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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

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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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

NOTICE OF MOTION AND MOTION FOR STAY AND PRELIMINARY INJUNCTION

Judge: Hon. Sallie Kim
Dept: Courtroom C, 15th Floor
Date: Nov. 16, 2026
Time: 9:30 a.m.

* Application for *Pro Hac Vice* Admission Forthcoming
**Out-of-State Licensee Renewal Pending

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* Application for *Pro Hac Vice* Admission Forthcoming

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NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on November 16, 2026, at 9:30 a.m., or as soon thereafter as Plaintiffs may be heard, Plaintiffs Arghavan Salles, Abigail Hatcher, Andrea Rosso, Ann D. Cohen-Wilson, Dolores Albarracín, Heidi Moseson, Jade Pagkas-Bather, Jonathan Kyle Daw, Katie Edwards, Kelton Minor, Michael D. Green, Sara Jackson, Suzanne Bell, Jordan Doe 1, Jordan Doe 2, Jordan Doe 3, and Jordan Doe 4 (collectively, "Plaintiffs"), will and hereby respectfully do move the Court for entry of an order on their own behalf and on behalf of two nationwide classes[1] (1) preliminarily enjoining and staying Defendants National Institutes of Health ("NIH"), Jay Bhattacharya, the Department of Health and Human Servies ("HHS"), Robert F. Kennedy, Jr., and the United States DOGE Services ("USDS") (collectively, "Defendants") from enforcing the Challenged Policies, described in detail below, on First Amendment and Administrative Procedure Act ("APA") grounds, and (2) reinstating the terminated grants on First Amendment grounds.

This motion is brought pursuant to Fed. R. Civ. P. 65(a) and Civil L.R. 65-2 and is based upon this Notice of Motion, Motion, and Memorandum and Points of Authorities; the accompanying Declarations and exhibits[2]; the pleadings and papers on file; any subsequent briefing; and any evidence and oral argument that may be requested or permitted by the Court.

[1] Plaintiffs will be filing a Motion for Provisional Class Certification shortly after filing the instant motion.

[2] In addition to the declarations submitted contemporaneously with this motion, the motion relies upon the declarations and accompanying exhibits submitted with Doe Plaintiffs' Administrative Motion to Proceed Pseudonymously (ECF 6), filed as ECF 7–10.

INTRODUCTION

Since January 2025, Defendants have systematically terminated and renegotiated NIH grants and denied research proposals in an effort to silence certain disfavored views. NIH grants fund private speech by researchers—the dissemination of results, the publication of manuscripts and articles, presentations at conferences and invited talks, and other research-related speech. But the government now seeks to impose ideological conformity on what grant recipients can communicate.

This began with a series of Executive Orders ("EOs") that sharply criticize diversity, equity, and inclusion ("DEI"), gender identity, and environmental justice. To implement the EOs, Defendants issued directives and protocols and, while doing so, expanded the list of disfavored views to also reach perspectives on vaccines, misinformation, and more. New and continuing grant materials are now screened by an automated tool for a list of 235 forbidden terms, including "Latinx," "lactating person," "systemic racism," and "climate change," as proxies for research-related speech expected to communicate the disfavored views. Researchers on many flagged grants are forced to parrot the government's preferred script—for example, using "pregnant woman" instead of "pregnant person," or "temperature fluctuations" instead of "climate change"—to obtain or retain funding. For other researchers, flagged grants are summarily terminated.

Plaintiffs seek preliminary relief on two categories of claims: First Amendment claims challenging NIH's policies and the resulting terminations, and APA claims challenging solely the policies. With respect to the First Amendment, Defendants' policies and resulting terminations constitute viewpoint-based discrimination in government funding for private speech and compelled speech as a condition of funding, both of which are unconstitutional. The terminations also constitute retaliation for applicants' constitutionally-protected views and research-related speech. While the First Amendment does not prohibit NIH from establishing scientific priorities, NIH may not use ideological criteria to suppress or penalize disfavored views. With respect to the APA, NIH's policies ignore Congress's requirements that agency decisions must be reasoned and reasonable, and that ultimate authority for awarding grants lies with Directors in its Institutes and Centers ("IC" or collectively "ICs"), not political officials. In addition, the policies contravene regulations allowing termination only if a grant no longer effectuates the priorities in place when it was awarded.

Plaintiffs are facing irreparable harm: silenced speech, compelled speech, upended research plans, halted clinical studies, jeopardized employment prospects, and more. In addition, the public is irreparably harmed when scientific work is delayed, distorted, or abandoned for ideological reasons because it loses the benefits, treatments, and cures from that research, potentially forever.

For the reasons set forth more fully below, this Court should stay and preliminarily enjoin NIH's unconstitutional, arbitrary, and unlawful policies and reinstate the unconstitutionally terminated grants.

