106)

("Reducing Hypertension among African American Men: A Mobile Stress Management Intervention to Address Health Disparities") and MD018459 ("Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach to metabolomics, lifestyles, and social determinants") have unusual records in NIH Reporter with Award Notice Dates of 5/4/25 and Budget End Dates and Project End Dates of 5/5/25. A Project End Date of 5/5/25 would normally indicate that these awards, made very recently, were no longer active. The Project End Dates for the remaining grants included in Exhibit A are as follows: MD015221, 6/30/26; MD019748, 5/31/29; MD018583, 12/31/27; MD014859, 11/30/25; MD018193, 6/30/27; MD014127, 12/31/25; MD015724, 4/30/26; MD012610, 7/31/25; MD016068, 2/28/27; MD015186, 1/31/26; MD015724, 4/30/26; MD014035, 1/31/26; MD013752, 1/31/26; MD014146, 4/30/26; MD013858, 1/31/26; MD016961, 3/31/26; MD014145, 4/30/26; MD016738, 4/30/26; MD019397, 4/30/26; MD015080, 5/31/26; MD019333, 12/31/25; MD019227, 1/31/26.

- 4. Lorsch notes (¶13) that 431 appeals of grant terminations have been received by NIH. This process is quite opaque, and at this point I have not been able to learn of any appeals that have been successful. In addition, although I have not been able to obtain specific information, colleagues have shared that some requests to appeal have been declined because the Notice of Funding Opportunities to which the applicant responded has been discontinued by the new administration so that there is no remedy for an appeal because there is no available funding opportunity for the specific grant that was terminated.
- 5. Lorsch states (¶16) that "any funds that are not re-obligated will return to the treasury at the end of the fiscal year consistent with standard practice." While this appears to suggest that returning appropriated funds to the treasury was a common occurrence, my

recollection is that, during my time as NIGMS Director, NIH fully obligated all appropriated funds, such that NIH had final balances of less than \$1000 out of an appropriation of nearly \$2 billion for each year's appropriated funds.

- 6. Lorsch states (¶22-26) that NIH has made good progress catching up with the delayed scientific review and advisory council meetings and claims that "NIH anticipates that it will have reviewed 100% of cycle III grant applications" (¶25). However, it is not clear whether 100% of applicants Lorsch refers to includes all applications that were submitted in response to Notices of Funding Opportunities that were active at the time of application submission that were subsequently "expired" i.e., there are some NOFOs that were active and had applications submitted and assigned out to specific peer reviewers but which were subsequently withdrawn by the new administration. It is not clear how many applications were connected to these withdrawn NOFOs and whether they are included in Lorsch's reporting. It is also not clear what the status is for applications that were submitted in response to active Notices of Funding Opportunities that have been subsequently "expired" with regard to advisory council review. It is possible that such applications may have completed scientific review at study section but then were withdrawn so that they were never made available for advisory council review.
- 7. In some cases, some applications, specifically F31 applications responding to F31-Diversity funding opportunities were repeatedly reassigned to different study sections and it is not clear if these applications were ever reviewed. My understanding is that for some of these F31-Diversity applications, reviewers asked NIH review staff if such applications could simply be assigned to the Parent funding announcement as the applications are identical except for a single page used to justify eligibility for the diversity program i.e., remove the one page diversity

¹ https://www.statnews.com/2025/02/07/trump-nih-scraps-prestigious-diversity-program/

3

statement for F31-Diversity grants and allow these applications to continue under the standard F31 parent track. However, these reviewers were told that continuing to review the F31-Diversity applications was not possible as a matter of NIH policy.

- 8. Lorsch states (¶27) that "[f]rom the date of the temporary pause through May 12, 2025, NIH issued 11,362 non-competitive grants. NIH has also issued 1,971 new competitive grants in that same time frame." I was able to essentially reproduce those numbers through searches of the public database NIH Reporter (https://reporter.nih.gov/). To put Lorsch's 2025 numbers in context, I note that from January 28, 2024 through May 12, 2024, NIH issued 14,995 non-competitive grants and 5,557 competitive grants. In the last Presidential transition year (2021), NIH issued 15,691 non-competitive grants and 6,685 competitive grants from January 28 through May 12. Thus, compared to the last Presidential transition year, NIH has issued 72% as many non-competitive grants and 29% as many competitive grants over this same time period.
- 9. Lorsch states (¶31) that "the parent (NRSA) programs remain active". The parent Notices of Funding Opportunities for the F30², F31³ and F32⁴ all had their expiration dates moved up to May 8, 2025 and there were no Notice of Funding Opportunities for the F-series grants active at the time of his declaration as seen from a screen shot from May 13 from the page Lorsch cites in ¶32.

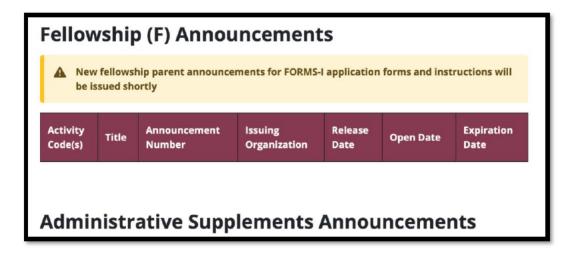
² https://grants.nih.gov/grants/guide/pa-files/PA-23-260.html

https://grants.nih.gov/grants/guide/pa-files/PA-23-272.html

⁴ https://grants.nih.gov/grants/guide/pa-files/PA-23-262.html



This page has now been updated with a comment that forms will be issued shortly.



However, no Notice of Funding Opportunity has yet appeared and NIH appears to be missing its own target dates. These delays are harmful as graduate students, both early in graduate school or later in graduate school and in the process of searching for postdoctoral fellowship opportunities, may be required to make career decisions based on the current uncertainty.

10. Also included and analyzed (¶34) in the Lorsch Declaration was Exhibit B with a list of 5,172 active NRSA grants.⁵ I have performed an analysis of the grants in Lorsch Decl.

-

⁵ The list includes 148 entries from Harvard which, based on recent reports of wide-ranging grant terminations at Harvard University, may in fact have been terminated. *See* https://www.bostonglobe.com/2025/05/16/metro/harvard-trump-administration-grant-terminations/

Exhibit B and my analysis is attached to this declaration as **Exhibit A**. This analysis reveals that 25% of these awards are expected to end by 9/30/2025 with an additional 33% expected to end by 9/30/26. Furthermore, an additional 5% of the grants are at risk for being terminated in fiscal year 2026 as they were awarded in response to a NOFO with a substantial diversity focus and require a non-competitive renewal award for continuation in fiscal year 2027. Finally, it is noted that NIH is making new and competitive renewal awards at a rate that is only 18% of the average rate for the same period in the five previous fiscal years. Taken together, these observations suggests that the level of NRSA funding will drop dramatically if present policies are continued.

11. I have been tracking the amount of the NIH appropriation remaining to be committed and the time remaining in the fiscal year. A recent analysis is attached as **Exhibit B**. The conclusion from this analysis is that, in order to fully allocate the funds appropriated for this fiscal year, NIH must commit more than \$27 B appropriated funds from May 1st through September 30th. Such a pace is has essentially never occurred over any month period over the past decade (and likely ever).

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 19th day of May, 2025, in Gibsonia, PA.

Jeremy M. Berg, Ph.D. Former Director (2003-2011)

National Institute of General Medical Sciences

National Institutes of Health

EXHIBIT A

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Analysis of Lorsch Exhibit B

Jeremy M. Berg

5/19/2025

The pdf file supplied as Exhibit B in association with the Lorsch declaration was converted to an Excel file using Adobe Acrobat. This resulted in 5161 records. This is slightly less than the 5172 records claimed in the Lorsch declaration. It is not clear whether this small difference is related to the conversion to the Excel file or an error in the declaration, but the small difference is not material to the following analysis.

The distribution of Activity codes for these awards is as follows:

F30: 750
F31: 1919
F32: 674
FM1: 3
T32: 1597
T34: 78
T35: 60
T90: 23
TL1: 47
TL4: 10

These 5161 records correspond to 5087 distinct grants with 74 having multiple records in the pdf. These all or essentially all correspond to grants for which both the new, competitive renewal, on non-competitive renewal awards and a supplement to that award (identifiable by a grant number that begins with "3").

With these grant numbers available, we can search the NIH Reporter database to recover the full records for these grants including information about the Funding Opportunity used to obtain each award.

In doing this search, five grants (F31DE033887, F31AR082294, F31HL163924, TL4GM118986, F31AG077880) were not found doing a search for active grants. Subsequent searches revealed that the first four grants ended on 9/30/24, 5/31/24, 8/1/24, and 6/30/24. The remaining grant (F31AG077880) has a project end date of 5/24/25 but is not listed as an active grant.

The remaining 5082 grant numbers were found among active grants on May 17, 2025.

Searching the NIH Reporter database for Active grants with these grant numbers and Activity codes (F30, F31, F32, FM1, T32, T35, T36, T90, TL1, TL4) resulted in 5225 records. This is slightly higher than 5172, presumably due to capturing some additional awards with the same core grant number such as supplements. The sources of this difference could be identified with more analysis but, again, the difference will not be material for the present work.

Funding announcements focused on increasing diversity in the biomedical workforce

These awards were made in response to 83 Notices of Funding Opportunities (NOFOs). Of these NOFOs, 18 had a substantial focus on increasing the diversity of the biomedical workforce (hereafter "Diversity Opportunities")

Grant end dates

Among the 5225 grants, 1075 had Project End Dates on or prior to 9/30/25. Thus, 21% of these NRSA awards will end by the end of the current fiscal year. For the grants that were awarded in response to a Diversity Opportunity this percentage is slightly higher at 25%. The activity codes for these diversity grants are 144 F31, 3 T32, and 15 T34.

Of the 4149 grants that extend past the end of this fiscal year, the number of grants anticipated to end is fiscal year 2026 is 1706. Of these, 222 where awarded in response to Diversity Opportunities. The activity codes for these applications are 205 F31, 1 F32, 11 T32, and 5 T34.

Challenges to maintaining a robust NRSA portfolio

In order to maintain a reasonable level of NRSA awards, NIH will have to make a substantial number of new or competitive renewal awards. We can examine how NIH has been doing in this regard since the start of the current administration.

Between January 20, 2025 and May 10, 2025, NIH awarded 120 new or competitive renewal awards with an activity code F30, F31, F32, FM1, T32, T35, T90, TL1, or TL4.

For comparison, the number of these awards over the period from January 20 through May 10 for earlier years were:

2020: 709 2021: 686 2022: 627 2023: 703 2024: 590

Thus, the number of these awards in during this administration is 18% of the average over the prevous 5 years.

EXHIBIT B

Time Remaining for Award Making in Fiscal Year 2025

Jeremy Berg 5/4/2025

The Rate of NIH Grant Making and the Risk of not Investing the Entire NIH Appropriation in Fiscal Year 2025

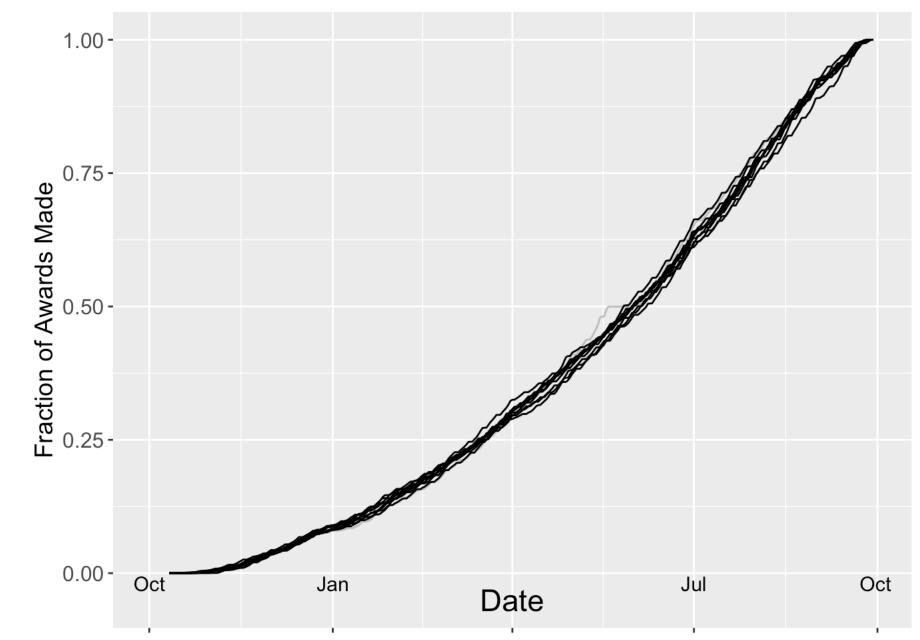
NIH has 27 institutes and centers, of which 24 have grant-making authority. In addition, some grants are funded through the NIH Office of the Director's Common Fund.

The rate does NIH award making

Data about NIH awards are available in the NIH Reporter database.

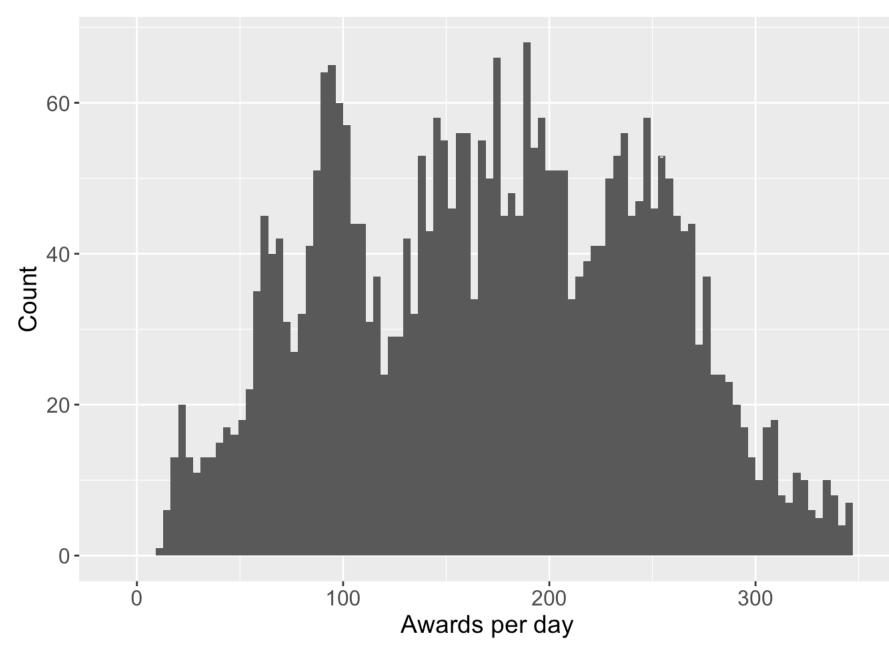
Data for fiscal years 2015-2024 reveal that the number of awards of all types (not including subawards) ranged from 50007 in fiscal year 2015 to 63483 in fiscal year 2024.

A plot of the fraction of awards over the course of these fiscal years is shown below:



The curves are very similar. They are not linear. The rate of making grant awards is relatively low at the beginning of each year and then increases before tapering off at the end of the year. This is due to several factors including the appropriations process (almost always delayed) and the timing of grant application submission opportunities, and the timing of advisory council meetings for grant approval (which occur three times per year).

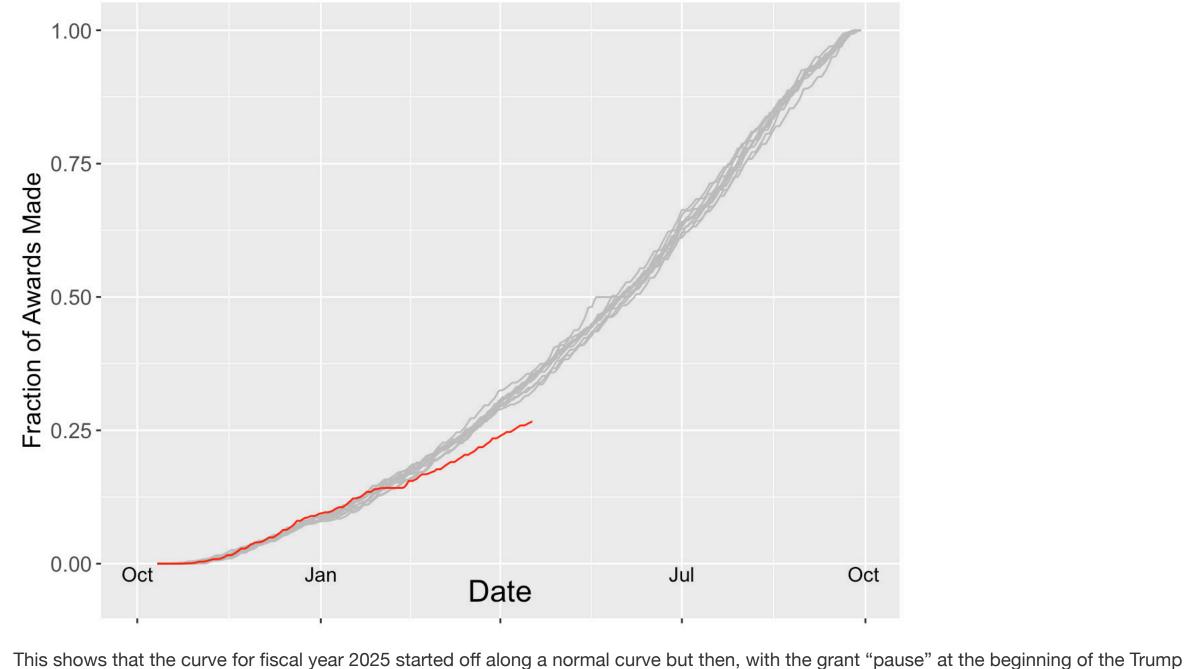
The daily number of grant awards ranges from 0 to 719. However, rather than just looking at daily rates, a more informative quantity is the rate over a more extended period of time. A histogram of the average daily rate over 30 day periods is shown below:



The median for the distribution is 174 with the 80%ile of 246, that is, 80% of all average daily rates are below this value.

Results for fiscal year 2025

The results for fiscal year to date can be added to the previous graph:



administration in early February 2025, the fiscal year 2025 diverged, lying below the other curves. It has remained there, due to a relatively low rate of award release.

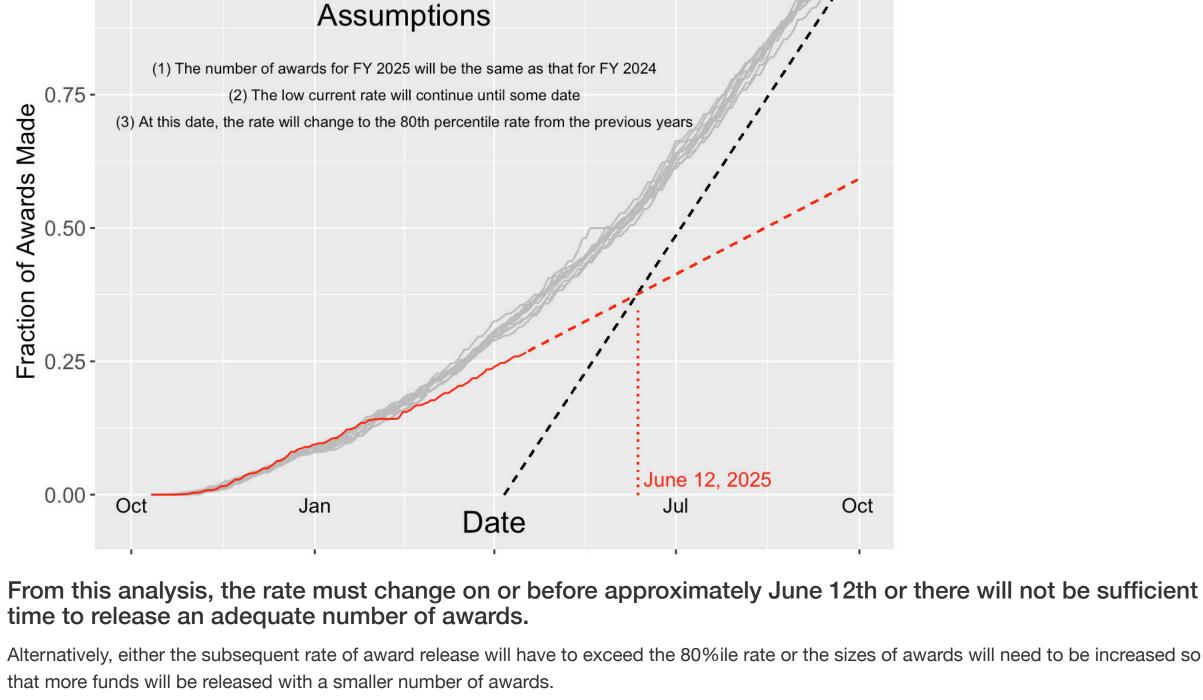
Does NIH have sufficient time to release its full appropriation in fiscal year 2025? We can address this important question but we need to make some assumptions.

One set of limiting assumptions are:

1. The number of awards for fiscal year 2025 will be the same as that for fiscal year 2024.

1.00 -

- 2. The low current rate will continue until some date;
- 3. At this date, the rate will change to the 80th percentile rate from the previous years.
- The results from these assumptions are shown below:



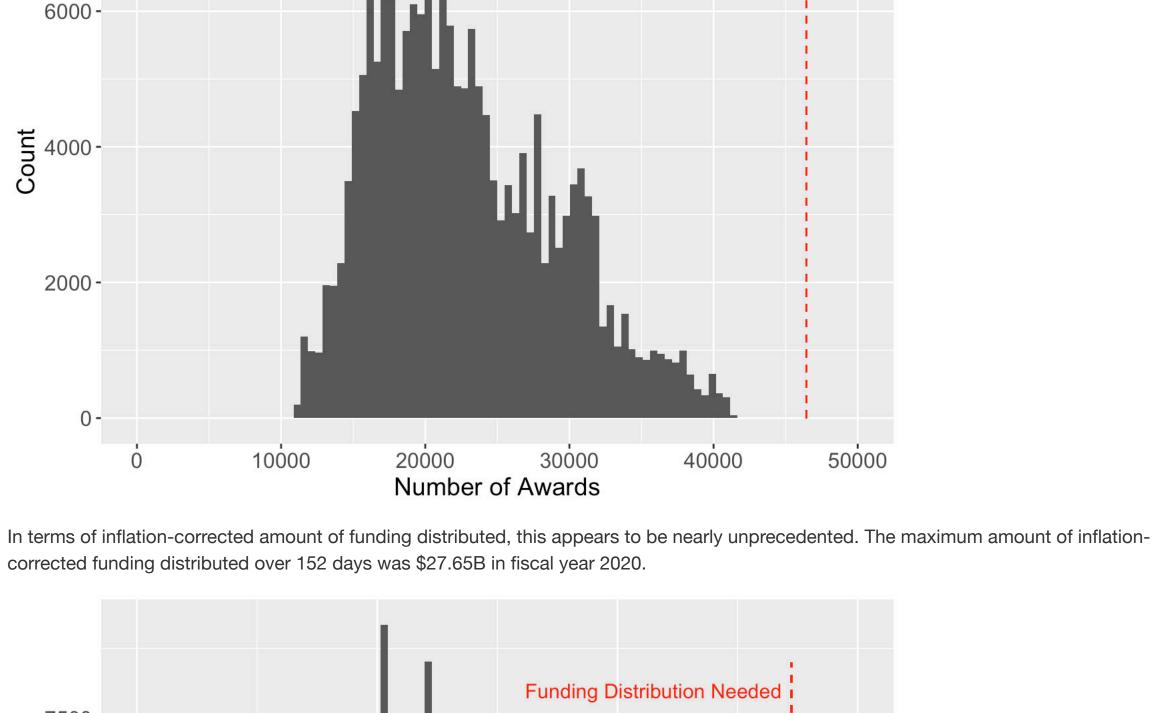
Sustained funding over five months

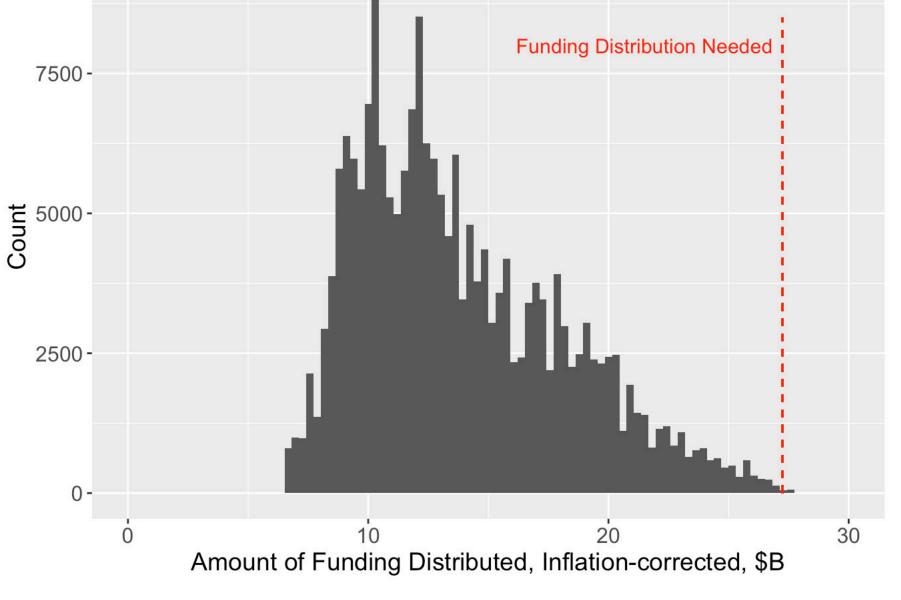
For the period from May 1st to September 30th, the number of awards that are needed to be made is 46444 and the amount of funding that needs to be distributed is \$27.25 B. This must occur over 152 days. Has this every occurred? This can examined by looking a fiscal years 2015 to 2024 over windows of 152 days. The amount of funding in each year was corrected for

inflation to 2025 dollars. The results are shown below.

Number of Awards Needed

For the number of awards, it appears that this number in unprecedented over this period of time.





This analysis suggests that it is even more imperative that the rate of fund distribution accelerate as soon as possible.

EXHIBIT 47

March 31, 2025

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicant organizations should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the (//grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grant (Parent T35)

Activity Code

T35 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t35&Search.x=0&Search_y=0&Search_Type=Activity) National Research Service Award (NRSA) Short-Term Research Training

Announcement Type

Reissue of PA-23-080 (https://grants.nih.gov/grants/guide/pa-files/PA-23-080.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=42231) associated with this funding opportunity

• March 31, 2025 - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

• April 4, 2024 - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html).

Funding Opportunity Number (FON)

PA-25-280

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.351, 93.866, 93.173, 93.867, 93.213, 93.273, 93.286, 93.847, 93.233, 93.113

Funding Opportunity Purpose

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grants (T35) to eligible, domestic institutions to develop and/or enhance research training opportunities for predoctoral students interested in careers within biomedical, behavioral, or clinical research workforce. Many NIH Institutes and Centers (ICs) use this NRSA program exclusively to support intensive, short-term research training experiences for health professional students (medical students, veterinary students, and/or students in other health-professional programs) during the summer. This program is also intended to encourage training of graduate students in the physical or quantitative sciences to pursue interests in careers within the biomedical research workforce by providing short-term exposure to, and involvement in, the health-related sciences. The training should be of sufficient depth to enable the trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

This Notice of Funding Opportunity (NOFO) does not allow Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Funding Opportunity Goal(s)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Key Dates

Posted Date

January 03, 2025

Open Date (Earliest Submission Date)

December 25, 2024

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH <u>standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm)</u> marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	August 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	August 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	August 2027	December 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028
January 25, 2028 *	January 25, 2028 *	May 07, 2028 *	July 2028	August 2028	December 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicant organizations are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

May 08, 2028

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

<u>Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u>, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and <u>eRA Commons</u> (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
- 3. Use <u>Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-280)</u> Workspace to prepare and submit your application and <u>eRA Commons (http://public.era.nih.gov/commons/)</u> to track your application.

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Section VII. Agency Contacts

Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall purpose of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url redirect.php?id=41125) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and develop an enhanced program of coursework, mentored research experiences, and technical and professional skills development appropriate for the appointed trainees that provides added value to already existing programs.

The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

Program Objective

The goal of the Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (T35) program is to develop and/or enhance research training opportunities for health professional students and for graduate students in the physical or quantitative sciences interested in careers in biomedical, behavioral and clinical research workforce that are relevant to the NIH mission. The T35 program provides short-term support for a period of at least 8, but no more than 12, weeks in a grant year for full-time training experiences under the supervision of experienced researchers. Trainees are exposed to mentors with active research careers and learn about further research training opportunities and research career options. The training program should be of sufficient depth to enable selected trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant institution, but the proposed program must be clearly distinct from related programs currently receiving Federal support.

Program Considerations

Institutional short-term training grants are intended to introduce predoctoral students to research that would not otherwise be available through their regular course of graduate study. The research experiences should be tailored to the individual to meet their training goals. Didactic instruction must

include training in the responsible conduct of research. Positions on NRSA short-term institutional training grants may not be used for courses and study leading to the MD, DDS, DO, DVM, or other clinical, health professional degree, nor to support residency training.

Research elective credit may be granted for students who complete a short-term, research training experience supported by the T35. The decision to award elective credit will be at the discretion of the sponsoring institution and must be consistent with the policies of the institution (see Funding Restrictions).

Recipient organizations may provide training to students enrolled at other institutions through a partnership or consortium structure. Consortia should be well justified to enhance the goals and objectives of the training program. Consortium partners will be identified by the applicant organization, and each partner institution must identify faculty at their location who have agreed to serve as mentors.

Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex of a trainee or faculty candidate as an eligibility or selection criterion, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicant organizations and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.

This Notice of Funding Opportunity (NOFO) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective applicant organizations MUST consult the Table of IC-Specific Information, Requirements and Staff Contacts
(https://grants.nih.gov/grants/guide/contacts/IC-specific-information-Ph-25-280.html), to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

Renewal

Resubmission

Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (<u>NIH Grants Policy Statement - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=41126)</u>). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120)</u>, and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T35 short-term institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants* and *Contracts*, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for this to be an allowable cost.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicant organizations are encouraged to consult the <u>Table of IC-Specific Information</u>, <u>Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)</u> for further information.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the NIH Guide for Grants and Contracts, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of \$25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicant Organizations

Eligible Organizations

Higher Education Institutions

- · Public/State Controlled Institutions of Higher Education
- · Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- · U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- · Faith-based or Community-based Organizations

Federal Governments

- · Eligible Agencies of the Federal Government
- · U.S. Territory or Possession

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicant organizations should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390). Applicant organizations must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- <u>eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300)</u> Applicant organizations must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with their organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program consistent with applicable law, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports

as required. The PD/PI has responsibility for the day to day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the <u>NIH Grants Policy Statement Section 1.2 Definition of Terms (//grants.nih.gov/grants/guide/url_redirect.php?id=11126)</u>.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423))

Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program. When building a training team, programs should include faculty who are committed to training, mentoring, and providing safe and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

Trainees

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the NIH.Grants.nih.gov/grants/guide/url_redirect.php?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

Short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the PharmD degree are eligible for short-term, research training positions.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise.

Conformance to the requirements in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the <u>How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u> and the <u>Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=11133)</u> must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the <u>How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u> and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Project Summary/Abstract. Provide an abstract of the entire application. Include the objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term faculty), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file "Advisory Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the <u>How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u>.

PHS 398 Cover Page Supplement

Follow all instructions provided in the <u>How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u>.

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Training Budget

Follow all instructions provided in the <u>How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u> with the following additional modifications:

• Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- · Faculty, Trainees, and Training Record
- Other Training Program
- Appendix Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicant organizations to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url redirect.php?id=82400).

Particular attention must be given to the required International <u>Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.php?id=61169)</u>. Applicant organizations should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective trainee candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

Training Program

Program Plan

Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique background and skill set that will enhance training. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The appropriate expertise (for example, a record of rigorous research), as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicant organizations should indicate the program director's percent effort in the proposed program).
- · A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor trainees prior to the start of the program.

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program

Program Faculty

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

The efforts made to recruit a pool of prospective program faculty from a range of career stages and scientific disciplines relevant to the training
goals, to provide potential role models within the training program and to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress.

 This should include a mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of all
 trainees. Include the planned format, duration, and frequency of mentor training activities for program faculty and a description of how mentor
 training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training.
 Examples of relevant topics include, but are not limited to:
 - · Aligning expectations.
 - · Maintaining effective communication.
 - · Fostering independence.
 - · Assessing scholars' understanding of scientific research.
 - Enhancing professional development.
 - o Articulating your mentoring philosophy and plan.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, and professional development, and how
 these activities will address the program's training goals and objectives.
- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicant organizations and trainees will be provided with information about the overall biomedical research workforce
 employment landscape, the variety of careers in the biomedical research workforce for which their training would be useful, and the career
 outcomes of graduates of the program (e.g., on publicly accessible websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.
- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational
 interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the
 biomedical research workforce.

Training Program Evaluation

The application should describe:

• How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is safe and supportive of trainee development.

• The program's procedures for responding to program evaluation findings.

Trainee Candidates and Retention Plans

Through the narrative and summaries of the information presented in the <u>Training Data Tables (https://grants.nih.gov/grants/forms/datatables.htm)</u> and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized
 test scores) that will allow a broad group of research-oriented trainees who have taken advantage of the research opportunities available to
 them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are
 encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the
 program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of all trainees within the program (i.e., retention). Applicant organizations are encouraged to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

Institutional Environment and Commitment to Training

• The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing a safe and supportive environment with procedures to ensure accountability and reporting of concerns. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the NOFO. Do not repeat information contained elsewhere in the application.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required <u>training tables (https://grants.nih.gov/grants/forms/data-tables.htm)</u>. The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training_Table 5 (https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree <u>Training Table 8</u> (https://grants.nih.gov/grants/forms/data-tables.htm)).
- The success of recent graduates transitioning to careers in the biomedical research workforce (<u>Training Table 8</u>).
 (https://grants.nih.gov/grants/forms/data-tables.htm)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Progress Report for Renewal Applications

For renewal applications include information in the "Program Overview" section to demonstrate that the program successfully trained a pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote safe and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- · Training, mentoring, and promoting a safe and supportive scientific environment.
- · Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also be described in the letter:

- · Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- · Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to
 devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and
 promotion decisions.
- Promoting safe and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4
 linesuppose: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm) regarding NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality research); ensuring the research facilities are accessible to trainees with disabilities.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discrimination, harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-22-129. (https://grants.nih.gov/grants/quide/notice-files/NOT-OD-22-129.html)).
- Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- · Supporting evaluation of the training program and procedures for responding to evaluation findings.

Other Training Program Section

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicant organizations are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicant organizations must then complete the submission process by tracking the status of the application in the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicant organizations are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the <u>How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)</u>.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u> (<u>//grants.nih.gov/grants/guide/url_redirect.php?id=11120</u>). The <u>National Research Service Award (NRSA) policies</u>

(//grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the <u>How to Apply - Application Guide</u> (https://grants.nih.gov/grants/guide/url redirect.php?id=82400). Paper applications will not be accepted.

Applicant organizations must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply-Application-Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, <u>2 CFR 200.113 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113)</u> and <u>NIH Grants Policy Statement Section 4.1.35 (https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm)</u>.

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

Post Submission Materials

Applicant organizations are required to follow the instructions for post-submission materials, as described in the-policy/drants.nih.gov/grants/guide/url_redirect.php?id=82299).

Any instructions provided here are in addition to the instructions in the policy.

Substitute the term "scholars" for all references to "trainees" in the SF424 (R&R) Application Guide, and substitute the term "career development" for all references to "training" in the SF424 (R&R) Application Guide.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system. While any information in the application relevant to the program goals can be included as part of the review process, the race, ethnicity, or sex of trainee candidates, trainees, or faculty may not be used as factors in the evaluation of applications.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will equip the trainees with the skills, knowledge and experiences necessary to transition to successful careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed.)

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major biomedical research training impact.

Training Program and Environment

- Does the application provide a compelling rationale for the proposed research training program and propose appropriate training goals and objectives relevant to the rationale?
- Will the courses, structured training activities, mentoring, and research experiences achieve the training program's goals and objectives, and provide opportunities for trainees to acquire skill and expertise in transparent, rigorous, reproducible and relevant research methodologies and tools applicable to the goals of the training program?
- Is there an effective mechanism to monitor mentoring and to promote the development, retention and success of all trainees throughout their training?
- Will the proposed training program provide the trainees appropriate information regarding the breadth of careers in the biomedical research
 workforce for which their training may be useful, and appropriate learning opportunities that allow them to develop the professional skills
 and networks necessary to transition into those careers?
- · Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote
 the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?
- Does the application provide a compelling rationale for the proposed short-term research training program and include appropriate training goals and objectives relevant to the rationale? Are the objectives, design, direction, and quality of the proposed short-term research training program likely to ensure effective training?
- Are the proposed courses, structured training activities, mentoring, and research experiences where applicable appropriate for the level
 of trainees and the area(s) of science to be supported by the program? Do the program activities appropriately introduce trainees to
 transparent, rigorous, and reproducible research methodologies?
- If appropriate, does the program provide training in inter- or multi-disciplinary research and/or provide training in state-of-the-art or novel
 methodologies and techniques?
 - Is the proposed program of training likely to ensure that trainees will acquire knowledge and skills necessary to prepare them for a research career? Does the program include features likely to encourage short-term trainees to consider careers in health-related research?
- · Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote
 the success of the program?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the appropriate background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) plan to commit sufficient effort to promote the program's success?
- Have the PD(s)/PI(s) demonstrated a strong commitment to training future researchers?
- Does the application describe how the PD(s)/PI(s) will receive appropriate training on effective mentoring practices to promote trainee success?
- · For applications designating multiple PDs/PIs:
 - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
 - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/Pls?

Preceptors/Mentors

- Does the proposed program demonstrate the presence of a sufficient pool of preceptors/mentors with appropriate expertise and adequate
 resources available to support the training goals and objectives proposed in the application (including short-term training, if applicable)?
- Is there a strong plan to ensure participating faculty receive appropriate training in the use of evidence-informed mentoring practices that promote the development of all trainees?
- Do participating faculty appropriately promote the trainees' career progression?
- Do the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable)
 proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely
 to provide strong and successful mentoring?

Trainees

• Does the proposed short-term training program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training goals and objectives? Are the outlined recruitment strategies likely to identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?

- Does the program have access to and the ability to recruit high quality, short-term trainees from the applicant institution or another healthprofessional school?
- · Are the recruiting procedures and trainee selection criteria appropriate and well defined?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the
 ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous
 institution, GPA, and standardized test scores)?

Training Record

- · How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?
- For applications that request short-term research training positions, is there a record of retaining health professional trainees in research training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format -* Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) *Subject Matter -* Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) *Faculty Participation -* Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) *Duration of Instruction -* Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) *Frequency of Instruction -* Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the short-term training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the short-term research training experience during the next project period?
- Does the program use current, evidence-informed training and mentoring approaches and continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by {LOCUS OF REVIEW} in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions, consistent with applicable law:

- · Scientific and technical merit of the proposed project as determined by scientific peer review.
- · Availability of funds.
- Relevance of the proposed project to program priorities.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures. (//grants.nih.gov/grants/guide/url_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the <u>eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)</u>. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?</u> id=11120).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in <u>Section IV.6. Funding Restrictions</u>. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the <u>NIH Grants Policy Statement Section 5. The Notice of Award (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://grants.nih.gov/grants/pre-award-process.htm#award)</u>

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at <u>2 CFR Part 200 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200)</u>, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php? id=11120)</u> as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the <u>NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) and <u>Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159).</u>
 </u>
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
 - HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in <u>NIH Grants Policy Statement Section 4</u>
<u>Public Policy Requirements, Objectives and Other Appropriation Mandates.</u>

(https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements objectives and other appropriation mandates.htm)

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

(https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions_uspension_termination_and_withholding_of_support.htm).

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171)</u>. Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the <u>NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?</u> id=41171).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-health-it (https://www.healthit.gov/topic/certification-health-it) to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- 1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- 2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement.

(https://grants.nih.gov/grants/policy/nihgps/HTML5/section 8/8.2.3 sharing research resources.htm#Data)

4. Reporting

When multiple years are involved, recipients will be required to submit the <u>Research Performance Progress Report (RPPR)</u> (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over \$25,000. See the https://www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

Other Reporting Requirements

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement Section 8.6 Closeout

(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in achieving its goals, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

For programs involving undergraduate students:

- · Successful completion of an undergraduate degree in a STEM field
- · Pending application for and/or enrollment in an advanced degree program in a STEM field
- · Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field

For programs involving graduate students:

- · Successful completion of a STEM graduate program
- · Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- · Subsequent independent research grant support from NIH or another source

For programs involving postdoctorates and early career investigators:

- Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- · Subsequent independent research grant support from NIH or another source

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this NOFO, prospective applications **MUST** consult the <u>Table of IC-Specific Information</u>, <u>Requirements</u>, <u>and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html</u>)</u>, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)

Email: <u>GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov)</u> (preferred method of contact)

Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Neeraj Agarwal

NEI - NATIONAL EYE INSTITUTE

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Edwin C Clayton

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E-mail: ed.clayton@nih.gov (mailto:ed.clayton@nih.gov)

Jennifer N. Baumgartner, Ph.D.