STATEMENT OF FACTS

A. NIH's Statutory Structure and Science-Based Grantmaking Process

"NIH's mission is to seek fundamental knowledge" and its goals include "foster[ing] fundamental creative discoveries." Decl. of Heanue ("Heanue") ¶ 5, Ex. 1. NIH accomplishes this largely through funding extramural research, conducted by non-NIH scientists, at non-NIH labs. A key aspect of this funding is to communicate "the results and accomplishments" of the research "to the public." Heanue ¶ 6, Ex. 2 § 8.2. Recipients "are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities." *Id.* § 8.4.1; *see also id.* § 8.2.1. In fiscal year 2025, NIH awarded $35.3 billion through 55,394 extramural grants to 2,719 universities, hospitals, and other organizations. Heanue ¶ 7, Ex. 3 at 2.

The granting process begins when NIH announces funding opportunities, and much of NIH's portfolio consists of investigator-initiated proposals. *Id.* at 4. Applications undergo two levels of review: 1) scientific and technical merit review by primarily non-governmental scientists; and 2) for those that survive peer review, consideration by the relevant IC. 42 U.S.C. §§ 282(b)(9), 289a(a), 289a-1(a)(2); 42 C.F.R. § 52h.7; Heanue, Ex. 2 § 2.4. Congress has assigned the ultimate funding decision to the relevant IC Director, who must "review and make the final [award] decision." 42 U.S.C. § 284(b)(2), (b)(3)(A). And Congress has listed the factors the IC Director considers in making that decision "consistent with the peer review process": the IC's mission and scientifically developed priorities, similar projects funded elsewhere, and the advice of the IC's staff and advisory council. *Id.* § 284(b)(3).

Once NIH selects a project, it issues a Notice of Award ("NOA") to the recipient institution and principal investigator ("PI"). Pursuant to the NIH Grants Policy Statement ("NIH GPS") which sets out

grant terms, researchers generally own the resulting expression, including through copyright. Heanue, Ex. 2 § 8.2.1. In addition, "each publication, press release, or other document about research supported by an NIH grant" must include a disclaimer that says "The content is *solely* the responsibility of the authors and does not necessarily represent the officials views of the [NIH]." *Id*. (emphasis added).

Project periods commonly span one to five years, during which NIH intends to support the research without requiring researchers to re-compete for their awards. 42 C.F.R. § 52.6(c). Instead, funding ordinarily issues following annual progress reports submitted by the researchers. *Id*.; Heanue, Ex. 2 § 8.4.1.1. Historically, this is not a moment to renegotiate the scope of an award. *See, e.g.*, Decl. of Bell ("Bell") ¶ 18; Decl. of Jackson ("Jackson") ¶ 22; Decl. of Doe 3, ECF 9 ("Doe 3") ¶ 17.

B. NIH Replaces Scientific Merit Review with Viewpoint-Based Screening

Starting in January 2025, NIH upended this grantmaking process. Although the language of the directives and policies has evolved over the past 19 months, the central criterion—alignment with the Administration's preferred views in research-related speech—has not.

1. NIH Begins Targeting Research Based on Viewpoint

The change began with a series of Executive Orders. In January 2025, Executive Order 14151 directed agencies to terminate all "equity-related" awards, including grants to "advance DEI, DEIA, or 'environmental justice' programs . . . or activities." Exec. Order No. 14151, 90 Fed. Reg. 8339, 8339–40 (Jan. 20, 2025). Executive Order 14173 described DEI as "dangerous, demeaning, and immoral"; "corrosive[ ] and pernicious"; and contrary to "traditional American values," and instructed the Office of Management and Budget to "[e]xcise references to DEI and DEIA principles, under whatever name they may appear," from federal grant procedures. Exec. Order No. 14173, §§ 1, 3(c), 90 Fed. Reg. 8633, 8633–34 (Jan. 21, 2025). And Executive Order 14168 declared that federal funds "shall not be used to promote gender ideology," defined as the "false claim" that a person can identify as a gender different from the person's sex. Exec. Order No. 14168, §§ 2(f), 3(g), 90 Fed. Reg. 8615, 8615–16 (Jan. 20, 2025).

On February 21, 2025, then-Acting NIH Director Matthew Memoli issued the first NIH-specific directive ("Memoli Directive") implementing those orders. Heanue ¶ 8, Ex. 4. The Memoli Directive

classified studies "based on diversity, equity, and inclusion (DEI) and gender identity" as "low-value and off-mission research programs" NIH would no longer support. *Id*. at 2.