National Center for Complementary and Integrative Health (NCCIH)

Phone: 301-402-4084

Email: jennifer.baumgartner@nih.gov (mailto:jennifer.baumgartner@nih.gov)

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Carol Shreffler, PhD

NIEHS - National Institute of Environmental Health Sciences

Phone: 984-287-3322

Email: Shreffl1@niehs.nih.gov (mailto:Shreffl1@niehs.nih.gov)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Karen Robinson Smith

NEI - NATIONAL EYE INSTITUTE

Phone: 301-435-8178

E-mail: kyr@nei.nih.gov (mailto:kyr@nei.nih.gov)

Debbie Chen

National Center for Complementary and Integrative Health (NCCIH)

Phone: 301-594-3788

Email: debbie.chen@nih.gov (mailto:debbie.chen@nih.gov)

Jenny Green

NIEHS - National Institute of Environmental Health Sciences

Phone: 984-287-3332

Email: jenny.greer@nih.gov (mailto:jenny.greer@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH <u>policy notices</u> (<u>//grants.nih.gov/grants/guide/url_redirect.php?id=11163</u>) may affect your application submission. A full list of policy notices published by NIH is provided in the <u>NIH Guide for Grants and Contracts</u> (<u>//grants.nih.gov/grants/guide/url_redirect.php?id=11164</u>). All awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u> (<u>//grants.nih.gov/grants/guide/url_redirect.php?id=11120</u>).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?01-03-25)

NIH Funding Opportunities and Notices (/grants/guide/index.html)







NIH... Turning Discovery Into Health®

EXHIBIT 48

The Wayback Machine - https://web.archive.org/web/20250122W5054/https://grants.htm.gov/grants/guide/pa-files/pa-25-250-html/25 Page 2 of 17

Department of Health and Human Services

Part 1. Overview Information

Number of Applications

Participating Organization(s) National Institutes of Health (NIH (https://web.archive.org/web/20250122105054/http://www.nih.gov/)) **Components of Participating Organizations** Office of The Director, National Institutes of Health (OD (https://web.archive.org/web/20250122105054/https://www.nih.gov/institutes-nih/nih-office-director)) National Eye Institute (NEI (https://web.archive.org/web/20250122105054/https://www.nei.nih.gov/)) National Heart, Lung, and Blood Institute (NHLBI (https://web.archive.org/web/20250122105054/https://www.nhlbi.nih.gov/) National Institute on Aging (NIA (https://web.archive.org/web/20250122105054/https://www.nia.nih.gov/)) National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://web.archive.org/web/20250122105054/https://www.niaaa.nih.gov/) National Institute of Biomedical Imaging and Bioengineering (NIBIE (https://web.archive.org/web/20250122105054/https://www.nibib.nih.gov/)) National Institute on Deafness and Other Communication Disorders (NIDCD (https://web.archive.org/web/20250122105054/https://www.nidcd.nih.gov/) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK National Institute of Environmental Health Sciences (NIEHS (https://web.archive.org/web/20250122105054/https://www.niehs.nih.gov/)) National Center for Complementary and Integrative Health (NCCIH (https://web.archive.org/web/20250122105054/https://nccih.nih.gov/) Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicant organizations should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants/guide/contacts/parent_T32.html)https://grants/guide/contac specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/quide/contacts/IC-specific-information-PA-25-280.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged. **Funding Opportunity Title** Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grant (Parent T35) **Activity Code** T35 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/funding/ac_search_results.htm? text_curr=t35&Search.x=0&Search.y=0&Search_Type=Activity) National Research Service Award (NRSA) Short-Term Research Training Reissue of PA-23-080 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/pa-files/PA-23-Announcement Type 080.html) **Related Notices** See Notices of Special Interest (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm? GuideDocID=42231) associated with this funding opportunity • April 4, 2024 - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html). **Funding Opportunity Number (FON)** PA-25-280 **Companion Funding Opportunity**

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s) 1:25-cv-10787-WG3Y1, 93.000, GUT, 93.201,

Funding (Dpr	ortunity	Purpose
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The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grants (T35) to eligible, domestic institutions to develop and/or enhance research training opportunities for predoctoral students interested in careers within biomedical, behavioral, or clinical research workforce. Many NIH Institutes and Centers (ICs) use this NRSA program exclusively to support intensive, short-term research training experiences for health professional students (medical students, veterinary students, and/or students in other health-professional programs) during the summer. This program is also intended to encourage training of graduate students in the physical or quantitative sciences to pursue interests in careers within the biomedical research workforce by providing short-term exposure to, and involvement in, the health-related sciences. The training should be of sufficient depth to enable the trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

This Notice of Funding Opportunity (NOFO) does not allow Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Funding Opportunity Goal(s)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability..

Key Dates

Posted Date

January 03, 2025

Open Date (Earliest Submission Date)

December 25, 2024

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH <u>standard due dates (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.</u>

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	August 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	August 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	August 2027	December 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028
January 25, 2028 *	January 25, 2028 *	May 07, 2028 *	July 2028	August 2028	December 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicant organizations are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date May 08, 2028

Due Dates for E.O. 12372 Not Applicable

Required Application Instructions

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply Application Guide,

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the NIH Guide for Grants and Contracts (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to all requirements (both in the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicant organizations must read and follow all application instructions in the How to Apply Application Guide,

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply Application Guide. J//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions. Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://web.archive.org/web/20250122105054/https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
- 3. Use Grants.gov (/web/20250122105054/https://grants.nih.gov/grants/guide/ApplyButtonSplash.cfm?dest=https://grants.gov/search-grants?

 oppStatuses=closed|archived|posted|forecasted&fon=PA-25-280) Workspace to prepare and submit your application and eRA Commons

 (https://web.archive.org/web/20250122105054/http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall purpose of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the https://grants.nih.gov/grants.nih.gov/grants/guide/url_redirect.php?id=41125) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and develop an enhanced program of coursework, mentored research experiences, and technical and professional skills development appropriate for the appointed trainees that provides added value to already existing programs.

The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

Program Objective

The goal of the Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (T35) program is to develop and/or enhance research training opportunities for health professional students and for graduate students in the physical or quantitative sciences interested in careers in biomedical, behavioral and clinical research workforce that are relevant to the NIH mission. The T35 program provides short-term support for a period of at least 8, but no more than 12, weeks in a grant year for full-time training experiences under the supervision of experienced researchers. Trainees are exposed to mentors with active research careers and learn about further research training opportunities and research career options. The training program should be of sufficient depth to enable selected trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant institution, but the proposed program must be clearly distinct from related programs currently receiving Federal support.

Program Considerations

Institutional short-term training grants are intended to introduce predoctoral students to research that would not otherwise be available through their regular course of graduate study. The research experiences should be tailored to the individual to meet their training goals. Didactic instruction must include training in the responsible conduct of research. Positions on NRSA short-term institutional training grants may not be used for courses and study leading to the MD, DDS, DO, DVM, or other clinical, health professional degree, nor to support residency training

Research elective credit may be granted for students who complete a short-term, research training experience supported by the T35. The decision to award elective credit will be at the discretion of the sponsoring institution and must be consistent with the policies of the institution (see Funding Restrictions).

Recipient organizations may provide training to students enrolled at other institutions through a partnership of consortium structure. Consortium structure. Consortium structure. goals and objectives of the training program. Consortium partners will be identified by the applicant organization, and each partner institution must identify faculty at their location who have agreed to serve as mentors.

Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of a trainee or faculty candidate as an eligibility or selection criterion, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicant organizations and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.

This Notice of Funding Opportunity (NOFO) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or comentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective applicant organizations MUST consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html), to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II Award Information

Section II. Award Information	
Funding Instrument	Grant: A <u>financial assistance</u> mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Renewal Resubmission Revision
	The OER Glossary (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php? id=11116) and the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials. Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.
	Need help determining whether you are doing a clinical trial? (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	Application budgets are not limited, but need to reflect the actual needs of the proposed project.
	Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (<u>NIH Grants Policy Statement - Institutional Research Training Grants</u> (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the <u>NIH Grants Policy Statement</u> (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.
Award Project Period	Awards for T35 short-term institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.
Other Award Budget Information	
Stipends, Tuition, and Fees	Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the NIH Guide for Grants and Contracts, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage

(https://web.archive.org/web/20250122105054/https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicant organizations are encouraged to consult the <u>Table of IC-Specific Information, Requirements and Staff Contacts</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) for further information.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the *NIH Guide for Grants and Contracts*, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://web.archive.org/web/20250122105054/https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of \$25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicant Organizations

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- · Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- · Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations $\mbox{\it are not}$ eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), and the control of the control of

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicant organizations should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management 125-CV-110787-WGV/web/2Document 172.76 ants. n. Filed 05/119/25 edirect page 239f Applicant organizations must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- <u>eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82300) Applicant organizations must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/Pl(s) must have an eRA Commons account. PD(s)/Pl(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/Pl is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including individuals from underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html) and Notice of NIH's Interest in Diversity, NOT-OD-20-031 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

For institutions/organizations proposing multiple PDs/Pls, visit the Multiple Program Director/Principal Investigator Policy

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/quide/url_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program consistent with applicable law, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required. The PD/PI has responsibility for the day to day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82423))

Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program. When building a training team, programs should include faculty who are committed to training, mentoring, and providing inclusive, safe, accessible, and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

Trainees

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

Short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not

eligible for short-term training positions. Within schools of pharmacy, only individual who are candidates for the Filed 05/19/25.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

 $All \ instructions \ in \ the \ \underline{How \ to \ Apply - Application \ Guide \ (\underline{https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url \ redirect.php?id=82400}) \ must \ be \ followed.$

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Project Summary/Abstract. Provide an abstract of the entire application. Include the objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term faculty), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file "Advisory_Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Cover Page Supplement

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Training Budget

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) with the following additional modifications:

• Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- · Faculty, Trainees, and Training Record
- · Other Training Program
- Appendix Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicant
 organizations to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Particular attention must be given to the required International Training Data Tables (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php? id=61169). Applicant organizations should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective trainee candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

Training Program

Program Plan

Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/Pls) will promote the success of the trainees and training program. Multiple PDs/Pls are encouraged, particularly when each brings a unique background and skill set that will enhance training. The application should expand on the information in the

biosketch(es) to addless to the 257FGVPE-0787-WGY Document 72-6 Filed 05/19/25 Page 9 of 17

- The appropriate expertise (for example, a record of rigorous research), as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicant organizations should indicate the program director's percent effort in the proposed program).
- A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor trainees from all backgrounds including trainees from groups underrepresented in the biomedical sciences (e.g., see Notice of NIH's Interest in Diversity

 $(\underline{\text{https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html})) \ prior \ to \ the \ start \ of \ the \ program. \\$

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program

Program Faculty

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

• The efforts made to recruit a pool of prospective program faculty from a wide variety of backgrounds, for example, faculty from underrepresented groups, and a range of career stages and scientific disciplines relevant to the training goals, to provide potential role models within the training program and to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress. This should include a mechanism to
 monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable
 mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including
 trainees from groups underrepresented in the biomedical sciences. Include the planned format, duration, and frequency of mentor training activities for program faculty and a
 description of how mentor training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training. Examples
 of relevant topics include, but are not limited to:
 - · Aligning expectations.
 - · Maintaining effective communication.
 - · Fostering independence.
 - · Assessing scholars' understanding of scientific research.
 - · Enhancing professional development.
 - · Addressing equity and inclusion.
 - · Articulating your mentoring philosophy and plan.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development, and how these activities will address the program's training goals and objectives.
- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicant organizations and trainees will be provided with information about the overall biomedical research workforce employment landscape, the
 variety of careers in the biomedical research workforce for which their training would be useful, and the career outcomes of graduates of the program (e.g., on publicly accessible
 websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.
- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities)
 that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Training Program Evaluation

The application should describe:

- How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is inclusive and supportive of trainee development.
- The program's procedures for responding to program evaluation findings.

Trainee Candidates and Retention Plans

Through the narrative and summaries of the information presented in the <u>Training Data Tables</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm) and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized test scores) that will allow a broad group of research-oriented trainees who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within the program (i.e., retention), including those from underrepresented groups. Applicant organizations are encouraged to consult the NIH's website to identify promising retention practices (https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

• The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing an inclusive, safe and supportive environment with procedures to ensure accountability and reporting of concerns. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the NOFO. Do not repeat information contained elsewhere in the application.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm). The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in <u>Training Table 5 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm</u>), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree <u>Training Table 8</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm)).
- The success of recent graduates transitioning to careers in the biomedical research workforce (<u>Training Table 8</u>). (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Progress Report for Renewal Applications

For renewal applications include information in the "Program Overview" section to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote inclusive, safe, accessible and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting an inclusive and supportive scientific environment.
- · Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- · Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also be described in the letter:

- · Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- · Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting safe, accessible, and inclusive and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4
 <a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_miregarding_NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality
- regarding NIH recipient institutions expectations to provide sate and healthful working condition for their employees and foster work environments conducive to high-quality research); ensuring the research facilities are accessible to trainees with disabilities; ensuring a positive, supportive, and inclusive research and training environment for individuals from all backgrounds.

 Ensuring that proper policies, procedures, and oversight are in place to prevent discrimination, harassment and other discriminatory practices and to appropriately respond to
- allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-22-129 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-129.html)).
- · Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- Supporting evaluation of the training program and procedures for responding to evaluation findings.

Other Training Program Section

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times - cv-10787-WGY Document 72-6 Filed 05/19/25 Page 11 of 17

Part I. contains information about Key Dates and times. Applicant organizations are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicant organizations must then complete the submission process by tracking the status of the application in the eRA Commons (eRA Commons (eRA Commons (eRA Commons (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicant organizations are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the <u>How to Apply - Application Guide</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.html).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Paper applications will not be accepted.

Applicant organizations must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens

your ability to complete the submission process on-time, you must follow the <u>Dealing with System Issues</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/Pl(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/Pl Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/quide/url redirect.php?id=82400).

See more tips (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35

 $(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm). \\$

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://web.archive.org/web/20250122105054/https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

Post Submission Materials

Applicant organizations are required to follow the instructions for post-submission materials, as described in the-policy (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82299).

Any instructions provided here are in addition to the instructions in the policy.

Substitute the term "scholars" for all references to "trainees" in the SF424 (R&R) Application Guide, and substitute the term "career development" for all references to "training" in the SF424 (R&R) Application Guide.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in Support of the NIH in Support of the NIH in Support of the NIH peer review system. While any information in the application relevant to the program goals can be included as part of the review process, the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of trainee candidates, trainees, or faculty may not, in and of themselves, be used as factors in the evaluation of applications.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will equip the trainees with the skills, knowledge and experiences necessary to transition to successful careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed.)

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major biomedical research training impact.

Training Program and Environment

- Does the application provide a compelling rationale for the proposed research training program and propose appropriate training goals and objectives relevant to the rationale?
- Will the courses, structured training activities, mentoring, and research experiences achieve the training program's goals and objectives, and provide opportunities for trainees to acquire skill and expertise in transparent, rigorous, reproducible and relevant research methodologies and tools applicable to the goals of the training program?
- Is there an effective mechanism to monitor mentoring and to promote the development, retention and success of all trainees throughout their training?
- Will the proposed training program provide the trainees appropriate information regarding the breadth of careers in the biomedical research workforce for which their training
 may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers?
- · Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?
- Does the application provide a compelling rationale for the proposed short-term research training program and include appropriate training goals and objectives relevant to the rationale? Are the objectives, design, direction, and quality of the proposed short-term research training program likely to ensure effective training?
- Are the proposed courses, structured training activities, mentoring, and research experiences where applicable appropriate for the level of trainees and the area(s) of
 science to be supported by the program? Do the program activities appropriately introduce trainees to transparent, rigorous, and reproducible research methodologies?
- If appropriate, does the program provide training in inter- or multi-disciplinary research and/or provide training in state-of-the-art or novel methodologies and techniques?
 - Is the proposed program of training likely to ensure that trainees will acquire knowledge and skills necessary to prepare them for a research career? Does the program include features likely to encourage short-term trainees to consider careers in health-related research?
- · Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/Pl(s) have the appropriate background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) plan to commit sufficient effort to promote the program's success?
- Have the PD(s)/PI(s) demonstrated a strong commitment to training future researchers?
- Does the application describe how the PD(s)/PI(s) will receive appropriate training on effective mentoring practices to promote trainee success?
- For applications designating multiple PDs/PIs:
 - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
 - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/Pls?

Preceptors/Mentors

- Does the proposed program demonstrate the presence of a sufficient pool of preceptors/mentors with appropriate expertise and adequate resources available to support the training goals and objectives proposed in the application (including short-term training, if applicable)?
- Is there a strong plan to ensure participating faculty receive appropriate training in the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including trainees from groups underrepresented in the biomedical sciences?
- Do participating faculty appropriately promote the trainees' career progression?
- Do the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable) proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely to provide strong and successful mentoring?

Trainees

- Does the proposed short-term training program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training goals and objectives? Are the outlined recruitment strategies likely to identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?
- Does the program have access to and the ability to recruit high quality, short-term trainees from the applicant institution or another health-professional school?
- Are the recruiting procedures and trainee selection criteria appropriate and well defined?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous institution, GPA, and standardized test scores)?

Training Record

- · How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the
 training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other
 accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?

• For applications that request short-term research training positions, is there a record of retaining health professionar trainees in general training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Recruitment Plan to Enhance Diversity

Reviewers will examine the strategies to be used in the recruitment of prospective candidates from underrepresented groups.

For purposes of this review, "recruitment" refers to outreach efforts intended to encourage individuals to apply for the program. "Recruitment" does not mean the appointment or hiring of an individual into the program. For renewals, the committee may consider the program's account of past experiences, including successful and unsuccessful strategies, but may not use the race, ethnicity, or sex of program trainees appointed during the previous funding period as factors in the evaluation.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format* - Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) *Subject Matter* - Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) *Faculty Participation* - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) *Duration of Instruction* - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) *Frequency of Instruction* - Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the short-term training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the short-term research training experience during the next project period?
- Does the program use current, evidence-informed training and mentoring approaches and continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

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Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by {LOCUS OF REVIEW} in accordance with NIH peer review policy and procedures (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions, consistent with applicable law:

- · Scientific and technical merit of the proposed project as determined by scientific peer review.
- · Availability of funds.
- · Relevance of the proposed project to program priorities.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement Section 2.5.1. Just-in-time Procedures. (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section 5/5 the notice of award.htm) and NIH Grants & Funding website, see Award Process. (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/pre-award-process.htm#award)

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A:

 General (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (https://web.archive.org/web/20250122105054/https://www.hhs.gov/sites/default/files/form-hhs690.pdf). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
 - HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates.

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements objectives and other appropriation mandate

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See <u>2 CFR Part 200.340 Termination (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support</u>

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41171).

Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41171).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit <a href="https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certification-ehrs/certificati

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- 1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- 2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PII) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://web.archive.org/web/20250122105054/https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the NIH Grants Policy. Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement.

 $(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data) and the properties of the$

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR)

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over \$25,000. See the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

Other Reporting Requirements

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php? id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement Section 8.6 Closeout (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications,

support from research Grans of Contracts, riving support from research Grants of Contracts of Contr

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in achieving its goals, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

For programs involving undergraduate students:

- · Successful completion of an undergraduate degree in a STEM field
- · Pending application for and/or enrollment in an advanced degree program in a STEM field
- · Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field

For programs involving graduate students:

- · Successful completion of a STEM graduate program
- · Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source

For programs involving postdoctorates and early career investigators:

- Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- · Subsequent independent research grant support from NIH or another source

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this NOFO, prospective applications **MUST** consult the <u>Table of IC-Specific Information</u>, <u>Requirements</u>, and <u>Staff Contacts (Inttps://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html</u>), to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

 $Finding \ Help \ Online: \ \underline{https://www.era.nih.gov/need-help.} \ (preferred \ method \ of \ contact) \ ($

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)

 $Email: \underline{GrantsInfo@nih.gov} \ \underline{(mailto:GrantsInfo@nih.gov)} \ (preferred \ method \ of \ contact)$

Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov)

Scientific/Research Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Neeraj Agarwal

NEI - NATIONAL EYE INSTITUTE

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E-mail: agarwalnee@nei.nih.gov (mailto:agarwalnee@nei.nih.gov)

Edwin C Clayton

NEI - NATIONAL EYE INSTITUTE

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E-mail: ed.clayton@nih.gov_(mailto:ed.clayton@nih.gov)

Jennifer N. Baumgartner, Ph.D.

National Center for Complementary and Integrative Health (NCCIH)

Phone: 301-402-4084

 $\textbf{Email:} \underline{jennifer.baumgartner@nih.gov} \underline{(mailto:\underline{jennifer.baumgartner@nih.gov)}$

Carol Shreffler, PhD

NIEHS - National Institute of Environmental Health Sciences

Phone: 984-287-3322

Email: Shreffl1@niehs.nih.gov (mailto:Shreffl1@niehs.nih.gov)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Karen Robinson Smith

NEI - NATIONAL EYE IN A PROPE 1:25-cv-10787-WGY Document 72-6 Filed 05/19/25 Page 17 of 17

Phone: 301-435-8178

E-mail: kyr@nei.nih.gov_(mailto:kyr@nei.nih.gov)

Debbie Chen

National Center for Complementary and Integrative Health (NCCIH)

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Email: <u>debbie.chen@nih.gov (mailto:debbie.chen@nih.gov)</u>

Jenny Greer

NIEHS - National Institute of Environmental Health Sciences

Phone: 984-287-3332

Email: jenny.greer@nih.gov (mailto:jenny.greer@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/web/20250122105054/https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?01-03-25) NIH Funding Opportunities and Notices (/web/20250122105054/https://grants.nih.gov/grants/guide/index.html)







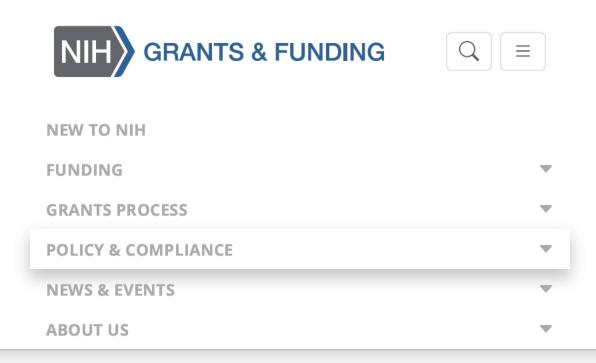
(https://web.archive.org/web/20250122105054/https://www.archive.org/web/20250122105054/https://www.

Department of Health and Human Services (HHS)

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EXHIBIT 49

An official website of the United States government Here's how you know.



Home > Policy & Compliance

- > Implementation of New Initiatives and Policies
- > Updates to NIH Institutional Training Grant Applications

Updates to NIH Institutional Training Grant Applications

This page provides details on the updates made to NIH institutional training grant applications for due dates on or after January 25, 2025.

On this page:

- Background
- Application Updates
- Peer Review Updates
- Notices, Reports, and Blogs

↑ Back to Top

Background

NIH has made significant investments to develop, implement, assess and disseminate innovative, effective approaches to research training and mentoring and to prepare trainees for a variety of <u>career paths</u> in the biomedical research workforce. Through these initiatives, the research community has identified the need for:

- Broader outreach activities to foster greater awareness of research training opportunities for potential trainees
- Increased mentorship opportunities to facilitate trainee success

NIH has leveraged the lessons of these initiatives to enhance institutional research training programs, including by enhancing opportunities to strengthen mentor training.

Applicability

The updates apply to applications that use the following activity codes:

- Institutional Training T series, e.g., T15, T32, T34, T35, T37, T90/R90, TL1, TL4
- International Institutional Training D43, D71, U2R
- Institutional Career Development K12, KL2

Application Updates

The updates to NIH Institutional Training Grant Applications include two key changes:

- 1. Mentor training expectations are more clearly defined in the parent T32 Notice of Funding Opportunity (NOFO).
- 2. Institutional Training <u>data tables</u> were updated to reduce burden and promote consistent information collection across training programs.

March 2025 Update:

- Recruitment Plans to Enhance Diversity are no longer required.
- Recruitment Plans to Enhance Diversity included in applications under review will not be evaluated or considered in funding decisions.
- A Trainee Diversity Report for institutional training grants, career development awards, and most research education grants is no longer required in Research Performance Progress Reports (RPPRs) and should not be included.
- The ability to generate the Trainee Diversity Report is no longer available to recipients.

Defining Mentor Training Expectations in Training Programs

The <u>Parent T32 NOFO</u> incorporates new language outlining expectations for mentor training and oversight into the program considerations, application instructions, and review criteria.

Programs should consider the following, in addition to other evidence-informed curricula, as potential mentor training components and are encouraged to adapt to program and trainee needs:

- Aligning expectations
- Maintaining effective communication
- Fostering independence
- Assessing understanding
- Enhancing professional development
- Articulating your mentoring philosophy and plan

Reviewers will assess the mentor training expectations included in the application.

Updates to Data Tables

Institutional Training data tables were updated to reduce burden, focus on trainee outcomes, and promote consistent information collection across training programs. For example:

 Tables 1 and 2: Applicants are expected to provide data only for the training stage(s) reflected in the proposed program.

- Table 5 (Publications of Those in Training) was reorganized so that the first column is the trainee (instead of the faculty member), and applicants are now allowed to include <u>interim</u> <u>research products</u> to which the trainee contributed.
- Table 6 (Applicants, Entrants, and their Characteristics for the Past Five Years) will no longer ask for trainee characteristics related to prior academic and research experience.
 - March 2025 Update: FORMS-I Training data tables 6a, 6b, and 7 have been revised to remove calculations for % underrepresented minorities.
- Table 8 (Program Outcomes: Predoctoral and Postdoctoral) no longer includes Part II "Those Clearly Associated with the Training Grant."

Peer Review Updates

Institutional training awards retain the five scored review criteria. For example, for Training Grants (Ts), reviewers will continue to score Training Program and Environment, Training Program Director(s)/Principal Investigator(s), Preceptors/Mentors, Trainees, and Training Record when determining the overall impact score.

NIH has moved "Training in the Responsible Conduct of Research" from the "Additional Review Considerations" and is now included as an "Additional Review Criteria." As such, reviewers will now evaluate "Training in the Responsible Conduct of Research" when determining scientific and technical merit, and in providing an overall impact score.

Notices, Reports, and Blogs Notices

- Reminder of Updates to NIH Training Grant Application Data
 Tables for Application Due Dates on or After January 25, 2025:

 NOT-OD-25-044 December 10, 2024
- Reminder that Multiple Changes Affecting Extramural
 Applications and Review are Coming for Application Due Dates

- Case 1:25-cv-10787-WG Mates Documenta រាជាក្នុង ក្រោត Gក្រាំខ្មែង នៃ១៤៦តនេ & កាតិព័ទ្ធ 6 of 9 on or After January 25, 2025: NOT-OD-25-035 November 21, 2024
 - Reminder: FORMS-I Grant Application Forms and Instructions
 Must be Used for Due Dates On or After January 25, 2025:

 NOT-OD-25-026 November 18, 2024
 - <u>Updates to NIH Institutional Training Grant Applications for</u>
 <u>Due Dates on or After January 25, 2025: NOT-OD-24-129</u> May 31, 2024
 - <u>Updates to NIH Training Grant Applications Registration Open</u> for June 5, 2024 Webinar: NOT-OD-24-124 – May 8, 2024

Blogs

• <u>Open Mike</u> ☐ Announcing updates to NIH Institutional Training Grant applications and required data tables – May 16, 2024

Resources

General

- How to Apply Application Guide
- Data Tables: FORMS-I
- <u>Drop-in-slides-Training-Grant-Application-Updates</u> (PPTX, 585 KB) (February 25, 2025)

See Also

Webinars & Videos

<u>Updates to NIH Training Grant Applications webinar</u> (June 5, 2024)

Contact

Email

For those with questions, please direct all inquiries to: <u>T32updates@mail.nih.gov</u>

This page last updated on: March 25, 2025 For technical issues <u>E-mail OER Webmaster</u>

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O No
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EXHIBIT 50

Exhibit E



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

DATE: 3/11/2025

TO: Ken Callahan Senior Advisor Policy and Implementation

FROM: Matthew J. Memoli, MD, MS Acting Director, NIH

SUBJECT: Initial Actions Regarding President Trump's Executive Orders – INFORMATION

ISSUE

In response to the request to review President Trump's Executive Orders issued between [PLACEHOLDER] and [PLACEHOLDER], determine which were relevant to the Office of the Assistant Secretary for Health's programs and policies, and describe the actions taken for alignment.

EXECUTIVE SUMMARY

Upon review of President Trump's Executive Orders issued since January 20, 2025, [PLACEHOLDER] were relevant to the programs and policies of the NIH. The following outlines each relevant executive order and actions taken for alignment.

EO 14162 - Putting America First in International Environmental Agreements

Prioritize U.S. interests in international environmental agreements, withdrawing the U.S. from the Paris Climate Agreement and halting funding to related climate initiatives, while revoking the U.S. International Climate Finance Plan and directing relevant agencies to rescind policies linked to it.

Implementation: N/A

Further Considerations: N/A

EO 14171 - Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce

Reinstates and amends Executive Order 13957 to create a new Schedule Policy/Career for confidential, policy-determining, policy-making, or policy-advocating positions, ensuring these roles are accountable to the President and exempt from standard adverse action procedures.

Implementation:

1. Create a new Schedule Policy/Career for confidential, policy-determining, policy-making, or policy-advocating positions.

Action Taken: Awaiting implementation guidance from HHS.

Status: In Progress

2. Maintaining the Integrity of the Career SES

Page 2 – Secretary, Health and Human Services

Action Taken: Review and Reclassification of SES Positions

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14179 - Removing Barriers to American Leadership in Artificial Intelligence

Aims to revoke previous policies that hinder AI innovation and establish a plan to sustain and enhance America's global dominance in AI, promoting economic competitiveness and national security.

Implementation:

1. Reporting Actions to Implement "Removing Barriers to American Leadership in Artificial Intelligence"

Action Taken: Data call to gather programmatic information related but not limited to statutes, regulations, guidance, intramural research, policies, public education documents and campaigns, communications, events, FACA committees, reports, other internal and external committees, and working groups.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14210 - Implementing the President's "Department of Government Efficiency" Workforce Optimization Initiative

Implement the "Department of Government Efficiency" workforce optimization initiative, focusing on reducing government waste, streamlining federal agencies, and eliminating non-essential positions and programs.

Implementation:

1. Submit Agency Reorganization Plans

Action Taken: 2/26/2025: Exec Sec sent email to department heads

Status: Not Started

2. Not-To-Exceed Appointments Expiring through May 3

Action Taken: Each ICO to submit employee NTE date with position description and impact if

extension is not approved.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14168 - Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government

Directs federal agencies to recognize only two immutable sexes (male and female) and to enforce sex-based rights and protections accordingly, rejecting the concept of gender identity.

Implementation:

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1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative

Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.

Status: In Progress

2. Removing "X" Option from VAMI Forms

Action Taken: Update the Visitor Access Management Initiative (VAMI) system by replacing gender

with sex and removing "X" as an option.

Status: Complete

3. Identify and Place Employees on Administrative Leave in Gender Ideology Positions

Action Taken: Seven employees were placed on administrative leave. Confirmed that NIH does not have any positions inculcating or promoting gender ideology. While the Sexual and Gender Minority Office (SGMRO) is technically on the NIH management organization chart, all positions in SGMRO are vacant, and NIH/DPCPSI has started the process to remove SGMRO from the DPCPSI organizational structure.

Status: Complete

4. Discussions with Tenure-Track Investigators Not on Administrative Leave

Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.

Status: In Progress

5. Changes to webpages, flyers, posters related to DEIA, gender

Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex. Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.

Status: Complete

6. Review of women's health or sex as a biological variable activities - Mar 20

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities. **Status:** In Progress

7. Review of women's health or sex as a biological variable activities - Mar 3

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities. **Status:** Complete

8. Remove Pronouns from Email, Outward Facing Media; Change 'Gender' to 'Sex'

Action Taken: System wide platforms, manuals disabled the use of pronouns, gender language (Zoom, Microsoft 365, NIH employee directory, email distribution lists, list servs, NIH rules of behavior, Visitor Access Management Initiative, nVistas, etc.).

Status: Complete

9. Communicating a consolidated list of terminated NIH contracts

Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts. Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around \$6M in anticipated funding. Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts. Disseminated

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direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. Provided cost savings data to HHS. Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.

Status: Complete

10. Ensure that data analyses align with administration guidance

Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.

Status: In Progress

11. Update agency forms for gender - clinical data forms

Action Taken: References to gender or to sex other than male/female will be removed from clinical data forms. A fast-track process for this effort has been established by our Office of Human Subjects Research Protection and our Institutional Review Board.

Status: In Progress

12. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts

Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders - including Executive Orders on DEI - will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications. **Status:** In Progress

13. Review peer review activities and terminate any that promote or inculcate gender ideology Action Taken: The NIH SGM Employee Resource Group and the SGM Scientific Interest Group was disbanded. CSR will identify and eliminate sub-topics that may not align with the E) guidance. The Reviewer Finder tool has been modified to remove all data on reviewer gender. CSR will not track demographics of its reviewers in their ~1200 peer review meetings and internal NIH dashboards for staff use have been modified to remove the ability to track gender.

Status: In Progress

14. Update FACA website to remove gender language

Action Taken: Removed phrase from the last sentence of the first paragraph of "Selection criteria for Advisory Committees" on the Office of Federal Advisory Committee Policy (OFACP) public website about including advisory committee members based on gender.

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Status: Complete

15. Terminate Special Interest Groups that Inculcate Gender

Action Taken: Council of councils SGM Working Group is paused--will be disbanded once FACA

Council activities are able to resume.

Status: In Progress

16. Revising inclusion of women in clinical research policy

Action Taken: Information on the inclusion of women in research related to implementation of

Defending Women EO and OPM memo.

Status: In Progress

17. Review and terminate agency contracts that promote gender ideology

Action Taken: Women-related agency contracts were were fully terminated (6), updated activities (2), and modified language/data fields (39). Disseminate direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders. We engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. We provided data related to actions taken on both executive orders back up to HHS, including cost savings data. As a result of a court order, OALM ensured compliance by providing the notice to all NIH contractor organizations by the stated deadline.

Status: Complete

18. Remove gender identifiers from agency forms - intramural individual development plans

Action Taken: NIH is removing the gender identifiers from internal OIR electronic development plan systems.

Status: In Progress

19. Review of pending awards and terminate any that promote or inculcate gender ideology

Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.

Status: In Progress

20. Review Notices of Funding Opportunity for Gender

Action Taken: NIH is currently reviewing all active and proposed Notices of Funding Opportunities and Notices of Special Interest to determine if they promote gender ideology and will take action as appropriate, including termination if needed.

Status: In Progress

21. Terminate Active Grants that Promote or Inculcate Gender Ideology

Action Taken: NIH is currently reviewing all active grants and supplements to determine if they promote gender ideology and will take action as appropriate.

Status: In Progress

22. Updating NIH Manual Chapter 1311 - Preventing and Addressing Harassment and Inappropriate Conduct

Action Taken: Updated NIH Manual Chapter 1311 to remove references to gender.

Status: Complete

23. Terminate trainings on gender ideology

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Action Taken: The only thing identified was the Women in Leadership program, which doesn't meet this definition. Confirmed that we do not have any other trainings that inculcate or promote gender ideology.

Status: Complete

24. NIAID Grants Related to Gender - Additional Consideration

Action Taken: Correspondence about NIAID grants related to gender, surgery, hormone therapy.

Status: Additional Consideration

25. List of Women Related Protocols

Action Taken: NIH is reviewing all survey instruments, forms, protocols, and clinical guidelines to ensure compliance with EO 14168.

Status: In Progress

26. Terminate Special Interest Groups that Inclucate Gender

Action Taken: Employee resource groups or special emphasis programs that inculcate or promote

gender ideology have been terminated.

Status: Complete

27. Guidance on Implementing Section 3(e) of Executive Order 14168 (Defending Women) in Accordance with the Paperwork Reduction Act and the Privacy Act

Action Taken: Guidance specifies how agencies can implement Section 3(e) of EO 14168 (Defending Women) in compliance with the Paperwork Reduction Act and the Privacy Act in a timely manner.

Status: In Progress

28. Withdraw Any Forms, Documents...That Inculcate or Promote Gender Ideology

Action Taken: NIH forms have been updated to remove gender identification.

Status: Complete

29. Terminate Active Contracts that Promote or Inculcate Gender Ideology

Action Taken: Review all agency contracts and terminate any that promote or inculcate gender

ideology.

Status: In Progress

30. Report on training activities

Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but

likely Defending Women, DEIA.

Status: Complete

31. Provide all updated or terminated reports that inculcate or promote gender ideology.

Action Taken: Updated or terminated reports that inculcate or promote gender ideology.

Status: Complete

32. Review of gender ideology positions and offices

Action Taken: Verification that Sexual and Gender Minority Office (SGMRO) has been disbanded

and there are no current gender ideology job positions related to SGMRO

Status: Complete

33. Removal of Gender Related Outward Facing Media

Action Taken: Removed outward facing media (websites, social media accounts, etc.) that inculcates

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or promotes gender ideology. Implemented a freeze on external communication (websites, social media, press releases, listservs, individual public inquiries on sensitive health topics).

Status: Complete

34. Removal of webpages related to DEIA and gender ideology

Action Taken: Summary of OIR webpages removed in response to DEIA and gender EOs/memos.

Status: Complete

35. Review of women's health or sex as a biological variable activities - Feb 20

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.

Status: Complete

36. Review of women's health or sex as a biological variable activities - Feb 12

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.

Status: Complete

37. Review of women's health or sex as a biological variable activities - Feb 6

Action Taken: An initial review of current and planned 'women's health or sex as a biological variable' official agency activities identified 92 current or planned activities.

Status: Complete

38. Tribal Sovereignty - Additional Consideration

Action Taken: Information on tribal sovereignty related to implementation of Defending Women EO

and OPM memo.

Status: Additional Consideration

39. Change gender to sex in NIH Databook

Action Taken: NIH Databook has updated about 16 reports that use "gender" or "women" in the title

and data.

Status: Complete

40. Ensure that intimate spaces designated for women, girls,or females (or for men, boys, or males) are designated by biological sex and not gender identity.

Action Taken: NIH has certified that gender neutral restrooms now use the terminology of men and women.

Status: Complete

41. Reporting on current or planned women's health and sex as a biological variable official agency activities

Action Taken: Summary of current or planned women's health and sex as a biological variable official agency activities - NIH FACA Charters and Membership Balance Plans , FACA Committee Membership, and Electronic Research Administration (eRA) Committee Management Module (CMM).

Status: Complete

42. Update Common Data Element (CDE) repository to address use of 'gender' and 'sex'

Action Taken: The Common Data Element (CDE) Repository contains a small number of CDEs that refer to gender; the National Library of Medicine (NLM) recommends adding a disclaimer to those items to clarify that "gender" should not be used to as a substitute for the data element "sex."

Status: Complete

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43. Terminate intramural gender ideology programs

Action Taken: NIH is currently reviewing all intramural programs to determine if they promote gender ideology and will take action as appropriate, including termination if needed, by the 30-day deadline.

Status: In Progress

44. Terminate applications that include gender ideology

Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Return to In Person Work

Mandates that all federal executive branch employees return to full-time in-person work at their duty stations, with department heads allowed to make necessary exemptions.

Implementation:

1. Guidance for Return to In-Person Work

Action Taken: Communication sent to supervisory employee's w/o exemption to return on 2/24. Preparing addition information to employees remote within 50-mile radius of office return 3/17. Provided guidance to all ICs and offices that these staff must return to the office unless they have an exemption.

Status: In Progress

2. Action Updates for Return to In-Person Work

Action Taken: Summary of Office of Research Facilities-led activities related to return to In-Person

work.

Status: In Progress

3. Updates to Return to Office

Action Taken: NED updates for all employees returning to office

Status: In Progress

4. Return to Office Guidance

Action Taken: Guidance on the return to Office

Status: Complete

5. Guidance on Exempting Military and Foreign Service Spouses from Return to Work

Action Taken: Guidance on Exempting Military and Foreign Service Spouses from Return to Work

Status: Additional Consideration

6. Approval to Proceed with Procurements to Support In-Person Work

Action Taken: Institutes and Centers are directed to carefully document, justify and support their minimal, immediate needs, in coordination with their acquisition staff. Reporting should include detailed itemizations of what funds are being obligated for.

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Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14151 - Ending Radical and Wasteful Government DEI Programs & Preferencing

Terminates all federal diversity, equity, and inclusion (DEI) programs, mandates, and policies, aiming to replace them with a merit-based system that rewards individual skills and performance.

Implementation:

1. Discussions with Tenure-Track Investigators Not on Administrative Leave

Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.

Status: In Progress

2. Placed DEIA Employees on Administrative Leave

Action Taken: 3/4/25: Ten employees were placed on administrative leave and five received probationary termination notices.

Status: Complete

3. Pause Approving Invoices or Completing Receiving for DEI Activities Performed by Contractors

Action Taken: In accordance with HHS guidance, OALM paused all payment of invoices related to DEI activities, and is coordinating with HHS on special review of these invoices prior to payment.

Status: Complete

4. Removal of DEIA Related Language from CY2025 Performance Plan

Action Taken: Updating Performance Plans by March 25, 2025.Review all remaining 2025 Performance Elements for Supervisory and Non-Supervisory employees and remove any DEIA related language. Establish new 2025 Performance plans.

Status: Complete

5. Changes to webpages, flyers, posters related to DEIA, gender

Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex. Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.

Status: Complete

6. Data Call to Redesignate CHCO Positions

Action Taken: Status: In Progress

7. Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies.

Action Taken: Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies, Rescission of "any guidance, instruction, recommendation, or document issued by the IWG is withdrawn as no longer representative of governmental policy related to the Presidential

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Memorandum of January 27, 2021 (Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking)." NIH is awaiting HHS direction as to whether HHS and NIH policy should be rescinded.

Status: In Progress

8. Termination of NIH Distinguished Scholars Program

Action Taken: Terminated the NIH Distinguished Scholars Program for tenured and tenure-track investigators, a program that was launched years ago to aid diversification of the biomedical workforce and mentoring for individuals otherwise not likely to pursue careers in biomedical research. **Status:** Complete

9. Communicating a consolidated list of terminated NIH contracts

Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts. Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around \$6M in anticipated funding. Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts. Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. Provided cost savings data to HHS. Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.

Status: Complete

10. Ensure that data analyses align with administration guidance

Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.

Status: In Progress

11. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts

Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications. **Status:** In Progress

12. Removal of DEI-Related Content from Microsoft 365

Action Taken: ICOs reviewed and verified their identified sites and content and ensured proper

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records management: **Status:** Complete

13. Summary of DEIA Activities January 21 through February 6, 2025

Action Taken: This is a summary of DEIA activities January 21 through February 6, 2025.

Status: Additional Consideration

14. Do Not Reinstate Contracts Terminated between Jan. 20th - Jan. 31st

Action Taken: Terminated 31 contracts focusing on DEI related activities impacting funding to the vendor since January 20, 2025. Cost savings is roughly \$6 million. The START document library includes additional information (email and spreadsheet).

Status: Complete

15. Compile a List of All DEI Websites and Equity Plans

Action Taken: List of all ICO DEI webpages and equity plans was compiled.

Status: Complete

16. Report on training activities

Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but

likely Defending Women, DEIA.

Status: Complete

17. Removal of webpages related to DEIA and gender ideology

Action Taken: Summary of OIR webpages removed in response to DEIA and gender EOs/memos.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Hiring Freeze

Imposes a freeze on the hiring of federal civilian employees across the executive branch, with exceptions for military personnel, national security, public safety, and certain other roles, aiming to reduce the federal workforce through efficiency improvements and attrition.

Implementation:

1. Federal Civilian Hiring Freeze

Action Taken: Paused efforts to develop process for manage hiring freeze exceptions to wait further information on the OPM Guidance on Agency RIF and Reorganization Plans. Canceled the Summer Internship Program for 2025.Freeze on the hiring of federal civilian employees as directed by the President on 1/20/2025.

Status: Complete

2. Request for Agency Performance Management Data

Action Taken: Agencies should report to on employees with less than fully successful in the last three

years.

Status: In Progress

3. Hiring Exemption Request Process

Action Taken: NIH is initiating a data call for Vacant Funded/Approved Positions and Hiring

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Exemptions.

Status: In Progress

4. Not-To-Exceed Appointments Expiring through May 3

Action Taken: Each ICO to submit employee NTE date with position description and impact if

extension is not approved.