NIH immediately put that policy into practice. On February 22, a DOGE representative sent Memoli a list of 18 funding opportunities that "may be worth . . . reviewing to make sure they align with your directive and priorities." Heanue, ¶ 9 Ex. 5. Minutes later, Memoli directed that all 18 be taken down. *Id*. Four days later, Executive Order 14222 instructed agency heads to "terminate or modify" existing grants "in consultation with the agency's DOGE Team Lead" where needed to "advance the [Administration's] policies." Exec. Order No. 14222, § 3(b), 90 Fed. Reg. 11095, 11095–96 (Feb. 26, 2025). On February 28, 2025, DOGE representative Rachel Riley told the Deputy Director of NIH's Office of Policy for Extramural Research Administration ("OPERA") that several grants "will need to be terminated" by the end of the day. Heanue ¶ 10, Ex. 6 at 7–8. Memoli then sent NIH staff a list of 16 grants for termination by "COB," and Riley sent more that evening under the subject line "Grants for immediate termination today." Heanue ¶ 11, Ex. 7; Heanue ¶ 12, Ex. 8. An accompanying template termination letter repeated the Memoli Directive's general criticisms of gender-identity research without any analysis of the particular project. Heanue, Ex. 8 at 13–14. On March 24, Memoli reported that NIH had "been asked to terminate" 120 additional grants by the end of that day. Heanue ¶ 13, Ex. 9.

At the same time, NIH converted the Memoli Directive into a review system governing every new and continuing award. Staff were instructed in internal guidance issued on March 4 to "completely excise all DEI activities." Heanue ¶ 14, Ex. 10 at 2. Projects whose "sole purpose" was deemed DEI-related could not be funded; for others, ICs could try to negotiate out the disfavored aims or activities. *Id*. at 2–3. But the guidance went beyond that, requiring that one category of projects—flagged because they contained language purportedly associated with DEI, such as "terminology related to structural racism"—be reworded to remove the "DEI language" even though, in NIH's view, the projects did "not support DEI activities." *Id*. at 3. Thus, even words that did not describe any funded activity could prevent an otherwise approved project from receiving funding.

NIH issued several additional versions of the guidance between March and May 2025 (collectively and including the March 4 guidance, "Award Assessments Guidance"). *See* Heanue ¶ 15, Ex. 11; Heanue ¶ 16, Ex. 12; Heanue ¶ 17, Ex. 13; Heanue ¶ 18, Ex. 14. This Guidance extended the

same machinery to additional disfavored views, including the "health effects of climate change" and "ways to improve vaccine interest." *See, e.g.*, Heanue, Ex. 14 at 21. Under this system, NIH personnel were directed to alter, withhold, or terminate projects that Defendants expected to express the disfavored views in research results, publications, and other speech.

2. NIH Implements New Directives to Accomplish the Same Goals

That first regime did not survive judicial review. After a bench trial, the District of Massachusetts found "not a shred of evidence" supporting NIH's assertions that "DEI" and "gender identity" research was unscientific, and vacated the Memoli Directive and Award Assessments Guidance. *Am. Pub. Health Ass'n v. NIH* ("*APHA*"), 791 F. Supp. 3d 119, 179, 181–84 (D. Mass. 2025).[3] But Defendants' efforts continued.

On August 7, 2025, the President directed agencies to establish senior-appointee review of grant opportunities and awards, and prohibited funding grants that promote racial preferences, reject a binary conception of sex, treat sex as mutable, or promote "anti-American values." Exec. Order No. 14332, §§ 3(a), 4(b)(ii)(A), (B), (D), 90 Fed. Reg. 38929, 38930–31 (Aug. 7, 2025). The EO also forbade the appointees from deferring to peer review, *id.* § 4(a), (c), and directed agencies to revise existing grants to permit immediate termination for no longer advancing agency priorities or "the national interest." *Id.* § 6(b).

Eight days later, NIH Director Jay Bhattacharya issued a Directive ("Bhattacharya Directive v1") to "clarify specific issues that currently require additional guidance." Heanue ¶ 19, Ex. 15 at 4. NIH revised the Directive on July 2, 2026 ("Bhattacharya Directive v2"), Heanue ¶ 20, Ex. 16, without publicly announcing the changes.

Building off NIH's animus against "gender identity research," Bhattacharya Directive v1 stated that studies identifying "the harms" of gender affirming care were "clearly more promising" than studies of such care as treatment. Heanue, Ex. 15 at 7.[4] Both versions prescribe how researchers may frame the

[3] The Supreme Court later stayed only the portions of the judgment vacating individual grant terminations, leaving vacatur of the directives unstayed. *NIH v. Am. Pub. Health Ass'n*, 145 S. Ct. 2658, 2658–61 (2025).

[4] Bhattacharya Directive v2 now calls research into the treatments' "utility" "more promising" than research involving their "use." Heanue, Ex. 16 at 6. Setting aside the difficulty of studying the utility of a therapy without studying its use, there is no evidence that implementation of the policy has changed.

relationship between race and health. Bhattacharya Directive v1 rejected research that attributes health outcomes to "poorly measured factors like systemic racism" but recognized that "redlining and housing discrimination are clearly defined practices" that can affect health and be discussed. Heanue, Ex. 15 at 6. Bhattacharya Directive v2 goes further, instructing that systemic racism "should not be presented as established background facts or otherwise included in proposed research." Heanue, Ex. 16 at 5.

Effective October 1, 2025, HHS adopted 2 C.F.R. part 200, which permits termination pursuant to an award's terms and conditions—including, "to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4) (2026). Before October 1, 2025, HHS regulations permitted the agency to terminate an award only for noncompliance, for cause, or on consent. 45 C.F.R. § 75.372(a) (2024).

3. NIH Creates New Systems to Screen, Renegotiate, and Terminate Grants

On November 18, 2025, NIH issued a "Reminder of Compliance Requirements for NIH Extramural Recipients Related to Renegotiated Aims, Objectives, Titles, and Abstracts" ("November Reminder"). Heanue ¶ 21, Ex. 17. The November Reminder memorialized NIH's new reality of "negotiating" changes in grant scope and language to align with the Bhattacharya Directive and "remind[s]" awardees that such changes "become new terms and conditions of award," with which the recipient "must comply." *Id*.

A month later, NIH converted Bhattacharya Directive v1 into an agency-wide screening and enforcement system, reflected in Guidance issued December 12, 2025 ("December 2025 Guidance"). Heanue ¶ 22, Ex. 18. This Guidance, too, requires each IC to review its full portfolio of ongoing awards, and prohibits competing and continuation awards until NIH has assessed the project and addressed any perceived misalignment with NIH's priorities. *Id*. at 2.

The alignment process now begins with a computational text-analysis tool that scans grants for terms associated with potential misalignment with NIH's priorities. *Id*. at 2–3. The screening list was generated from grants terminated since January 2025 and is grouped into the same categories targeted by the vacated Award Assessments Guidance: DEI, gender, climate change, misinformation, and vaccine hesitancy. Decl. of Doe 1, ECF 7 ("Doe 1") ¶ 13, Ex. 2. Among other examples, the screening list includes "gender identity," "systemic racism," "Latinx," "pregnant person," "lactating individual," and

"climate crisis." *Id*. at 12–16. Thus, although the December 2025 Guidance declares the earlier Award Assessments Guidance no longer operative, NIH continues to use its categories and terminology to identify grants for additional scrutiny. *Compare* Heanue, Ex. 18 at 2, *with* Heanue, Ex. 14 at 21.

If the IC identifies any aspect of a project as potentially misaligned, it must be renegotiated, denied, or terminated. Heanue, Ex. 18 at 2, 5. ICs are instructed to focus on the use of terms such as "health equity" and "structural racism," and to replace that language where possible. *Id*. at 3. When the language used in a project's specific aims, abstract, budget, title, and other award materials is revised, in line with the November Reminder, the changes—including the new language—become binding terms of the award and noncompliance may trigger immediate termination. *Id*. at 5; *see also* Heanue, Ex. 17.

The December 2025 Guidance acknowledges that, in some cases, the project's entire premise may depend on the targeted framing, making renegotiation impossible. Heanue, Ex. 18 at 3. It directs ICs to terminate awards misaligned with existing priorities pursuant to 2 C.F.R. § 200.340(a)(4), regardless of the priorities in place when the grant was awarded. *Id.* at 6. And if an existing award's NOA does not contain a provision authorizing termination for nonalignment with agency priorities under 2 C.F.R. § 200.340(a)(4), the Guidance directs the IC to wait until the next budget period, issue a new NOA containing that language, and then terminate. *Id*.

In addition to the new flagging process that occurs at the IC level, NIH has created a level of final extra-statutory review for both new and continuing awards that occurs at the Office of Extramural Research ("OER") and/or HHS. NIH uses "Status 19"—formerly an administrative stage preceding release of funds—as the holding point for this review. Doe 1 ¶ 13, Ex. 3 at 3, 5. For new grants, this final review occurs after scientific peer review and approval by the IC Director. *Id*. at 6. Now, OER and an "HHS counselor" must review the applications before NIH issues the award; if either questions the project, it returns to the program officer for further renegotiation, after which it must pass through Status 19 again. *Id.* at 5–7. This has left hundreds of scientifically-vetted and IC-approved grants delayed for months or blocked altogether. *Id.* at 6; *see also* Doe 1 ¶¶ 16–17; Decl. of Minor ("Minor") ¶¶ 19–21; Decl. of Moseson ("Moseson") ¶¶ 28–31, 37.

Finally, some of NIH's new policies have not been publicly disclosed. Without public acknowledgement, NIH appears to have created limits on research into the public health impacts of

policy interventions, claiming policymakers are not "mission-relevant stakeholder groups." Heanue, ¶ 23, Ex. 19 at 4. But NIH is not using this new justification neutrally, and instead, it appears to be using it to target only that research that could be expected to uncover negative health impacts of policies favored by the Administration or positive impacts of disfavored policies. *See, e.g.*, Moseson ¶¶ 31–32; Decl. of Pagkas-Bather ("Pagkas-Bather") ¶¶ 15–17; Decl. of Ankuda ("Ankuda") ¶ 15.