Status: In Progress

5. Allowing Renewal of Current NIH Fellows

Action Taken: Renewal of current fellows is allowable and should proceed - non-FTE fellows (IRTAs, CRTAs, and Visiting Fellows). Pause on the recruitment and on-boarding of non-FTE fellows remains in effect.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14170 - Reforming the Federal Hiring Process And Restoring Merit To Government Service ("Restoring Merit")

Aims to overhaul the federal hiring process by prioritizing merit, practical skills, and dedication to the Constitution, while eliminating impermissible factors such as race, sex, and commitment to illegal racial discrimination or gender identity.

Implementation:

1. Review hiring practices and committee charters and processes

Action Taken: Review NIH hiring practices to assure they are in compliance and that all job announcements are in compliance as well as all hiring committee charters and processes.

Status: In Progress

2. Request for Agency Performance Management Data

Action Taken: Agencies should report to on employees with less than fully successful in the last three

years.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Regulatory Freeze Pending Review

Directs all executive departments and agencies to halt the proposal or issuance of new rules until they are reviewed and approved by newly appointed department or agency heads, with exceptions for emergency situations.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Restoring Accountability for Career Senior Executives

The Director of OPM and Director of OMB shall issue SES Performance Plans that agencies must adopt;

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prioritize accountability in the SES system; reassign agency SES members to align with the administration's agenda; terminate existing Executive Resources Board (ERB) and Performance Review Board and create new boards; and agency heads should take action to address SES officials who do not carry out their duties consistently with the administration's principles.

Implementation:

1. Maintaining the Integrity of the Career SES

Action Taken: Review and Reclassification of SES Positions

Status: In Progress

2. Guidance on Career Reserved SES Positions and Agency Redesignation Requests

Action Taken: Agencies should 1) develop a revised, proposed list of career reserved positions, consistent with agency organic statutes and guidance and 2) submit a single request to OPM to redesignate each current career reserved position that is not on the list.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

<u>Presidential Action - Declaring A National Emergency At The Southern Border Of The United States</u>

Declares a national emergency due to threats such as cartels, criminal gangs, and terrorists, and directs the Department of Defense and Armed Forces to support efforts to secure the southern border.

Implementation: N/A

Further Considerations: N/A

<u>Presidential Action - Expanding Migrant Operations Center at Naval Station Guantanamo Bay to Full Capacity</u>

Directs the Secretary of Defense and the Secretary of Homeland Security to expand the center to provide additional detention space for high-priority criminal aliens unlawfully present in the United States

Implementation: N/A

Further Considerations: N/A

EO 14148 - Initial Rescissions of Harmful Executive Orders and Actions

Rescinds several executive orders from the previous administration, focusing on reversing policies related to diversity, equity, and inclusion (DEI), climate change, and immigration.

Implementation: N/A

Further Considerations: N/A

EO 14155 - Withdrawing The United States From The World Health Organization

Directs the U.S. to withdraw from the WHO due to its mishandling of global health crises, failure to implement reforms, and disproportionate financial demands, while establishing new U.S. leadership positions to safeguard public health and biosecurity.

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Implementation:

1. Evaluating NIH WHO Collaborating Centers

Action Taken: Reviewing the 3 NIH WHO Collaborating Centers and putting a pause on any funding

that may be going to the WHO.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14158 - Establishing and Implementing the President's Department of Government Efficiency

Creates the Department of Government Efficiency (DOGE) to modernize federal technology and software, aiming to maximize governmental efficiency and productivity.

Implementation:

1. Purchase Card Reinstatements

Action Taken: Coordinated with leadership across the NIH Institutes and Centers to freeze 870 credit cards, reducing its open credit cards to only around 8% of its prior usage, to effectively reduce credit card spend to the minimum emergency amount.

Status: Complete

2. Not-To-Exceed Appointments Expiring through May 3

Action Taken: Each ICO to submit employee NTE date with position description and impact if extension is not approved.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14173 - Ending Illegal Discrimination and restoring merit-based opportunity

Eliminates all forms of illegal discrimination in federal employment and contracting, promoting a meritbased system that prioritizes skills, qualifications, and performance.

Implementation:

1. Eliminate all illegal discrimination in federal employment and contracting.

Action Taken: We are carefully looking at all NIH hiring practices to assure they are in compliance and that all job announcements are in compliance as well as all hiring committee charters and processes.

Status: In Progress

2. Align Programs for American Indians and Alaska Natives with the Administration's Priorities

Action Taken: Agencies added their program-specific authorities and summarize the program in the guidance for OGC review.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

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EO 14177 - President's Council of Advisors on Science and Technology - The White House

Reestablishes the President's Council of Advisors on Science and Technology (PCAST) to provide guidance on science, technology, and innovation policy, focusing on areas like artificial intelligence and quantum computing.

Implementation: N/A

Further Considerations: N/A

EO 14180 - Council to Assess the Federal Emergency Management Agency

Establishes a review council to evaluate FEMA's efficacy, priorities, and competence, and to recommend improvements or structural changes to enhance disaster response and recovery.

Implementation: N/A

Further Considerations: N/A

EO 14181 - Emergency Measures to Provide Water Resources in California and Improve Disaster Response in Certain Areas - The White House

Directs federal agencies to take immediate action to ensure adequate water resources in Southern California and improve disaster response, including overriding any state or local policies that hinder these efforts.

Implementation: N/A

Further Considerations: N/A

EO 14183 - Prioritizing Military Excellence and Readiness

Directs the Department of Defense to update policies to exclude individuals with gender dysphoria from military service, citing concerns over unit cohesion, mental and physical readiness, and overall military effectiveness.

Implementation: N/A

Further Considerations: N/A

EO 14184 - Reinstating Service Members Discharged Under the Military's COVID-19 Vaccination Mandate - The White House

Directs the Secretary of Defense and the Secretary of Homeland Security to reinstate service members who were discharged solely for refusing the COVID-19 vaccine, allowing them to return to their former rank with full back pay and benefits.

Implementation: N/A

Further Considerations: N/A

EO 14185 - Restoring America's Fighting Force

Eliminate race- and sex-based preferences within the U.S. Armed Forces, abolish Diversity, Equity, and

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Inclusion (DEI) offices, and promote a merit-based, color-blind system to enhance military effectiveness and readiness.

Implementation: N/A

Further Considerations: N/A

EO 14188 - Additional Measures to Combat Anti-Semitism

Directs federal agencies to use all legal tools to prosecute and hold accountable those responsible for anti-Semitic harassment and violence, especially in schools and on campuses.

Implementation: N/A

Further Considerations: N/A

EO 14189 - Celebrating America's 250th Birthday - The White House

Establishes the White House Task Force on Celebrating America's 250th Birthday to plan and execute a grand celebration for the 250th anniversary of American Independence on July 4, 2026, and to honor the history of the nation.

Implementation: N/A

Further Considerations: N/A

EO 14191 - Expanding Educational Freedom and Opportunity for Families

Directs states and relevant agencies to promote expanded educational opportunities for K-12 education.

Implementation: N/A

Further Considerations: N/A

EO 14192 - Unleashing Prosperity through Deregulation - The White House

Directs all agencies, unless prohibited by law, to identify at least 10 existing regulations to be repealed every time it proposes a new regulation.

Implementation: N/A

Further Considerations: N/A

EO 14199 - Withdrawing the United States From and Ending Funding to Certain United Nations Organizations and Reviewing United States Support to All International Organizations

Withdraw the U.S. from certain United Nations organizations, halt funding, and review all U.S. support for international organizations to align with American interests.

Implementation:

1. Reviewing NIH programs for any involvement in the United Nations

Action Taken: We are reviewing NIH programs for any involvement in the United Nations and will take appropriate action.

Status: In Progress

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Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14084 - Promoting the Arts, the Humanities and Museum and Library Services

We will enhance to high-quality arts and humanities education and programming with the aim of enabling every child in America to obtain the broad creative skills and enrichment vital to succeed.

Implementation:

1. Request information on activities relevant to Promoting the Arts, the Humanities, and Museum and Library Services.

Action Taken: An NIH-internal data call regarding ICO activities relevant to EO 14084 (Promoting the Arts, the Humanities, and Museum and Library Services) was sent to P&E Principals and Alternates on Tuesday, February 25th. Responses have been compiled and are attached. **Status:** Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14187 - Protecting Children from Chemical and Surgical Mutilation (Protecting Children EO)

The United States will not fund, sponsor, promote, assist, or support the so-called "transition" of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures.

Implementation:

1. Prohibit Federal Funding, Sponsoring, Promoting, Assisting, or Supporting the So-called 'Transition' of a Child from One Sex to Another."

Action Taken: NIH will identify research that promotes chemical and surgical mutilation, and some award activities may be suspended as a result. NIH will identify research that promotes chemical and surgical mutilation, and some award activities may be suspended as a result.

Status: Additional Consideration

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14219 - Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Regulatory Initiative

Focus the executive branch's limited enforcement resources on regulations squarely authorized by constitutional Federal statutes, and to commence the deconstruction of the overbearing and burdensome administrative state. Ending Federal overreach and restoring the constitutional separation of powers is a priority of my Administration.

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative

Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.

Status: In Progress

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Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Honoring Jocelyn Nungaray

The Anahuac National Wildlife Refuge, a scenic area for coastal wildlife and recreation along the Gulf of America near Jocelyn's home in Texas, will forever honor and preserve the memory of a beautiful American, Jocelyn Nungaray.

Implementation: N/A

Further Considerations: N/A

EO 14222 - Implementing the President's "Department of Government Efficiency" Cost Efficiency Initiative

This order commences a transformation in Federal spending on contracts, grants, and loans to ensure Government spending is transparent and Government employees are accountable to the American public.

Implementation:

1. Data Call: GSA Non-Essential Contracts

Action Taken: Coordinated with the NIH Director to established categories of spend that aligned with Presidential Appointee priorities and could continue, established a reporting system that categorizes how the NIH Acquisition Workforce is obligating funds within these categories. Established a contract approval process for routing individual requests for consideration of other procurement requirements to the NIH Director for mission critical needs that may not fit squarely within an approved spend category. Paused the issuance of any new Contracting Officer warrants or other Delegations of Procurement Authority. Coordinated the termination of 113 non-essential contract awards for an estimated cost savings of approximately \$14.6M thus far. Additional reviews seeking further cost savings opportunities remain ongoing. Coordinated with HHS to provide data that will be publicly posted regarding NIH's justifications for certain contracts are mission critical. Developed a system to provide Department of Government Efficiency staff with weekly reports detailing all NIH contracting activities, and OALM advised NIH Dr. Memoli reviewed and approved the contracts in question.

Status: Complete

2. Purchase Card Reinstatements

Action Taken: Coordinated with leadership across the NIH Institutes and Centers to freeze 870 credit cards, reducing its open credit cards to only around 8% of its prior usage, to effectively reduce credit card spend to the minimum emergency amount.

Status: Complete

3. Data Call: Reporting to OPM FY 2024 Taxpayer-Funded Union Time Use

Action Taken: Status: In Progress

4. Data Call: Taxpayer-Funded Union Time Information

Action Taken: Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

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EO 14169 - Reevaluating and Realigning United States Foreign Aid

It is the policy of United States that no further United States foreign assistance shall be disbursed in a manner that is not fully aligned with the foreign policy of the President of the United States. 90-day pause in United States foreign development assistance for assessment of programmatic efficiencies and consistency with United States foreign policy. Reviews of United States foreign assistance programs. Determinations. Resumption of paused development assistance funding. Waiver.

Implementation:

1. Review of NIH support for foreign research

Action Taken: OPERA and OER leadership, in consultation with Fogarty International Center and the Office of General Counsel are finalizing a decision memo confirming the applicability of this EO to NIH financial assistance mechanisms.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14204 - Addressing Egregious Actions of the Republic of South Africa

In shocking disregard of its citizens' rights, the Republic of South Africa (South Africa) recently enacted Expropriation Act 13 of 2024 (Act), to enable the government of South Africa to seize ethnic minority Afrikaners' agricultural property without compensation. This Act follows countless government policies designed to dismantle equal opportunity in employment, education, and business, and hateful rhetoric and government actions fueling disproportionate violence against racially disfavored landowners.

Implementation:

1. Researching the Applicability of 14204 to NIH

Action Taken: OER and OPERA is working with FIC and OGC on a decision memo confirming the applicability of this EO to NIH financial assistance mechanisms.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14182 - Enforcing the Hyde Amendment

It is the policy of the United States, consistent with the Hyde Amendment, to end the forced use of Federal taxpayer dollars to fund or promote elective abortion

Implementation: N/A

Further Considerations: N/A

<u>Presidential Action - Amendment To Duties To Address The Flow Of Illicit Drugs Across Our Northern Border</u>

Adjusts the tariffs imposed on articles of Canada in Executive Order 14193 of February 1, 2025

Implementation: N/A

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Further Considerations: N/A

Presidential Action - Addressing Risks from Perkins Coie LLP

Suspends active security clearances and ceases provision of Government goods to Perkins Coie, terminates existing contracts and requires Government contractors to disclose any business with Perkins Coie, directs agencies to refrain from hiring Perkins Coie employees and limits their access to Federal buildings, and directs EEOC to investigate racial discrimination at large law firms

Implementation: N/A

Further Considerations: N/A

<u>Presidential Action - Amendment To Duties To Address The Flow Of Illicit Drugs Across Our Southern Border</u>

Adjusts the tariffs imposed on articles of Mexico in Executive Order 14194 of February 1, 2025

Implementation: N/A

Further Considerations: N/A

<u>Presidential Action - Establishment Of The Strategic Bitcoin Reserve And United States Digital Asset Stockpile</u>

Establishes a Strategic Bitcoin Reserve and a United States Digital Asset Stockpile that can serve as a secure account for orderly and strategic management of the United States' other digital asset holdings

Implementation: N/A

Further Considerations: N/A

Presidential Action - Restoring Public Service Loan Forgiveness

The Secretary of Education shall propose revisions to 34 C.F.R. 685.219, Public Service Loan Forgiveness Program, in coordination with the Secretary of the Treasury as appropriate, that ensure the definition of "public service" excludes organizations that engage in activities that have a substantial illegal purpose.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Establishing The White House Task Force On The FIFA World Cup 2026

Establishes a WH task force to assist in the planning, organization, and execution of the events surrounding the 2025 FIFA Club World Cup and the 2026 FIFA World Cup.

Implementation: N/A

Further Considerations: N/A

EO 14228 - Further Amendment to Duties Addressing the Synthetic Opioid Supply Chain in the People's Republic of China

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Increases tariffs on goods from the People's Republic of China due to that nation's perceived failure to adequately address the flow of synthetic opioids, such as fentanyl, into the United States.

Implementation: N/A

Further Considerations: N/A

EO 14194 - Amendment to Duties to Address the Situation at our Southern Border

Aims to address the situation at the U.S. southern border by imposing additional duties on products imported from Mexico, with the stated goal of pressuring Mexico to take stronger actions against illegal immigration and drug trafficking.

Implementation: N/A

Further Considerations: N/A

EO 14223 - Addressing The Threat To National Security from Imports of Timber, Lumber

Aims to ensure reliable, secure, and resilient domestic supply chains of timber, lumber, and their derivative products.

Implementation: N/A

Further Considerations: N/A

EO 14225 - Immediate Expansion of American Timber Production

Aims to increase domestic timber production to protect our national and economic security.

Implementation: N/A

Further Considerations: N/A

EO 14224 - Designating English as the Official Language of The United States

Formalizes English as the nation's official language.

Implementation: N/A

Further Considerations: N/A

EO 14221 - Making America Healthy Again by Empowering Patients with Clear, Accurate, and **Actionable Healthcare Pricing Information**

Increases transparency in healthcare pricing, allowing consumers to make more informed decisions.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Suspension of Security Clearances and Evaluation of Government Contracts

Protect national security by addressing potential risks associated with individuals holding security clearances and companies with government contracts.

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Implementation: N/A

Further Considerations: N/A

EO 14220 - Addressing the Threat to National Security From Imports of Copper

Ensures a reliable, secure, and resilient domestic copper supply chain.

Implementation: N/A

Further Considerations: N/A

Presidential Action - President Trump Takes Decisive Action to Deliver Relief to Kentucky

Provide federal assistance to Kentucky in the aftermath of a disaster or emergency.

Implementation: N/A

Further Considerations: N/A

Presidential Action - America First Investment Policy

Memorandum that prioritizes the interests of American workers and businesses in international trade.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Defending American Companies and Innovators From Overseas Extortion and Unfair Fines and Penalties

Safeguards U.S. economic interests by preventing foreign entities from using unfair practices to harm American businesses.

Implementation: N/A

Further Considerations: N/A

EO 14217 - Commencing the Reduction of the Federal Bureaucracy

Aims to reduce the size of the Federal Government to minimize government waste and abuse, reduce inflation, and promote American freedom and innovation.

Implementation: N/A

Further Considerations: N/A

Proclamation 10898 - 80th Anniversary of the Battle of Iwo Jima

Serves to commemorate and honor the historical significance of the Battle of Iwo Jima.

Implementation: N/A

Further Considerations: N/A

Presidential Action - President Trump Announces Appointments to Council of Governors

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Appoints a bipartisan group of state leaders tasked with strengthening state-federal partnerships on key national security, disaster response, and military coordination issues to the Council of Governors.

Implementation: N/A

Further Considerations: N/A

EO 14218 - Ending Taxpayer Subsidization of Open Borders

Aims to stop federal funding from supporting programs that benefit undocumented immigrants or policies that facilitate illegal immigration.

Implementation: N/A

Further Considerations: N/A

EO 14215 - Ensuring Accountability for All Agencies

Aims to increase accountability and transparency within federal agencies.

Implementation: N/A

Further Considerations: N/A

EO 14216 - Expanding Access to In Vitro Fertilization

Ensure reliable access to IVF treatment, including by easing unnecessary statutory or regulatory burdens to make IVF treatment drastically more affordable.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Radical Transparency About Wasteful Spending

This memorandum aims to enhance public awareness and accountability concerning government spending through increased transparency regarding wasteful expenditures.

Implementation: N/A

Further Considerations: N/A

Proclamation 10897 - President George Washington's Birthday, 2025

Commemorates George Washington's legacy, promotes civic values, and fosters national unity.

Implementation: N/A

Further Considerations: N/A

Presidential Action - President Donald J. Trump Approves Kentucky Emergency Declaration

Authorizes federal assistance to supplement state and local response efforts in Kentucky during an emergency or disaster.

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Implementation: N/A

Further Considerations: N/A

EO 14214 - Keeping Education Accessible and Ending Covid-19 Vaccine Mandates in Schools

EO 14214 aims to prevent schools and universities from requiring COVID-19 vaccination for students, citing concerns about personal freedom, parental authority, and access to education.

Implementation: N/A

Further Considerations: N/A

EO 14213 - Establishing the National Energy Dominance Council

Establishes the National Energy Dominance Council to advise the President on how to expand domestic energy production and reduce reliance on foreign sources.

Implementation: N/A

Further Considerations: N/A

EO 14212 - Establishing the President's Make America Healthy Again Commission

Establishes the President's Make America Healthy Again Commission to address and improve the health of Americans, particularly children, by focusing on reversing chronic diseases.

Implementation: N/A

Further Considerations: N/A

EO 14211 - One Voice for America's Foreign Relations

Aims to ensure that all individuals involved in implementing the President's foreign policy do so under his authority and direction, with a unified and consistent voice.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Nominations Sent to the Senate

Officially submits a list of nominees for various government positions to the Senate for confirmation.

Implementation: N/A

Further Considerations: N/A

Proclamation 10895 - Adjusting Imports of Aluminum into The United States

Adjusts tariffs on aluminum imports to protect American industries and jobs from the harmful effects of unfair trade practices.

Implementation: N/A

Further Considerations: N/A

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Presidential Action - President Trump Announces the President's Intelligence Advisory Board

Establishes a board to advise the President on intelligence matters.

Implementation: N/A

Further Considerations: N/A

Proclamation 10896 - Adjusting Imports of Steel into The United States

Aims to adjust steel imports into the United States to protect national security and domestic steel industries.

Implementation: N/A

Further Considerations: N/A

EO 14209 - Pausing Foreign Corrupt Practices Act Enforcement to Further American Economic and National Security

Aims to temporarily pause certain Foreign Corrupt Practices Act enforcement actions to prioritize American economic and national security interests.

Implementation: N/A

Further Considerations: N/A

EO 14207 - Eliminating the Federal Executive Institute

Aims to eliminate the Federal Executive Institute to reduce federal spending and streamline government operations.

Implementation: N/A

Further Considerations: N/A

EO 14208 - Ending Procurement and Forced Use of Paper Straws

Aims to eliminate the federal government's procurement and mandatory use of paper straws.

Implementation: N/A

Further Considerations: N/A

Proclamation 10894 - Gulf of America Day, 2025

Proclamation 10894 aims to recognize and celebrate the importance of the Gulf of Mexico region to the United States, while also promoting the use of the name "Gulf of America" as a preferred alternative.

Implementation: N/A

Further Considerations: N/A

EO 14206 - Protecting Second Amendment Rights

Aims to protect and defend Second Amendment rights by directing federal agencies to uphold those rights

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and prevent unlawful infringement.

Implementation: N/A

Further Considerations: N/A

EO 14205 - Establishment of The White House Faith Office

Establishes the White House Faith Office to strengthen partnerships between the government and faithbased organizations to address social issues.

Implementation: N/A

Further Considerations: N/A

Presidential Action - President Trump Announces Appointments to the White House Faith Office

Announces Appointments to the White House Faith Office

Implementation: N/A

Further Considerations: N/A

EO 14203 - Imposing Sanctions on the International Criminal Court

Aims to impose sanctions on the International Criminal Court (ICC) personnel involved in investigations or prosecutions of U.S. persons or those of U.S. allies.