C. The Challenged Policies Are Disrupting Plaintiffs' Ongoing Research

Collectively, the Memoli Directive, Bhattacharya Directives v1 and v2, November Reminder, Award Assessments Guidance, December 12 Guidance, and unwritten agency protocols, including keyword flags and OER review, constitute the "Challenged Policies." Plaintiffs are 17 researchers working at universities and nonprofit research institutions in fields ranging from Alzheimer's disease and kidney failure to reproductive health, HIV prevention, violence prevention, and climate-related health risks. They seek relief for themselves and two proposed nationwide classes: the "Termination Class" of researchers whose grants were terminated under the Challenged Policies (which terminations are "the Terminations"), and the "Policy Class" of researchers whose existing or prospective NIH funding is subject to termination, denial, rephrasing or renegotiation under those Policies, including those deterred from applying. Compl. ¶¶ 188–205. As discussed in more detail below, the Challenged Policies are burdening researchers' private expression of disfavored views, *see infra Section* I.A.1, compelling speech as a condition of funding, *see infra Section* I.A.2, and causing irreparable harm, *see infra Section* III.

LEGAL STANDARD

To obtain a preliminary injunction, a party must show that: (1) they are "likely to succeed on the merits," (2) they are "likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [their] favor," and (4) an "injunction is in the public interest." *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). Alternatively, a preliminary injunction may issue where a plaintiff shows "serious questions going to the merits," "the balance of hardships tips sharply in the plaintiff's favor, and the other two *Winter* factors are satisfied." *Id.* (marks and citation omitted).

The "likelihood of success on the merits . . . is the most important factor." *Meinecke v. City of Seattle*, 99 F.4th 514, 521 (9th Cir. 2024). And "[i]t is all the more critical 'when a plaintiff alleges a constitutional violation and injury.'" *Id*. (quoting *Baird v. Bonta*, 81 F.4th 1036, 1040 (9th Cir. 2023)). Accordingly, in First Amendment cases, "the moving party bears the initial burden of making a colorable claim that its . . . rights have been infringed, or are threatened . . ., at which point the burden shifts to the government to justify the restriction on speech." *Id*. (marks and citation omitted).

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THEIR CLAIMS

A. The Challenged Policies and Terminations Violate the First Amendment

The Challenged Policies violate the First Amendment for two reasons. First, by systematically targeting grants that the government suspects will lead to speech that communicates disfavored views, the Challenged Policies violate the First Amendment's prohibitions on viewpoint-based discrimination and unreasonable restrictions in government support for private speech. Second, by requiring researchers to parrot the government's script in their work to get or keep funding, the Challenged Policies impose an unconstitutional condition. The Terminations also violate the First Amendment for those reasons—and for a third one, too: they constitute retaliation for protected speech.

1. The Challenged Policies and Terminations Violate First Amendment Rules Governing Funding of Private Speech

The Terminations and Challenged Policies discriminate against researchers and projects that Defendants expect to communicate disfavored views through private speech. This violates the First Amendment. "[I]deologically driven attempts to suppress a particular point of view are presumptively unconstitutional in funding, as in other contexts," *Thakur v. Trump*, 176 F.4th 1187, 1200 (9th Cir. 2026) (quoting *Rosenberger v. Rector & Visitors of Univ. of Virginia*, 515 U.S. 819, 830 (1995)), and the government may not "aim at the suppression of dangerous ideas" or "leverage its power to award [funds] on the basis of subjective criteria into a penalty on disfavored viewpoints" "even in the provision of subsidies," *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 587 (1998) (quoting *Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 550 (1983)).

Even when it comes to government funds, "[t]he government must abstain from regulating speech when the specific motivating ideology or the opinion or perspective of the speaker is the

rationale for the restriction." *Rosenberger*, 515 U.S. at 829. Though the government has broad discretion to choose its message when it is speaking, and it has no affirmative obligation to fund private speech at all, once it "design[s a program] to facilitate private speech," the First Amendment's ban on viewpoint discrimination—both against speech and speakers—governs. *See Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 542, 548 (2001). In addition, the government may not "distort [the] usual functioning" of the funded speech. *Id*. at 543.

The same rules are reflected in forum doctrine, which offers an alternative lens for evaluating restrictions imposed on government support for private speech. *Thakur*, 176 F.4th at 1201, n.6. *See also Rosenberger*, 515 U.S. at 835 (applying forum doctrine to "funding of speech"); *Christian Legal Soc'y Chapter of the Univ. of Cal., Hastings Coll. of the L. v. Martinez*, 561 U.S. 661, 683 (2010) (forum doctrine applies when government "is dangling the carrot of subsidy, not wielding the stick of prohibition"); *Koala v. Khosla*, 931 F.3d 887, 902 (9th Cir. 2019) (government funding is a "metaphysical forum"). "Under th[e forum] framework, restrictions on access to government initiatives 'must be [not only] viewpoint neutral,'" but also "reasonable" in light of the forum. *Thakur*, 176 F.4th at 1201, n.6 (quoting *Martinez*, 561 U.S. at 679).

a. NIH Grants Support Private Speech

Through its extramural funding, NIH supports private speech. NIH instructs that funded researchers "are expected" to "provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities," and "to publish the results of research in peer-reviewed journals." Heanue, Ex. 2 § 8.4.1; *see also id*. § 8.2. Researchers thus write articles and manuscripts, present at conferences, and give invited talks in connection with their NIH grants.

Plaintiffs' and class members' NIH grants at issue have already led to hundreds of articles and manuscripts. *See*, *e.g.*, Decl. of Cohen-Wilson ("Cohen") ¶ 14 (over forty articles); Decl. of Rosso ("Rosso") ¶ 14 (nearly a dozen articles); Bell ¶ 15 (seven publications). And they have resulted in a substantial number of conference presentations, invited talks, and plenary sessions. *See*, *e.g.*, Bell ¶ 15 (six academic conferences, seven invited talks); Rosso ¶ 15 (national and international conferences); Moseson ¶ 22 (large, national conference presentation and seventy-five-minute session for hundreds of researchers, clinicians, and advocates); Decl. of Daw ("Daw") ¶ 18 ("several conference papers"); Decl.

of Green ("Green") ¶ 11 (two lead-author conference abstracts); Doe 3 ¶ 14 (presentations at two national scientific conferences).

This dissemination and discussion of NIH-funded research is private speech. To determine "whether the government intends to speak for itself or to regulate private expression," courts conduct a "holistic inquiry" that typically considers three factors: "[1] the history of the expression at issue; [2] the public's likely perception as to who (the government or a private person) is speaking; and [3] the extent to which the government has actively shaped or controlled the expression." *Shurtleff v. City of Bos., Massachusetts*, 596 U.S. 243, 252 (2022). Here, each factor supports a finding of private speech.

Start with history. Since Congress first established the Institutes that would become NIH, it has directed them to study health in-house and to "assist[ ] and foster[ ]" research by others. *See* Pub. L. No. 75-244, 50 Stat. 559 (imposing this requirement on the National Cancer Institute in 1937). *See also* Pub. L. No. 79-487, 60 Stat. 421 (same for mental health in 1946); Pub. L. No. 80-655, 62 Stat. 464 (heart health in 1948); Pub. L. No. 81-692, 64 Stat. 443 (other institutes in 1950). Much like the statutes of the 1930s, 40s, and 50s, today's statutory regime states that the ICs exist not only to "conduct" but also to "support" research. *See, e.g.*, 42 U.S.C. §§ 285, 285b, 285b-7(b)(1), 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285k, 285l, 285m. NIH's extramural funding is that support.

Second, the public is likely to perceive the speech that results from NIH-funded research as private speech. Indeed, NIH requires that "[e]ach publication, press release, or other document about research supported by an NIH award" include the following disclaimer: "'The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.'" Heanue, Ex. 2 § 8.2.1; *see also id.* § 14.9 (requiring disclaimer for NIH-funded conferences). NIH itself therefore considers the speech to be private, and, given the disclaimers, "[m]embers of the public encountering a book, article, . . . or educational program supported by [NIH] funding would reasonably attribute its content to its author or sponsoring institution, not [the government]." *See Am. Council of Learned Societies v. Nat'l Endowment for the Humans.* ("*ACLS*"), No. 25-cv-3657 (CM), 2026 WL 1256545, at *43 (S.D.N.Y. May 7, 2026) (relying on similar disclaimer to reach this conclusion for National Endowment for the Humanities ("NEH") funding).

Finally, NIH does not exercise the type of control over the speech that results from NIH funding that is characteristic of government speech. NIH's mission—to "seek fundamental knowledge," "expand the knowledge base," and "foster fundamental creative discoveries"—makes clear its disinterest in shaping or controlling research results, publications, or presentations. *See* Heanue, Ex. 1. *See also ACLS*, 2026 WL 1256545, at *43 (looking to agency's "declarations of purpose" to find that NEH funds private speech). NIH's process and regulations back this up: Extramural grants are often "*investigator-initiated* or *unsolicited*," shaped by the grant applicant's, not the government's, "research idea or training need." Heanue, Ex. 3 at 4 (emphasis in original). NIH does not review articles before they are published or conference presentations before they are made. *See, e.g.*, Heanue, Ex. 2 § 8.2.2 (requiring grantee to publish NIH-funded results on government site only after "the author's final version . . . has been accepted for journal publication"). And researchers generally retain intellectual property rights in the speech they publish as a result of NIH funding. *Id*. § 8.2.1.

b. The Terminations and Challenged Policies Discriminate Based on Viewpoint

Though the speech that results from NIH funding is private speech, Defendants are systematically discriminating against it based on actual or perceived viewpoint. As described in more detail below, NIH has targeted views such as (1) the inclusion of historically disadvantaged groups is desirable, and various forms of societal injustice can be relevant to health outcomes (the "DEI" views); (2) gender identity is real, transgender people exist and gender-affirming care can have health benefits; (3) changes in weather are caused by climate change and climate change has health impacts; (4) vaccine hesitancy is undesirable; and (5) the dissemination of inaccurate information can harm public health.