Implementation: N/A

Further Considerations: N/A

EO 14202 - Eradicating Anti-Christian Bias

Aims to eliminate perceived anti-Christian bias within federal programs and policies.

Implementation: N/A

Further Considerations: N/A

Presidential Action - Memorandum for the Heads of Executive Departments and Agencies

Aims to stop federal funding of NGOs that undermine U.S. interests and align future funding with national priorities.

Implementation: N/A

Further Considerations: N/A

EO 14201 - Keeping Men Out of Women's Sports

Aims to prohibit biological males from participating in women's sports to preserve fairness and protect opportunities for female athletes.

Implementation: N/A

Further Considerations: N/A

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<u>Presidential Action - Amendment to Duties Addressing the Synthetic Opioid Supply Chain in the People's Republic of China</u>

Amends a previous executive order (*Executive Order 14195: Imposing Duties To Address the Synthetic Opioid Supply Chain in the People's Republic of China*) to remove the *de minimis* exemption for tariffs on certain goods from China related to the synthetic opioid supply chain, once the Commerce Secretary certifies efficient tariff collection systems are in place.

Implementation: N/A

Further Considerations: N/A

Presidential Action - U.S. Hostage and Wrongful Detainee Day, 2025

Proclaims March 9, 2025, as U.S. Hostage and Wrongful Detainee Day

Implementation: N/A

Further Considerations: N/A

MEMO OPM - OPM Memo: Initial Guidance Regarding President Trump's Executive Order Defending Women

The memorandum from Charles Ezell, Acting Director of the U.S. Office of Personnel Management, provides initial guidance to federal agencies on complying with President Trump's Executive Order to end federal funding and promotion of gender ideology, with specific actions and deadlines for implementation.

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative

Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.

Status: In Progress

2. Removing "X" Option from VAMI Forms

Action Taken: Update the Visitor Access Management Initiative (VAMI) system by replacing gender

with sex and removing "X" as an option.

Status: Complete

3. Identify and Place Employees on Administrative Leave in Gender Ideology Positions

Action Taken: Seven employees were placed on administrative leave. Confirmed that NIH does not have any positions inculcating or promoting gender ideology. While the Sexual and Gender Minority Office (SGMRO) is technically on the NIH management organization chart, all positions in SGMRO are vacant, and NIH/DPCPSI has started the process to remove SGMRO from the DPCPSI organizational structure.

Status: Complete

4. Discussions with Tenure-Track Investigators Not on Administrative Leave

Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.

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Status: In Progress

5. Changes to webpages, flyers, posters related to DEIA, gender

Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex. Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.

Status: Complete

6. Review of women's health or sex as a biological variable activities - Mar 20

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.

Status: In Progress

7. Review of women's health or sex as a biological variable activities - Mar 3

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.

Status: Complete

8. Remove Pronouns from Email, Outward Facing Media; Change 'Gender' to 'Sex'

Action Taken: System wide platforms, manuals disabled the use of pronouns, gender language (Zoom, Microsoft 365, NIH employee directory, email distribution lists, list servs, NIH rules of behavior, Visitor Access Management Initiative, nVistas, etc.).

Status: Complete

9. Communicating a consolidated list of terminated NIH contracts

Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts. Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around \$6M in anticipated funding. Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts. Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. Provided cost savings data to HHS. Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.

Status: Complete

10. Ensure that data analyses align with administration guidance

Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.

Status: In Progress

11. Update agency forms for gender - clinical data forms

Action Taken: References to gender or to sex other than male/female will be removed from clinical data forms. A fast-track process for this effort has been established by our Office of Human Subjects Research Protection and our Institutional Review Board.

Status: In Progress

12. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts

Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in

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other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications. Status: In Progress

13. Review peer review activities and terminate any that promote or inculcate gender ideology Action Taken: The NIH SGM Employee Resource Group and the SGM Scientific Interest Group was disbanded. CSR will identify and eliminate sub-topics that may not align with the E) guidance. The Reviewer Finder tool has been modified to remove all data on reviewer gender. CSR will not track demographics of its reviewers in their ~1200 peer review meetings and internal NIH dashboards for staff use have been modified to remove the ability to track gender.

Status: In Progress

14. Update FACA website to remove gender language

Action Taken: Removed phrase from the last sentence of the first paragraph of "Selection criteria for Advisory Committees" on the Office of Federal Advisory Committee Policy (OFACP) public website about including advisory committee members based on gender.

Status: Complete

15. Terminate Special Interest Groups that Inculcate Gender

Action Taken: Council of councils SGM Working Group is paused--will be disbanded once FACA Council activities are able to resume.

Status: In Progress

16. Revising inclusion of women in clinical research policy

Action Taken: Information on the inclusion of women in research related to implementation of

Defending Women EO and OPM memo.

Status: In Progress

17. Review and terminate agency contracts that promote gender ideology

Action Taken: Women-related agency contracts were were fully terminated (6), updated activities (2), and modified language/data fields (39). Disseminate direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders. We engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. We provided data related to actions taken on both executive orders back up to HHS, including cost savings data. As a result of a court order, OALM ensured compliance by providing the notice to all NIH contractor organizations by the stated deadline.

Status: Complete

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18. Remove gender identifiers from agency forms - intramural individual development plans Action Taken: NIH is removing the gender identifiers from internal OIR electronic development plan systems.

Status: In Progress

19. Review of pending awards and terminate any that promote or inculcate gender ideology

Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.

Status: In Progress

20. Review Notices of Funding Opportunity for Gender

Action Taken: NIH is currently reviewing all active and proposed Notices of Funding Opportunities and Notices of Special Interest to determine if they promote gender ideology and will take action as appropriate, including termination if needed.

Status: In Progress

21. Terminate Active Grants that Promote or Inculcate Gender Ideology

Action Taken: NIH is currently reviewing all active grants and supplements to determine if they promote gender ideology and will take action as appropriate.

Status: In Progress

22. Updating NIH Manual Chapter 1311 - Preventing and Addressing Harassment and Inappropriate Conduct

Action Taken: Updated NIH Manual Chapter 1311 to remove references to gender.

Status: Complete

23. Terminate trainings on gender ideology

Action Taken: The only thing identified was the Women in Leadership program, which doesn't meet this definition. Confirmed that we do not have any other trainings that inculcate or promote gender ideology.

Status: Complete

24. NIAID Grants Related to Gender - Additional Consideration

Action Taken: Correspondence about NIAID grants related to gender, surgery, hormone therapy.

Status: Additional Consideration

25. List of Women Related Protocols

Action Taken: NIH is reviewing all survey instruments, forms, protocols, and clinical guidelines to ensure compliance with EO 14168.

Status: In Progress

26. Terminate Special Interest Groups that Inclucate Gender

Action Taken: Employee resource groups or special emphasis programs that inculcate or promote gender ideology have been terminated.

Status: Complete

27. Withdraw Any Forms, Documents...That Inculcate or Promote Gender Ideology

Action Taken: NIH forms have been updated to remove gender identification.

Status: Complete

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28. Terminate Active Contracts that Promote or Inculcate Gender Ideology

Action Taken: Review all agency contracts and terminate any that promote or inculcate gender

ideology.

Status: In Progress

29. Report on training activities

Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but

likely Defending Women, DEIA.

Status: Complete

30. Provide all updated or terminated reports that inculcate or promote gender ideology.

Action Taken: Updated or terminated reports that inculcate or promote gender ideology.

Status: Complete

31. Review of gender ideology positions and offices

Action Taken: Verification that Sexual and Gender Minority Office (SGMRO) has been disbanded

and there are no current gender ideology job positions related to SGMRO

Status: Complete

32. Removal of Gender Related Outward Facing Media

Action Taken: Removed outward facing media (websites, social media accounts, etc.) that inculcates or promotes gender ideology. Implemented a freeze on external communication (websites, social media, press releases, listservs, individual public inquiries on sensitive health topics).

Status: Complete

33. Removal of webpages related to DEIA and gender ideology

Action Taken: Summary of OIR webpages removed in response to DEIA and gender EOs/memos.

Status: Complete

34. Review of women's health or sex as a biological variable activities - Feb 20

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.

Status: Complete

35. Review of women's health or sex as a biological variable activities - Feb 12

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.

Status: Complete

36. Review of women's health or sex as a biological variable activities - Feb 6

Action Taken: An initial review of current and planned 'women's health or sex as a biological

variable' official agency activities identified 92 current or planned activities.

Status: Complete

37. Tribal Sovereignty - Additional Consideration

Action Taken: Information on tribal sovereignty related to implementation of Defending Women EO

and OPM memo.

Status: Additional Consideration

38. Change gender to sex in NIH Databook

Action Taken: NIH Databook has updated about 16 reports that use "gender" or "women" in the title

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and data.

Status: Complete

39. Ensure that intimate spaces designated for women, girls, or females (or for men, boys, or males) are designated by biological sex and not gender identity.

Action Taken: NIH has certified that gender neutral restrooms now use the terminology of men and women.

Status: Complete

40. Reporting on current or planned women's health and sex as a biological variable official agency activities

Action Taken: Summary of current or planned women's health and sex as a biological variable official agency activities - NIH FACA Charters and Membership Balance Plans, FACA Committee Membership, and Electronic Research Administration (eRA) Committee Management Module (CMM).

Status: Complete

41. Update Common Data Element (CDE) repository to address use of 'gender' and 'sex'

Action Taken: The Common Data Element (CDE) Repository contains a small number of CDEs that refer to gender; the National Library of Medicine (NLM) recommends adding a disclaimer to those items to clarify that "gender" should not be used to as a substitute for the data element "sex."

Status: Complete

42. Terminate intramural gender ideology programs

Action Taken: NIH is currently reviewing all intramural programs to determine if they promote gender ideology and will take action as appropriate, including termination if needed, by the 30-day deadline.

Status: In Progress

43. Terminate applications that include gender ideology

Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OMB - OMB Memo: Freeze Funding

The memorandum from the Office of Management and Budget, dated January 27, 2025, directs Federal agencies to temporarily pause all financial assistance programs to align with President Donald J. Trump's priorities and executive orders, effective January 28, 2025, at 5:00 PM.

Implementation:

1. Purchase Card Reinstatements

Action Taken: Coordinated with leadership across the NIH Institutes and Centers to freeze 870 credit cards, reducing its open credit cards to only around 8% of its prior usage, to effectively reduce credit

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card spend to the minimum emergency amount.

Status: Complete

2. Resume payments previously paused due to an EO and directives from the Office of Management and Budget (OMB).

Action Taken: As a result of multiple court orders, OALM ensured compliance by providing required legal notices to all NIH contractor organizations by the stated deadlines.OER outlined the priority order for releasing funds.

Status: Complete

3. NIH authorizes IC funding

Action Taken: ICs are authorized to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements grants. Until further notice, as awards are issued, ICs must follow their existing FY25 IC funding policies and use the previously approved negotiated indirect cost rates.

Status: Complete

4. Temporary Restraining Order in National Council of Nonprofits et al. v. Office of Management and Budget et al.,

Action Taken: Restraining order that allows federal agencies to un-pause funding - OMB

Memorandum M-25-13

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Initial Guidance Regarding DEIA Executive Orders

Pursuant to its authority under 5 U.S.C. § 1103(a)(1) and (a)(5), the U.S. Office of Personnel Management ("OPM") is providing the following initial guidance to agencies regarding the President's executive orders titled Ending Radical and Wasteful Government DEI Programs and Preferencing and Initial Rescissions of Harmful Executive Orders and Actions, which repeals Executive Order 14035, Diversity, Equity, Inclusion and Accessibility in the Federal Workforce.

Implementation:

1. Discussions with Tenure-Track Investigators Not on Administrative Leave

Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.

Status: In Progress

2. Placed DEIA Employees on Administrative Leave

Action Taken: 3/4/25: Ten employees were placed on administrative leave and five received probationary termination notices.

Status: Complete

3. Removal of DEIA Related Language from CY2025 Performance Plan

Action Taken: Updating Performance Plans by March 25, 2025. Review all remaining 2025 Performance Elements for Supervisory and Non-Supervisory employees and remove any DEIA related

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language. Establish new 2025 Performance plans.

Status: Complete

4. Changes to webpages, flyers, posters related to DEIA, gender

Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex. Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.

Status: Complete

5. Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies.

Action Taken: Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies, Rescission of "any guidance, instruction, recommendation, or document issued by the IWG is withdrawn as no longer representative of governmental policy related to the Presidential Memorandum of January 27, 2021 (Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking)." NIH is awaiting HHS direction as to whether HHS and NIH policy should be rescinded.

Status: In Progress

6. Termination of NIH Distinguished Scholars Program

Action Taken: Terminated the NIH Distinguished Scholars Program for tenured and tenure-track investigators, a program that was launched years ago to aid diversification of the biomedical workforce and mentoring for individuals otherwise not likely to pursue careers in biomedical research.

Status: Complete

7. Communicating a consolidated list of terminated NIH contracts

Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts. Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around \$6M in anticipated funding. Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts. Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. Provided cost savings data to HHS. Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.

Status: Complete

8. Ensure that data analyses align with administration guidance

Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.

Status: In Progress

9. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts

Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference

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grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications.

Status: In Progress

10. Removal of DEI-Related Content from Microsoft 365

Action Taken: ICOs reviewed and verified their identified sites and content and ensured proper

records management: **Status:** Complete

11. Summary of DEIA Activities January 21 through February 6, 2025

Action Taken: This is a summary of DEIA activities January 21 through February 6, 2025.

Status: Additional Consideration

12. Compile a List of All DEI Websites and Equity Plans

Action Taken: List of all ICO DEI webpages and equity plans was compiled.

Status: Complete

13. Report on training activities

Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but

likely Defending Women, DEIA.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Deferred Resignation Program

Deferred Resignation Program

Implementation:

1. Contact Employees on Extended Leave about DRP

Action Taken: NIH contacted employees on extended leave to notify them to review to the Fork in the Road email or the OPM webpage.

Status: Complete

2. Provide Additional Guidance on Compliance with the Age Discrimination in Employment Act in the Implementation of DRP Agreements

Action Taken: OPM is providing additional guidance to agencies regarding implementation of the Deferred Resignation Program ("DRP"). Agencies should treat the DRP as an "exit incentive program" under section 7 of the Age Discrimination in Employment Act (ADEA). Accordingly, agencies should provide employees aged 40 and over with a supplemental notice containing

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additional, agency-specific information necessary to comply with the OWBPA.

Status: Complete

3. Building Awareness of Guidance for Collective Bargaining Obligations to Deferred Resignation Offer

Action Taken: Agencies review all CBAs to determine whether provisions regarding resignation are covered by the CBA. To the extent any union proposals concerning employment conditions are not covered by a government-wide regulation or the CBA and the agency has discretion on implementation of certain aspects of the deferred resignation program, there may be some limited collective bargaining obligations. For example, negotiable proposals may include such matters as: Informing the employee of any benefits available or not available after resignation and of any applicable reemployment rights;

Status: Complete

4. Extension of Fork in the Road (DRP)

Action Taken: Employees who wanted to accept Deferred Resignation, replied to OPM's HR email address from their government email address with the word "resign".

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance Regarding RIFs of DEIA Offices

In accordance with that order, each agency, department, or commission head shall take action to terminate, to the maximum extent allowed by law, all DEI, DEIA, and "environmental justice" offices and positions within sixty days.

Implementation:

1. Placed DEIA Employees on Administrative Leave

Action Taken: 3/4/25: Ten employees were placed on administrative leave and five received probationary termination notices.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OMB - OPM Memo: Federal Civilian Hiring Freeze Guidance

This memorandum provides additional guidance regarding the freeze on the hiring of federal civilian employees as directed by the President on January 20, 2025, via Presidential Memorandum (PM) entitled "Hiring Freeze." This guidance clarifies immediate actions to be taken by Heads of executive departments and agencies to implement the PM and provides information on the types of exemptions authorized under this hiring freeze as well as instructions on how departments and agencies can request exemptions from the Office of Personnel Management (OPM) for critical situations where additional exemptions may be warranted.

Implementation:

1. Federal Civilian Hiring Freeze

Action Taken: Paused efforts to develop process for manage hiring freeze exceptions to wait further

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information on the OPM Guidance on Agency RIF and Reorganization Plans. Canceled the Summer Internship Program for 2025.Freeze on the hiring of federal civilian employees as directed by the President on 1/20/2025.

Status: Complete

2. Not-To-Exceed Appointments Expiring through May 3

Action Taken: Each ICO to submit employee NTE date with position description and impact if

extension is not approved.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Implementing President Trump's Executive Order titled, "Restoring Accountability To Policy-Influencing Positions Within the Federal Workforce"

On January 20, 2025, the President signed an Executive Order entitled, "Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce ("Restoring Accountability")." This Executive Order reinstates and amends Executive Order 13957 of October 21, 2020.1 It creates a new Schedule Policy/Career in the excepted service for positions that are of a confidential, policy-determining, policy-making, or policyadvocating character (policy-influencing positions) and filled by individuals not normally subject to replacement or change as a result of a Presidential transition. Such career positions will be rescheduled into Schedule Policy/Career and thereby exempted from the adverse action procedures set forth in chapter 75 of title 5 of the United States Code.

Implementation: N/A

Further Considerations: N/A

MEMO OPM, OMB - OPM Memo: Agency Return to Office Implementation Plans

The Office of Management and Budget (OMB) and the Office of Personnel Management (OPM) are issuing this memorandum to provide further guidance to agencies on implementation of the January 20, 2025, Presidential Memorandum (PM) Return to In-Person Work.

Implementation:

1. Action Updates for Return to In-Person Work

Action Taken: Summary of Office of Research Facilities-led activities related to return to In-Person

work.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Revocation of Executive Order 14003

On January 20, 2025, President Trump signed Executive Order 14171 entitled, "Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce" ("Restoring Accountability"). Restoring Accountability revoked Executive Order 14003 of January 22, 2021 (Protecting the Federal Workforce).1 Executive Order 14003 rescinded several executive orders President Trump signed that regulated the federal workforce. The revocation of Executive Order 14003 order does not immediately reinstate those

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orders.2 However, in light of Restoring Accountability, agencies should return to the policies of the first Trump Administration on discipline and unacceptable performance, as discussed below, as soon as practicable.

Implementation: N/A

Further Considerations: N/A

MEMO OPM - OPM Memo: Guidance Regarding Redesignating SES CIO Positions

Pursuant to its authority under 5 U.S.C. §§ 1103(a)(1), (5), and (7); 3132(b)(1) and 5 C.F.R. § 214.403, the U.S. Office of Personnel Management ("OPM") is providing guidance to agencies regarding agency Senior Executive Service ("SES") Chief Information Officer ("CIO") positions currently designated as career reserved. The role of agency CIOs has changed dramatically in recent years. No longer the station of impartial and apolitical technocrats, the modern agency CIO role demands policy-making and policy-determining capabilities across a range of controversial political topics. See 5 C.F.R. § 214.402(c)(1). In light of this new reality, OPM recommends that each agency with a CIO role classified as SES and designated as career reserved, send a request that OPM redesignate the position to "general" no later than Friday, February 14, 2025.

Implementation:

1. Redesignate SES CIO Positions

Action Taken: OPM recommends that each agency with a CIO role classified as SES and designated as career reserved, send a request that OPM redesignate the position to "general" no later than Friday, February 14, 2025.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

<u>MEMO OPM - OPM Memo: Further Guidance Regarding Ending DEIA Offices Programs and</u> Initiatives

This memo is providing additional guidance regarding the President's executive orders, including those titled, "Ending Radical and Wasteful Government DEI Programs and Preferencing," "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," and "Initial Rescissions of Harmful Executive Orders and Actions."

Implementation:

1. Termination of NIH Distinguished Scholars Program

Action Taken: Terminated the NIH Distinguished Scholars Program for tenured and tenure-track investigators, a program that was launched years ago to aid diversification of the biomedical workforce and mentoring for individuals otherwise not likely to pursue careers in biomedical research. **Status:** Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO HHS, Dorothy Fink, Acting Secretary - HHS Guidance: Immediate Pause on Issuing Documents and Public Communications

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Presidential appointees need to review and approve any regulations, guidance documents and other public documents and communications (including social media).

Implementation:

1. Immediate Pause on Issuing Documents and Public Communications

Action Taken: Unless reviewed by a Presidential appointee, refrain from sending documents for publication to the Office of the Federal Register; refrain from publicly issuing any document or communication, refrain from participating in any public speaking engagements, refrain from issuing official correspondence to public officials regarding department regulations or policy.

Status: In Progress

2. Acquisition Guidance on Memo "Immediate Pause on Issuing Documents and Public Communications"

Action Taken: All acquisition workforce members must refrain from publicly issuing any document or participating in any communication until it has been reviewed and approved by a Presidential appointee.

Status: Complete

3. Resume Specific Communications Captured in Initial Communication Freeze

Action Taken: Ongoing changes to status will be updated as new information comes in. As of 2/26/25 - Center for Scientific Review (CSR) can begin sending notices incrementally to the Office of the Federal Register to advertise meetings of scientific review groups/study sections. Effective March 3 - all travel cards are frozen for 30 days and travel is on hold, including NIH scientists participating in public scientific conferences for the presentation of scientific data or for the purposes of learning about scientific data.

Status: In Progress

4. Identify high priority acquisition activities related to communications freeze

Action Taken: Data call to identify high priority acquisition activities related to communications pause.

Status: Complete

5. Information requested on Federal Advisory Committee Act (FACA) bodies, including estimated spending.

Action Taken: NIH reported information on Federal Advisory Committee Act (FACA) bodies, including estimated spending to HHS.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO HHS Acquisitions - HHS Guidance: Acquisition Guidance on Pause on Issuing Documents and Public Communications

Pausing communications with prospective vendors.

Implementation:

1. Identify high priority acquisition activities related to communications freeze

Action Taken: Data call to identify high priority acquisition activities related to communications pause.