Defendants are unconstitutionally screening for projects and researchers they expect to communicate these views in a wide variety of research areas, based both on their perception of the "specific motivating ideology or the opinion or perspective of the" researchers, *see Rosenberger*, 515

U.S. at 829,[5] and their perception of what the research results and related publications are likely to say given research plans, designs, and motivations.[6]

i. Defendants Disfavor Particular Messages

Though NIH has never clearly explained what it understands "DEI" to be, it has made clear that it views DEI as a disfavored ideology and that it will deny, terminate, or otherwise penalize projects it believes support or are "based on" DEI. *See, e.g.*, Heanue, Ex. 4 at 2 (disfavoring studies "based on" DEI); Heanue, Ex. 16 at 5 (disfavoring research "based on [specific] beliefs" about "race or ethnicity"); Heanue, Ex. 15 at 5 (same for "ideologies"). NIH has penalized grants for using "DEI language," including "statement[s] regarding institutional commitment to diversity," even in projects that "do[ ] not support DEI activities." Heanue, Ex. 10 at 3. And NIH has directed ICs to "[p]ay particular [negative] attention" to phrases it perceives as proxies for pro-DEI views, like "health equity" and "structural racism." Heanue, Ex. 18 at 3. This viewpoint bias is perhaps clearest from the prohibited terms list, which includes many phrases that *support* diversity—"advancing diversity," "bolster diversity," "broaden diversity," "commitment diversity," "embrace diversity," "encourage diversity," "improve diversity," "need diversity," "support diversity"—but none that *oppose* it. Doe 1, Ex. 2 at 12–16.

Plaintiffs' experiences bear out this bias. *See, e.g.*, Green ¶¶ 12–13, 16–17 (NIH twice directed "remov[ing] any DEI language" to retain funding, and funding was approved only after researcher removed "racism," "discrimination in healthcare," "health equity," "health disparities," "race," and "unequal" from grant materials); Decl. of Albarracín ("Albarracín") ¶¶ 13–17 (grant was flagged and researcher retained funding only after removing "health disparities," "ethnic minority," "culturally diverse," "vulnerable," and "diverse backgrounds"); Rosso ¶¶ 16, 17, 20 (NIH required renegotiation

[5] Defendants have looked for "statement[s] regarding institutional commitment to diversity," Heanue, Ex. 10 at 3; they have required the removal of "DEI language" from researchers' biosketches, "even [where] the project itself is not focused on DEI," Heanue, Ex. 12 at 6; and they have directed ICs to look for forbidden terms in grants' "fram[ing] or justif[ication]." Heanue, Ex. 18 at 3; *see also* Heanue, Ex. 16 at 5 (prohibiting statements even in a proposal's "background facts").

[6] Defendants single out "study design[s]" that focus on "race and sex" as requiring scientific justification (notwithstanding the rigorous peer review all applications undergo), Heanue, Ex. 15 at 5; Heanue, Ex. 16 at 4–5, and they forbid certain language from being used "to define participant attributes, comparator group attributes, and to whom the study findings apply." Heanue, Ex. 15 at 6; Heanue, Ex. 16 at 6; *see also* Heanue, Ex. 18 at 3–4 (prohibiting "Latinx" to describe populations).

because of "DEI" concern, and grant initially regained funding only after replacing references to "African Americans," "disinvested" communities, "racial disparities" and "structural racism" with language about "socioeconomic differences"); Cohen ¶¶ 16, 18 (NIH required that "language regarding structural racism and health inequity" be cut to continue funding and ultimately terminated grant because the hypothesis' "reliance on racism . . . as key drivers of the hypothesized effects does not align with NIH's priorities"); Decl. of Hatcher ("Hatcher") ¶ 12 (NIH directed researcher to remove "underrepresented," "diverse," "health equity," "structural inequity," and people "marginalized by race, disability, sexuality, and/or poverty" from grant materials); Doe 1 ¶ 12 (application looking at impact of changes in abortion policy flagged for saying "equity" and "structural nature of inequitable outcomes" in project aims section, allowed to proceed only after removal); Jackson ¶ 21 (NIH directed removal of "any DEI language" from annual progress report in order to retain funding); Pagkas-Bather ¶ 12 (NIH instructed researcher to remove clause about "Black and Latinx people").