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Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OMB, Office of Information and Regulatory Affairs - OMB Guidance: Guidance on Implementing Section 3(e) of Executive Order 14168 in Accordance with the Paperwork Reduction Act and the Privacy Act

Specifies how agencies can implement Section 3(e) of EO 14168 in compliance with the PRA and the Privacy Act in a timely manner.

Implementation:

1. Guidance on Implementing Section 3(e) of Executive Order 14168 (Defending Women) in Accordance with the Paperwork Reduction Act and the Privacy Act

Action Taken: Guidance specifies how agencies can implement Section 3(e) of EO 14168 (Defending Women) in compliance with the Paperwork Reduction Act and the Privacy Act in a timely manner.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Agency RIF and Reorganization Plans Requested by Implementing the President's "Department of Government Efficiency" Workforce Optimization Initiative

President Trump required that "Agency Heads shall promptly undertake preparations to initiate large-scale reductions in force (RIFs), consistent with applicable law." President Trump also directed that, no later than March 13, 2025, agencies develop Agency Reorganization Plans. The U.S. Office of Management and Budget ("OMB") and the U.S. Office of Personnel Management ("OPM") now submit guidance on these Agency RIF and Reorganization Plans ("ARRP"), along with the instruction that such plans be submitted to OMB and OPM.

Implementation:

1. Submit Agency Reorganization Plans

Action Taken: 2/26/2025: Exec Sec sent email to department heads

Status: Not Started

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Presidential Memorandum Return to In-Person Work

Guidance from OPM

Implementation:

1. Return to Office Guidance

Action Taken: Guidance on the return to Office

Status: Complete

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2. Approval to Proceed with Procurements to Support In-Person Work

Action Taken: Institutes and Centers are directed to carefully document, justify and support their minimal, immediate needs, in coordination with their acquisition staff. Reporting should include detailed itemizations of what funds are being obligated for.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

<u>MEMO OPM - OPM Memo: Revised Guidance on Probationary Periods, Administrative Leave</u> and Details

The U.S. Office of Personnel Management (OPM) is aware of recent litigation challenging the terminations of various probationary employees in different departments of the federal government. OPM is issuing this **revised guidance**, which revises and updates its earlier memo of January 20, 2025. The revised memorandum clarifies and confirms that OPM has not directed, and is not directing, your agency to take specific performance-based actions against probationary employees. Agencies have and continue to have ultimate decision-making authority over such personnel actions.

Implementation: N/A

Further Considerations: N/A

MEMO OPM - OPM Memo: Request for Agency Performance Data

To assist OPM in developing those metrics, no later than Friday, March 7, 2025, all agencies should submit data regarding their performance management plans and policies—including those contained in collective bargaining agreements—and identify any barriers to ensuring that 1) agency performance plans make meaningful distinctions based on relative employee performance and 2) the agency has the ability to swiftly terminate poor performing employees who cannot or will not improve.

Implementation:

1. Request for Agency Performance Management Data

Action Taken: Agencies should report to on employees with less than fully successful in the last three years.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Exempting Military Spouses and Foreign Service Spouses from Agency Return to Office Plans

Guidance on Exempting Military Spouses and Foreign Service Spouses from Agency Return to Office Plans

Implementation:

1. Guidance on Exempting Military and Foreign Service Spouses from Return to Work Action Taken: Guidance on Exempting Military and Foreign Service Spouses from Return to Work Status: Additional Consideration

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Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Maintaining the Integrity of the Career Senior Executive Service

Review and Reclassification of Positions: Each agency head should take the following actions:

- 1. Promptly identify all agency SES positions that were either (a) general designated SES positions on January 19, 2021; or (b) were general designated SES positions filled by noncareer appointments for a majority of the prior administration's tenure.
- 2. With respect to SES positions described in paragraph (1) that were designated as general and have been redesignated as career reserved, each agency head should promptly take all necessary actions to revert such positions back to the general designation, except with respect to any specific positions that the agency head requests should remain as career reserved positions pursuant to paragraph (3).
- 3. Within 45 days of the date of this memorandum each agency head should report the positions identified in the review prescribed by paragraph (1) (or those positions in the process of being redesignated), to the Office of Personnel Management ("OPM") at allocation-management@opm.govmailto:. If an agency head believes that the President's goals and priorities would be better served by keeping any such positions as career reserved positions, the agency head shall submit a request to retain the specific position as a designated career reserved position and explain the reasons therefore. Agency heads will send the request and explanation to OPM at allocation-management@opm.govmailto:.
- 4. Agencies shall coordinate with OPM to implement these actions, and request support including (a) identifying agency SES positions redesignated from general to career reserved after January, 19, 2021, (b) consultations regarding appropriate procedures for reassignments, pursuant to 5 U.S.C. 3395, and/or details, pursuant to 5 CFR 317.903, should an agency head determine such movement of a career executive is warranted to support the agency's mission, and, (c) any necessary guidance regarding implementation of paragraph (1), (2), and (3).

Implementation:

1. Maintaining the Integrity of the Career SES

Action Taken: Review and Reclassification of SES Positions

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance Regarding Redesignating CHCO Positions

OPM is providing guidance to agencies regarding agency Chief Human Capital Officer (CHCO) positions currently designated as career reserved Senior Executive Service (SES).

Implementation: N/A

Further Considerations: N/A

MEMO GSA - GSA Memo: Assistance with Terminating, Descoping, and Justifying Consulting Contracts

Review a list of GSA identified contracts and confirm if they are essential or non-essential.

Implementation:

1. Data Call: GSA Non-Essential Contracts

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Action Taken: Coordinated with the NIH Director to established categories of spend that aligned with Presidential Appointee priorities and could continue, established a reporting system that categorizes how the NIH Acquisition Workforce is obligating funds within these categories. Established a contract approval process for routing individual requests for consideration of other procurement requirements to the NIH Director for mission critical needs that may not fit squarely within an approved spend category. Paused the issuance of any new Contracting Officer warrants or other Delegations of Procurement Authority. Coordinated the termination of 113 non-essential contract awards for an estimated cost savings of approximately \$14.6M thus far. Additional reviews seeking further cost savings opportunities remain ongoing. Coordinated with HHS to provide data that will be publicly posted regarding NIH's justifications for certain contracts are mission critical. Developed a system to provide Department of Government Efficiency staff with weekly reports detailing all NIH contracting activities, and OALM advised NIH Dr. Memoli reviewed and approved the contracts in question.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

<u>MEMO OPM - OPM Memo: Agency Reporting to OPM for FY 2024 Taxpayer-Funded Union</u> Time Use

U.S. Office of Personnel Management (OPM) is requiring agencies subject to the Federal Service Labor-Management Relations Statute to administer the Statute in a manner consistent with the requirements of an effective and efficient government and, to authorize taxpayer-funded union time only in amounts that are reasonable, necessary, and in the public interest and to monitor its use to see that it is used efficiently.

Implementation:

1. Data Call: Reporting to OPM FY 2024 Taxpayer-Funded Union Time Use

Action Taken: Status: In Progress

2. Data Call: Taxpayer-Funded Union Time Information

Action Taken: Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance Regarding Redesignating CHCO Positions

To ensure accurate and consistent classification of CHCO positions, OPM recommends that each agency with a CHCO role designated career-reserved SES send a request that OPM convert the role to SES.

Implementation:

1. Data Call to Redesignate CHCO Positions

Action Taken: Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

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REQUEST HHS - Coordinating Committee on Women's Health (CCWH) regarding Executive Order 14168

Description

Implementation:

1. Review of women's health or sex as a biological variable activities - Mar 3

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities. **Status:** Complete

2. Review of women's health or sex as a biological variable activities - Feb 20

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities. **Status:** Complete

3. Review of women's health or sex as a biological variable activities - Feb 12

Action Taken: A list of 'women's health or sex as a biological variable' official agency activities. **Status:** Complete

4. Review of women's health or sex as a biological variable activities - Feb 6

Action Taken: An initial review of current and planned 'women's health or sex as a biological variable' official agency activities identified 92 current or planned activities.

Status: Complete

5. Reporting on current or planned women's health and sex as a biological variable official agency activities

Action Taken: Summary of current or planned women's health and sex as a biological variable official agency activities - NIH FACA Charters and Membership Balance Plans, FACA Committee Membership, and Electronic Research Administration (eRA) Committee Management Module (CMM).

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Secretarial Directive on DEI-Related Funding

Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. The START document library includes additional information (memo)

Implementation:

1. Pause Approving Invoices or Completing Receiving for DEI Activities Performed by Contractors

Action Taken: In accordance with HHS guidance, OALM paused all payment of invoices related to DEI activities, and is coordinating with HHS on special review of these invoices prior to payment. **Status:** Complete

2. Do Not Reinstate Contracts Terminated between Jan. 20th – Jan. 31st

Action Taken: Terminated 31 contracts focusing on DEI related activities impacting funding to the

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vendor since January 20, 2025. Cost savings is roughly \$6 million. The START document library includes additional information (email and spreadsheet).

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST OMB - GSA Assistance with Terminating, Descoping, and Justifying Consulting Contracts

In the enclosed spreadsheet, based on available procurement data, we have identified contracts your agency has awarded that may involve non-essential consulting. We ask that you complete the survey below for each contract. In the survey, indicate whether you plan to terminate the contract. If you do not plan to terminate a contract or descope requirement(s), write a one-sentence explanation in the space provided explaining why the consulting contract(s) is essential for your agency to fulfill its statutory purposes. In addition, please include the name of the person who represents that the consulting contract is essential. Finally, please use the survey to add any consulting contracts your agency has awarded that are not listed in the enclosed spreadsheet, and provide the information described above for each.

Implementation:

1. Communicating a consolidated list of terminated NIH contracts

Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts. Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around \$6M in anticipated funding. Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts. Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. Provided cost savings data to HHS. Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.

Status: Complete

2. Assistance with Terminating, Descoping, and Justifying Consulting Contracts

Action Taken: Data call for consulting contracts to terminate, descope, justify complete. No data in START.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST OMB - GSA Identification of Contracts that may be Wasteful, Underutilized, Inefficiently Managed or Inconsistent with Presidential Directives

GSA is seeking ideas on new shared service opportunities, chances to reduce duplication, or otherwise drive better outcomes.

Identification of any Federal Acquisition Service (FAS) contracts that are inconsistent with recently adopted Presidential Directives.

Implementation:

1. Communicating a consolidated list of terminated NIH contracts

Action Taken: In response to a variety of EOs, memos, other requests the communication of a

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consolidated list of terminated NIH contracts. Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around \$6M in anticipated funding. Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts. Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. Provided cost savings data to HHS. Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.

Status: Complete

2. Assistance with Terminating, Descoping, and Justifying Advertising and Marketing Contracts Action Taken: Olga Acosta requested a due date extension to GSA for 3/21/2025.

Status: In Progress

3. GSA Identification of Contracts that may be Wasteful, Underutilized, Inefficiently Managed or Inconsistent with Presidential Directives

Action Taken: Identification of contracts that may be wasteful, underutilized, inefficiently managed or inconsistent with Presidential Directives.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Temporary Restraining Order - New York, et al. v. US. Office of Management and Budget (No. 25-cv-39) (Feb. 10, 2025, D. R.I.)

On 2/10/25k a district court issued a further order directing the Defendants, including the Department of Health and Human Services, to resume payments previously paused as a result of an executive order and directives from the Office of Management and Budget (0MB). In its order, the court addressed the argument that some continued pauses in funding were made pursuant to possible findings of fraud. The court rejected that argument and held that such funding pauses, viz., payment pauses made to "root out fraud," violate the plain text of the court's original temporary restraining order. Based on the Rhode Island District Court's order ofthis afternoon, and after consulting with the Department of Justice, this office provides the following guidance: All payments that are due under existing grants and contracts should be un-paused immediately.

Implementation:

1. Resume payments previously paused due to an EO and directives from the Office of Management and Budget (OMB).

Action Taken: As a result of multiple court orders, OALM ensured compliance by providing required legal notices to all NIH contractor organizations by the stated deadlines.OER outlined the priority order for releasing funds.

Status: Complete

2. NIH authorizes IC funding

Action Taken: ICs are authorized to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements grants. Until further notice, as awards are issued, ICs must follow their existing FY25 IC funding policies and use the previously approved negotiated indirect cost rates.

Status: Complete

Page 47 – Secretary, Health and Human Services

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Pausing FAIR Act

NIH leadership has decided to pause the FAIR Act Inventory activities until we receive further guidance from HHS.

Implementation:

1. Pausing of the FAIR Act Inventory activities

Action Taken: Due to an evolving administrative environment, NIH leadership has decided to pause the FAIR Act Inventory activities until we receive further guidance from HHS.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST White House - Agency to Review all CFR Regulations and Guidance Documents

If a consultation is needed by DOJ, consultation request due 3/19/2025

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative

Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EXHIBIT 51

Research General Terms and Conditions Agency Specific Requirements for the National Institutes of Health (NIH) (April 8, 2021)

NIH Home Page: http://www.nih.gov/
NIH Office of Extramural Research Home Page: http://grants.nih.gov/grants/oer.htm
NIH Grants Policy Statement: http://grants.nih.gov/grants/policy/policy.htm
NIH Forms and Applications: http://grants.nih.gov/grants/forms.htm

I. NIH Implementation of the Research General Terms and Conditions

- A. The Research General Terms and Conditions apply to all NIH grants and cooperative agreements with the exception of the automatic carryover provision found in <u>2 CFR § 200.308(e)(3)</u>). Automatic carryover authority will be indicated on the Notice of Award (NoA) (See II.d below).
- B. NIH Implementation of the Research General Terms and Conditions includes: 1) The Uniform Guidance as codified in 2 CFR §200; 2) conditions on activities and expenditure of funds in statutory requirements, such as those included in appropriations acts detailed at: http://grants.nih.gov/grants/policy/appropriations info.htm; and 3) the NIH Grants Policy Statement.
- C. For certain funding mechanisms, NIH implements streamlined requirements for progress report submission, the Notice of Award (NoA), and financial reporting. Known as the Streamlined Noncompeting Award Process (SNAP), NIH routinely applies SNAP to most Research Project (R-series) awards (except R35s, R41s, and R43s), and Career Development Awards (K-series). NIH grantees are expected to follow the SNAP process for those awards that are issued under the SNAP, as indicated on the NoA. Agency-specific requirements listed below will indicate where differences exist between SNAP and non-SNAP grants. Additional information on SNAP can be found in the NIHGPS, at 8.4.1.2, "Streamlined Noncompeting Award Process".

II. Prior Approval Requirements Not Included in or Modified from the Research General Terms & Conditions

- a. Transfer of funds budgeted for participant support costs to other categories of expense (200.308(c)(5)): Waived, unless change in scope. For the purposes of Kirschstein NRSA programs, this term does not apply. NIH will continue to use the terms trainees, traineerelated expenses, and trainee travel in accordance with NRSA Regulations. Participant support costs are only allowable when identified in specific FOAs.
- b. Subawarding, transferring or contracting out any work under a Federal award (200.308(c)(6)): NIH prior approval is required for the transfer of a significant part of the research or substantive programmatic effort only when the transfer represents a change of scope unless the transfer is to a foreign entity. If the transfer is to a foreign entity, prior approval must be obtained in order to complete the appropriate administrative assurances.

- c. Initiate a one-time extension of the period of performance by up to 12 months
 (200.308(e)(2)): Recipients are required to notify NIH of their initiation of a one-time nocost extension. Recipients are encouraged to use the No-Cost Extension Notification
 feature in the eRA Commons and can submit notifications up to the last day of the current
 end date, essentially waiving the 10-day requirement.
- d. Carry forward unobligated balances to subsequent periods of performance (200.308(e)(3)): NIH prior approval may be required for carryover of unobligated balances on all P mechanisms except P01s; cooperative agreements (U's); Institutional National Research Service Awards (T's); Phase I SBIR & STTR (R43, R41); clinical trials (regardless of mechanism) and awards to individuals. The NIH Notice of Award will state whether prior approval is or is not required for carry over.
- e. Subawards based on fixed amounts at any dollar amount, provided the subawards meet the requirements for fixed amount awards in 200.201(200.333): NIH prior approval is required in order for recipients to provide subawards based on fixed amounts (as defined in 2 CFR 200.45) to which the conditions in 2 CFR 200.201 apply.
- <u>f.</u> <u>Direct charge the salaries of administrative and clerical staff (200.413(c)(1)):</u> NIH prior approval is not required to rebudget funds to direct charge the salaries of administrative and clerical staff if the following conditions are met: administrative or clerical services are integral to the project or activity; individuals involved can be specifically identified with the project or activity; the costs are not also recovered as indirect costs. The only time a prior approval request would need to be submitted is when additional funds are requested for such a position or the incurrence of such costs constitutes a change of scope.
- g. <u>Direct charge special arrangements and alterations costs incurred specifically for a Federal award (200.462(a)):</u> NIH prior approval is required for Alterations and Renovations that exceed \$500,000.

III. Allowable Direct Costs Aside from Those in 2 CFR 200

a. The allowability of direct costs not specifically covered by the provisions of 2 CFR 200, Subpart E shall be in accordance with the NIHGPS or the NIH Funding Opportunity Announcement published in the NIH Guide for Grants and Contracts, if more current.

IV. Non-Adoption of 2 CFR 200.240(a)(2) Termination Clause

a. NIH does not adopt 2 CFR § 200.240(a)(2), stating that the Federal awarding agency may terminate a Federal award if the award no longer effectuates the program goals or agency priorities. NIH derives and exercises discretionary decision-making related to program goals and priorities, separate and distinct from non-compliance, as described within the NIH GPS Section 2.4.4 Disposition of Applications.

V. Contact Information

a. Contact Information for Technical Matters

The NIH Scientific Program Official as identified on the Notice of Award is responsible for the scientific monitoring of the research.

b. Contact Information for Administrative Matters

The NIH Grants Management Officers/Specialist as identified on the Notice of Award is the official to be notified when required by the General Terms and Conditions.

c. Contact Information for Intellectual Property Matters

The NIH point of contact for intellectual property matters is:

Division of Extramural Inventions and Technology Resources Office of Policy for Extramural Research Administration, NIH 6705 Rockledge Dr., Rm. 1136, MSC 7980 Bethesda, MD 20892-7980 Telephone: 301/435-1986

Inventions should be reported using Interagency Edison (located at http://www.iedison.gov/).

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining the NIH GPS. Interim changes to NIH grants policy will be published in the NIH Guide for Grants and Contracts. Each change will be described, including its applicability and effective date.

VI. Agency-Specific Requirements Related to Articles in The Research General Terms And Conditions

Part II Subpart B of the NIHGPS includes additional policy guidance as well as terms and conditions that vary from standard terms and conditions because of the type of grant, grantee, or grant-supported activity. These terms and conditions may apply in addition to or in lieu of those in the Research General Terms and Conditions. Each section of Part II Subpart B of the NIHGPS specifies how the coverage relates to Section II Subpart A of the NIHGPS, and consequently to the Research General Terms and Conditions.

Part II Subpart B includes:

- Multiple Program Director/Principal Investigator Applications and Awards
- Construction, Modernization, or Major Alteration and Renovation of Research Facilities
- Ruth L. Kirschstein National Research Service Awards

- Research Career Development Awards
- Modular Applications and Awards
- Support of Scientific Meetings (Conference Grants)
- Consortium Agreements
- Grants to Foreign Institutions, International Organizations, and Domestic Grants with
- Foreign Components
- Grants to Federal Institutions and Payments to Federal Employees Under Grants
- Grants to For-Profit Organizations
- Research Patient Care Costs

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining the NIH GPS. Interim changes to NIH grants policy will be published in the NIH Guide for Grants and Contracts. Each change will be described, including its applicability and effective date

VII. Revised Budget Requirements

- a. While a modified, streamlined, progress report is still a feature of grants awarded under the Streamlined Non-competing Award Process (SNAP) authorities, a streamlined version of the RPPR has replaced the eSNAP module in the eRA Commons. For all SNAP awards, the progress report is submitted using this streamlined version of the RPPR that does not include detailed budget information.
- b. For non-SNAP awards, revised budget information should be submitted according to the instructions in Section H of the RPPR Instruction Guide.

VIII. Technical Reporting

NIH requires grantees to report on scientific progress using the Research Performance Progress Report (RPPR) module in eRA Commons. Annual progress reports submitted in any format other than the RPPR will not be processed by the NIH and will require resubmission through the RPPR.

As of January 1, 2017, NIH has replaced the Final Progress Report with the Final RPPR (F-RPPR). Generally, the format will be the same as the annual RPPR, making it easier for recipients to navigate through the F-RPPR based on familiarity with the existing format of the annual RPPR. Effective February 9, 2017, if the recipient organization has submitted a renewal application on or before the date by which an F-RPPR would be required for the current competitive segment, then submission of an "Interim-RPPR" via eRA Commons is now required. Based on this requirement, NIH has discontinued the policy for renewal applications whereby, "whether funded or not," the progress report contained in the renewal application may serve in lieu of a separate final progress report.

IX. Financial Reporting

- a. Generally, for SNAP awards, a Federal Financial Report (FFR) is required at the end of a competitive segment only. It must be submitted within 120 days after the end of the competitive segment and must report the cumulative support awarded for the entire competitive segment. An FFR must be submitted at this time whether or not a competing continuation award is made.
- b. For non-SNAP awards, the FFR is required annually. The report must be submitted for each budget period, no later than 90 days after the end of the calendar quarter in which the budget period ends. The report must also cover any authorized extension in time of the budget period. For non-SNAP awards, the final FFR must be submitted within 120 days after the end of the competitive segment.
- c. For grants eligible for automatic carryover, the FFR must specify the amount to be carried over to the next budget period. The notification must be provided under item 12, "Remarks," on the FFR.
- d. If more frequent reporting is required, the NoA will specify both the frequency and due date.

FFRs must be submitted electronically to NIH using the FFR system located in the eRA Commons. Questions concerning specific financial matters should be directed to the Government Accounting Branch, 301-451-9210, or visit the Government Accounting web-page at https://ofm.od.nih.gov/Pages/Government-Accounts-Branch.aspx.

X. Incremental Funding Actions

A. SNAP:

- 1. Instructions for submitting SNAP progress reports are included in the RPPR Instruction Guide.
- 2. Career Development Awards that are issued under SNAP are to follow the RPPR instructions for SNAP and the CDA instructions of the RPRR at Section 7.1.
- 3. NIH will use the quarterly FFR cash transaction data submitted to the Payment Management System (PMS) to monitor the financial aspects of SNAP awards. Final FFR expenditure data is required to be submitted to NIH within 120 days of the end of a competitive segment (see 200.344).

B. Non-SNAP

- 1. Instructions for submitting non-SNAP progress reports are included in the RPPR Instruction Guide.
- 2. Institutional Research Training Grant, Including Ruth L. Kirschstein National Research Service Awards are to follow the specific training grant instructions of the RPPR at Section 7.4.

3. A FFR is required to be reported annually to NIH for non-SNAP awards. Final FFR expenditure data is required to be submitted to NIH within 120 days of the end of a competitive segment (see 200.344).

EXHIBIT 52

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, et al.,

Defendants.

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

SUPPLEMENTAL DECLARATION OF NICOLE MAPHIS

- I, Nicole Maphis, pursuant to 28 U.S.C. § 1746, declare as follows:
- 1. I provided a sworn declaration in this case dated April 20, 2025. I offer this additional declaration as a supplement to that first declaration.
- 2. On May 8, 2025, I checked the status of my pending MOSAIC K99/ROO application on the NIH era commons webpage. As shown on that webpage, my application status had changed to "Application withdrawn." A true and correct copy of that page is attached as Exhibit A.
- 3. That same page had a document entitled 'Administrative Withdrawal' linked to the Correspondence tab. I clicked on that link and found a notice from the Department of Health & Human Services, dated May 6, 2025, that reads: "This application responded to a discontinued program that no longer effectuated NIH priorities which included elements based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other

protected characteristics, which harms the health of Americans. Therefore, this application has been administratively withdrawn." A true and correct copy of this notice is attached as Exhibit B.

Page 3 of 9

- 4. My pending MOSAIC K99/ROO application sought a grant to study the relationship between alcohol use and Alzheimer's Disease. That proposed study has no relationship to "DEI studies" as described in this May 6 notice.
- 5. I received no email or other notice from NIH informing me of this change in the status of my application or reason for that change.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 15th day of May, 2025.

Nicole M. Maphis

EXHIBIT A



Status



« Return to PI Search

Notes & Tips:

- Important: The NIH provides the JIT (Just in Time) link in the Commons for scored applications. Please await instructions from the NIH on whether to complete this information
- Reminder: All PDF files should be flattened before uploading to ensure successful submission. See instructions on how to flatten a PDF.



Page 5 of 9

Status Result - List of Applications/Awards ?

▼ K99AA032041

2 07/01/2025 - Maphis, Nicole Neural Excitatory

06/30/2030 Marie (PD/PI)

(Project Period)

Role of Neural Excitatory

Inhibitory Balance on the

Spread of Pathological Tau

in Alcohol Dependence

(Title)

Application/Award	Grants.gov Tracking#	Proposal Title	PD/PI Name	eSubmission Status	Current Application Status	Status Date	Available Actions
1K99AA032041-01A1	GRANT14299745	Role of Neural Excitatory	Maphis, Nicole	Submission Complete	Withdrawn	05/06/2025	

Application/Award	Grants.gov Tracking#	Proposal Title	PD/PI Name	eSubmission Status	Current Application Status	Status Date	Available Actions
		Inhibitory Balance on the Spread of Pathological Tau in Alcohol Dependence	(PI)				
1K99AA032041-01	GRANT14068451	Neuroexcitability and Tauopathy: Unraveling the Link Between Alcohol Use Disorder and Alzheimer's Disease	Maphis, Nicole (PI)	Submission Complete	Not Discussed	06/12/2024	JIT







09/01/2019 - TBD (Project Period)

Maphis, Nicole Marie (PD/PI) The role of microglia autophagy in the clearance of pathological tau following immunotherapy (Title)

Administratively Withdrawn by IC

> Application ID Not Yet Assigned



09/01/2019 - TBD (Project Period)

Maphis, Nicole Marie (PD/PI) The role of microglia autophagy in the clearance of pathological tau following immunotherapy (Title)

Application has been entered into computer

eRA - End-to-End Grants Management Solutions

NIH Grants and Funding National Institutes of Health HHS - U.S. Dept. of Health and Human Services

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EXHIBIT B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health Bethesda, Maryland 20892 www.nih.gov

May 6, 2025

This application responded to a discontinued program that no longer effectuated NIH priorities which included elements based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, this application has been administratively withdrawn.

EXHIBIT 53

nature

nature > news > article

NEWS | 16 May 2025

Can NIH-funded research on racism and health survive Trump's cuts?

The US administration has cancelled 'DEI grants' without defining DEI, leaving health-equity researchers in the dark.

By Smriti Mallapaty

You have full access to this article via your institution.



Funding is being rescinded from research into health disparities among people from minority ethnic groups in the United States. Credit: Getty

Dinushika Mohottige had anticipated the termination of her research grant, but it still stung – and left her with questions.



How Trump 2.0 is slashing NIH-backed research – in charts

In 2024, Mohottige, a nephrologist at the Icahn School of Medicine at Mount Sinai in New York City, was awarded a grant by the US National Institutes of Health (NIH) to study how structural racism contributes to kidney disease in a group of Black individuals who are already vulnerable to the condition because of a genetic variant.

The NIH, <u>a major funder of biomedical science worldwide</u>, scored her grant application highly, and by February, Mohottige had even received a notice that her second year of funding had been awarded. But about two week later, the funds were frozen — and on 19 March, the grant was terminated. The notice of termination stated that the award had been cancelled because it related

to diversity, equity and inclusion (DEI). US President Donald Trump, who took office in January, has targeted the concept of DEI as "radical" and as undermining US civil-rights laws by prioritizing certain groups over others. "It is the policy of NIH not to prioritize such research programs," the termination notice stated.

Mohottige found this reasoning confusing because her research proposal did not contain language referring to DEI, which many understand to relate to workforce hiring and training practices. "It begs the question, what does DEI mean to the issuers of this notice? Does it mean the term 'structural racism'? Does it mean 'Black Americans'? Does it mean that we can no longer do rigorous science to really understand why the devastating burden of health disparities exist in this country and around the globe?" asks Mohottige, who emphasizes that her views do not represent those of her institution.

Mohottige is one of several researchers studying health inequities whose NIH <u>grants have been cancelled</u> with the same justification. The terminations have raised concerns about the extent to which research in the field will get swept up in <u>the mass cuts to scientific research by the Trump administration</u>.

The NIH did not respond to *Nature*'s queries about how it defines DEI and about health-disparity researchers' lives and careers being upended.

Most vulnerable

In January, Trump <u>signed two executive orders</u> calling for the termination of all government DEI programmes and grants funding DEI work. But the orders don't define DEI other than to say that DEI policies "threaten the safety of American men, women, and children across the Nation by diminishing the importance of individual merit, aptitude, hard work, and determination when selecting people for jobs and services in key sectors of American society". The orders also call for grant recipients to be in compliance with federal anti-discrimination laws.



Exclusive: Trump White House directs NIH to study 'regret' after transgender people transition

This means that "you could interpret DEI to mean many things", says one health-disparity researcher who spoke to *Nature* on the condition of anonymity out of fear of reprisal, as did others in this article.

At a public event on 21 April, <u>Trump-appointed NIH director Jayanta Bhattacharya</u> said that the anti-DEI orders had been misunderstood. "I don't think that they're aimed at stopping fundamental research that advances the health and well-being of minority populations."



NIH director Jay Bhattacharya says that work on the biological consequences of characteristics such as race and sex is important. Credit: Andrew Harnik/Gettv

And in <u>an interview with Science published on 5 May</u>, Bhattacharya distinguished between studies that look at the biological consequences of individual characteristics such as age, race and sex, which he said were important, and those involving "politicized, DEI kinds of ideology", which he didn't define but said didn't contribute to improving health.

Despite Bhattacharya's statements, the anonymous researcher says that their own experiences and those of their colleagues suggest that studies on the biological consequences of characteristics are being treated as DEI work. The researcher's own grant looking at chronic kidney disease in people from minority ethnic groups was terminated this month because of its supposed connection to DEI.

NIH staff members have been given lists of **terms**, seen by *Nature*, that are to be used as reasons to reject proposals or flag grants for investigation. They include 'inequity', 'racism', 'underserved' and 'SDOH', which stands for the social determinants of health – non-medical factors, such as socio-economic status and access to healthy food, <u>that can explain differences in health</u> outcomes.

The NIH did not respond to *Nature*'s queries about whether the agency considers racism and social determinants of health as factors contributing to health or whether they are deemed politicized ideology.

A chilling effect

Given the confusion and the cuts made already, "there's going to be a chilling effect on this line of research", says a programme officer at an NIH institute, who was granted anonymity because they aren't authorized to speak to the press. "We will end up having less inclusive research" because people are afraid to submit applications to study health equity, or because they quit academia for lack of funding.

Ultimately, researchers worry for the people their work serves. "This is going to have a detrimental effect on the people who tend to be worst off already due to marginalization," says another anonymous researcher, whose grant exploring theories of health equity and injustice was flagged as DEI-related and terminated.

Cancelling grants that focus on health disparities will mean "going back in time", says Jill Becker, a neuroscientist at the University of Michigan in Ann Arbor who studies sex differences. "We know that socio-economic status and race can influence health outcomes — those two are intricately entwined."

Guidance sought

A leading concern for academics studying health equity at the moment is a lack of clear guidance. In reference to the interpretation of DEI among staff at the NIH, "there's been really little clarity on how, what, who is interpreting this language, who is deciding it, who is executing it and also what's going to happen with the appeals," says Nancy Krieger, a social epidemiologist at Harvard University in Cambridge, Massachusetts, who had a health-disparity grant cancelled on 28 February. Krieger has since filed an appeal with the NIH, as has Mohottige.



NIH cuts triggered a host of lawsuits: Nature's guide to what's next

This ambiguity was highlighted by a US judge overseeing <u>a lawsuit that seeks to reinstate</u> terminated grants at the NIH: "I understand the administration is against DEI," the judge said at a hearing on 8 May. "Respectfully, I just don't know what you mean," he said, adding, "there has to be some working definition" of DEI.

Government lawyers representing the NIH filed documents on 12 May alleging that the agency had "exercised its discretion to terminate DEI grants that it determined did not promote health, while preserving grants into health disparities". The filings did not elaborate on how this review was undertaken, nor whether it was conducted by NIH staff members. <u>Testimony from high-ranking</u>

<u>NIH officials in a separate lawsuit</u> indicates that a representative of <u>billionaire Elon Musk's US Department of Government</u> <u>Efficiency</u> handed spreadsheets of grants to be terminated to agency employees.

Becker says researchers are modifying their applications to avoid being flagged, for example by avoiding using the term 'racial disparities' and using **terms** such as 'sex differences' less frequently. "It is biasing how we're presenting the work," she says.

"People are calling now and saying: 'Can we just take the word equity out of our title?' like it's a bad thing," says another programme officer at an NIH institute who also spoke on the condition of anonymity. In the best-case scenario, researchers will find ways of doing the same work by another name, but in the worst case, the work just won't get done, and "we go back to only studying white men", the officer says.

doi: https://doi.org/10.1038/d41586-025-01538-6

Additional reporting by Max Kozlov.

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Nature (*Nature***)** ISSN 1476-4687 (online) ISSN 0028-0836 (print)

EXHIBIT 54

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, et al.,

Defendants.

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

SUPPLEMENTAL DECLARATION OF KATIE EDWARDS

- I, Katie Edwards, pursuant to 28 U.S.C. § 1746, declare as follows:
- 1. I provided a sworn declaration in this case dated April 24, 2025. ECF No. 38-20. I offer this additional declaration as a supplement to that declaration.
- 2. I am offering this supplemental declaration in my individual capacity and not on behalf of my employer.
- 3. Since my April 24, 2025 declaration, I have had to reduce the hours of at least four team members whose jobs were funded largely or entirely through the terminated NIH grants that were discussed in that declaration. Specifically, those individuals were funded through the terminated R01 grant discussed in detail in that declaration (Project Number 5R01MD016384), and their work focused on the research funded through that grant. *See* ECF No. 38-20 ¶ 9. Prior to the termination of this grant, some of these individuals worked as many as ten to twenty hours a week on that project; now, because of this termination, they each work substantially fewer hours a week; they have consequently lost pay, and that reduction of hours has already had a substantial negative effect on this study.
- 4. As noted in my April 24, 2025 declaration, this grant funded a survey that collected data from over 3,100 participants. ECF No. 38-20 ¶ 11. Prior to the termination of the grant, the work of these individuals included sending out surveys every six months to participants,

- following up with and sending reminders to the participants to complete their surveys, compensating participants as a result of their participation in the study, and generally liaising with and responding to study-related questions from the participants.
- 5. But because NIH terminated this grant, we have had to completely stop collecting data for this study, and we have put the study on hold, meaning most of the study's participants at this time are unable to complete all of the surveys the study originally set out to perform. See ECF No. 38-20 ¶¶ 11, 23. As I elaborated on in my April 24, 2025 declaration, cutting off the study prematurely will have several negative consequences for the study itself, the area of research, and the participants and communities served by this research. See ECF No. 38-20 ¶ 23.
- 6. Although my co-investigators and I have continued to try to raise funds to replace the funding from this grant and the other terminated NIH grants I mentioned in my April 24, 2025 declaration, I have to date only been able to raise approximately \$10,000 in funds to replace those terminated funds. To put that figure in perspective, the award for just the R01 grant discussed above for just the 2025-2026 fiscal year amounted to over \$750,000.00 in funding.
- 7. My co-investigators and I will keep trying to raise replacement funding. We are passionate about our field and work, and we are committed to addressing the health equity needs of our study participants and the broader populations served by our research. But I still do not anticipate being able to raise nearly enough money to secure the amount of funding (millions of dollars) that we would have had with the NIH grants that have been terminated since March 2025.
- 8. Without replacing the funding from those terminated grants, I anticipate having to let go of or substantially reduce the hours of far more staff members over the next few months. That would not only negatively affect their jobs and livelihoods, but it would also negatively affect the studies they work on, the participants they work with, and the populations who would be served by the research that will now be limited, stalled, or even fully cut off because of these terminations.
- 9. I have continued to regularly work more than 15 hours a day, trying to juggle my research with my efforts to replace funding lost because of these NIH grant terminations. But because I have had to focus so much on raising funds to make up for the loss of funding resulting

from the termination of the NIH grants, the amount of time I can spend conducting my research, reviewing literature, or designing new studies to address the public health needs of the communities served by my research has been significantly reduced.

Kattle Edwards

I declare under penalty of perjury that the foregoing is true and correct.

Executed this _____ day of May, 2025.

Katie Edwards

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, et al.,

Defendants.

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

DECLARATION OF SHALINI GOEL AGARWAL

- I, Shalini Agarwal, an attorney admitted to practice before this Court, do hereby state the following under penalty of perjury, pursuant to 28 U.S.C. § 1746:
- 1. I am an attorney admitted to appear and practice pro hac vice before this court. I represent Plaintiffs in the above-captioned action.
- 2. I submit this declaration in support of Plaintiffs' Reply in Support of their Motion for Preliminary Injunction, pursuant to Federal Rule of Civil Procedure 65.
- 3. The facts set forth herein are based upon my personal knowledge or a review of the files in my possession.
- 4. I have attached to this declaration true and correct copies of publicly promulgated or issued documents and factual declarations, as follows:
- 5. Attached hereto as Exhibit 43 is a true and correct copy of a PDF of a National Institutes of Health (NIH) webpage last updated September 13, 2024 and titled "Contracts." The PDF was captured on April 18, 2025. The first citation to Exhibit 16 in the Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Injunction (ECF No. 41 at 21) was intended to

reference the document attached hereto. Plaintiffs inadvertently omitted this exhibit from the original filing and so attach it here.

- 6. Attached hereto as Exhibit 44 is a February 21, 2025 memorandum titled "Directive on NIH Priorities" issued by Matthew J. Memoli, Acting Director of NIH.
- 7. Attached hereto as Exhibit 45 is the supplemental declaration of Scott Delaney and accompanying exhibits.
- 8. Attached hereto as Exhibit 46 is the supplemental declaration of Jeremy Berg and accompanying exhibits.
- 9. Attached hereto as Exhibit 47 is a true and correct copy of NIH's current Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (Parent T35) funding opportunity, dated March 31, 2025. The previous version of the same Notice of Funding Opportunity is attached hereto as Exhibit 48, captured from the Wayback Machine as it appeared on January 22, 2025. A comparison between the two shows that all mentions of recruitment of individuals from underrepresented communities have been removed from the current version.
- 10. Attached hereto as Exhibit 49 is a true and correct copy of a PDF of an NIH webpage last updated March 25, 2025 and titled "Updates to NIH Institutional Training Grant Applications." The PDF was captured May 19, 2025.
- 11. Attached hereto as Exhibit 50 is a true and correct copy of ECF No. 276-5 from Washington v. Trump, No. 2:25-cv-00244-LK (W.D. Wash. 2025), which consists of a March 11, 2025 document with the subject line "Initial Actions Regarding President Trump's Executive Orders INFORMATION."

12. Attached hereto as Exhibit 51 is a document titled "Research General Terms and Conditions, Agency Specific Requirements for the National Institutes of Health (NIH)" and dated April 8, 2021.

13. Attached hereto as Exhibit 52 is the supplemental declaration of Plaintiff Nicole Maphis and accompanying exhibits.

14. Attached hereto as Exhibit 53 is a true and correct copy of a May 16, 2025 article from *Nature* by Smriti Mallapaty, titled *Can NIH-funded research on racism and health survive Trump's cuts?*

15. Attached hereto as Exhibit 54 is the supplemental declaration of Plaintiff Katie Edwards.

Dated: May 19, 2025

Washington, DC

/s/ Shalini Goel Agarwal
Shalini Goel Agarwal
Protect Democracy Project
2020 Pennsylvania Ave., NW, Ste. 163
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202-579-4582
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Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2025, a true 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.

<u>/s/ Shalini Goel Agarwal</u> Shalini Goel Agarwal

EXHIBIT 43

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Home > Funding > Funding Categories > Contracts

Contracts

What is a Contract?

A contract is a legal agreement binding parties that has:

- Defined requirements
- Specific deliverables
- Defined schedule

A contract may be cost or price based.

Grants vs. Contracts

• Assistance • Legally binding agreemen ↑ Back to Top

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Contract
 acquire goods or services for the direct use or benefit of the government. Award based on stated evaluation factors
More government oversight and controlDeliverables

Finding a Contract Solicitation

All contract solicitations are posted on the Contract Opportunities page in Sam.gov. This site serves as the fed-wide portal that supports searching, monitoring, and retrieving contract opportunities for the federal government.

Or you can search for NIH specific opportunities in the NIH Request for Proposal Directory

by the NIH institute or center of interest.

Types of Contracts Fixed Price

- Firm price for delivery of a product or service
- May result from sealed bids or negotiations
- Most often for supplies and standard services

Cost Reimbursement

- Contract contains a negotiated estimate
- May or may not have a fixed fee
- Used when
 - Uncertainties involved in contract performance do not permit costs to be estimated with sufficient accuracy use any type of fixed-price contract

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- Used when costs cannot be estimated with sufficient accuracy to use any type of fixed-price contract
- Most Research and Development (R&D) contracts are costreimbursement

How Contracts Are Evaluated

- Contract awards from proposals are usually made on the basis of best value.
- Evaluation factors for award
 - Technical criteria
 - Cost
 - Past performance
 - o Small disadvantaged business participation
- Best value considers all factors based on the relative importance
- Technical evaluation criteria are reviewed by independent peer review
 - o Sample technical evaluation criteria
 - Technical approach
 - Personnel
 - Facilities
- · Technical criteria are often weighted
- · Reviewers determine technical acceptability

Submitting a Contract Proposal

Search for a contract opportunity on <u>Contract Opportunities</u> \square page in Sam.gov or <u>NIH Request for Proposal Directory</u> \square .

Read the solicitation carefully! It should contain all the information needed to prepare a proposal.

- Registration requirements
- Statement of Work (SOW) or Statement of Objectives (SOO)
- · Instructions to offerors

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- Type of contract
- Set- aside restrictions
- How and where to submit the proposal
- Evaluation factors for award

When Developing a Proposal

- 1. Convince reviewers of your technical abilities!
 - Demonstrate your understanding of the requirement
 - o Demonstrate the soundness of your technical approach
 - Show the strengths of your technical team
 - Present facilities
 - See <u>Technical Proposal Instructions</u>
- 2. Ensure your proposal is cost competitive
 - See <u>Business Cost Proposal Instructions</u> ☐

Review Criteria

To find the criteria reviewers will use to evaluate your application, see Section V of your funding opportunity.

See Also

Contract Regulations

Policies and procedures for acquisition by all executive agencies are codified in the <u>Federal Acquisition Regulations (FAR)</u> .

Contact

These <u>Acquisition Offices</u>
☐ service the NIH Institutes and Centers.

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