Similarly, NIH disfavors particular views on gender and sex—including that gender identity exists, that a person can be or identify as transgender, and that gender affirming care can have benefits. As with "DEI," NIH has stated that it must "ensure" it is not supporting studies "based on" gender identity. Heanue, Ex. 4 at 2. It has explicitly favored "research that aims to identify and treat the *harms*" of gender affirming care for minors over "studies that involve the use of [such care] to treat gender dysphoria." Heanue, Ex. 15 at 7 (emphasis added). And it has prohibited and flagged terms like "Latinx," "pregnant individual," and "lactating person," *see* Heanue, Ex. 18 at 3–4; Doe 1, Ex. 2 at 16—all of which stand as proxies for the belief that transgender, non-binary, and gender-nonconforming people exist and are worthy of inclusion.

Plaintiffs' experiences also bear this viewpoint bias out. *See* Hatcher ¶ 12 (NIH directed researcher to remove "sexual gender minority" and "pregnant person"); Moseson ¶ 23 (NIH directed researcher to change "pregnant people" to "pregnant women" in research about abortion care); Albarracín ¶ 17 (researchers removed "transgender," "gender," and "LGBT" from application at NIH's direction); Decl. of Edwards ("Edwards") ¶¶ 15–18 (NIH directed researcher to use "biological sex" instead of "gender"); Pagkas-Bather ¶ 12 (NIH instructed researcher to remove "sexual and gender minorities"); Decl. of Doe 4, ECF 10 ("Doe 4") ¶ 17 (NIH directed researcher not to foreground

LGBTQ populations especially at risk of child sex trafficking and in another grant application to remove "gender" to comply with EO 14151); Doe 3 ¶¶ 16–18 (NIH advised researcher to omit "gender-affirming" language to continue grant funding after months-long delay).

NIH has also penalized the views that extreme weather is connected through the phenomenon of climate change, and that climate change can impact health. *See* Heanue, Ex. 14 at 21 (research looking at "health effects of climate change" is "not consistent with HHS/NIH priorities"). The forbidden terms list includes "changing climate," "climate change," "climate crisis," "environmental justice," "fossil fuel," and "global warming." Doe 1, Ex. 2 at 12. And NIH has advised Plaintiffs studying the health effects of weather to talk about "temperature fluctuations" and "extreme heat," "not climate change." Minor ¶ 22; Bell ¶ 31.

In addition, NIH has expressly stated that "[i]t is the policy of NIH not to prioritize research activities that . . . explore ways to improve vaccine interest and commitment." Heanue, Ex. 11 at 4; Heanue, Ex. 14 at 21. *See also* Albarracín ¶ 26 (application funded after removal of words like "reluctance to vaccinate," "intentions to vaccinate," "vaccination norms"). It has also directed employees to review "grants [that] fight misinformation or disinformation." Heanue ¶ 24, Ex. 20 at 3–5; Decl. of Doe 5 ("Doe 5") ¶¶ 18–19 (grant studying health misinformation on social media terminated as an "attempt[] to influence the public's opinion"); Albarracín ¶ 26 (grant on termination list for connection to misinformation). And it has directed researchers to remove the term "abortion" from grant materials. *See* Bell ¶ 17; Moseson ¶ 23. *See also* Doe 1 ¶ 17 (high-scoring application about impacts of restrictions on abortion care deemed "non-aligned with NIH priorities" for "trying to influence policy").

ii. The Challenged Policies and Terminations Target Viewpoints

Courts considering similar grant policies and terminations by the Trump Administration have consistently held they are viewpoint-based. *See Thakur*, 176 F.4th at 1201 (in this context, "DEI . . . reflect[s a] perspective") (citation modified); *ACLS*, 2026 WL 1256545, at *44 ("DEI is, of course, a viewpoint."); *Rhode Island Latino Arts v. Nat'l Endowment for the Arts* ("*RILA*"), 800 F. Supp. 3d 351, 362 (D.R.I. 2025) (NEA's policy of penalizing applications "deemed to promote gender ideology" is viewpoint-based). *See also Schiff v. U.S. Off. of Pers. Mgmt.*, 784 F. Supp. 3d 380, 393–94 (D. Mass.

2025) (HHS policy of removing all scientific articles that acknowledge "the existence of people who identify themselves as transgender" is viewpoint-based).

This conclusion follows from the Supreme Court's opinion in *Rosenberger*, where the Court considered whether a prohibition on funding religious publications targeted content (the topic of religion) or viewpoint (religious perspectives). Recognizing that religion has been a "subject[] of philosophic inquiry throughout human history," the Court nevertheless concluded that, in context, "viewpoint discrimination [was] the proper way to interpret" the discrimination at issue because the government allowed discussion of all *subjects*, including religion, as long as they were not discussed from "religious editorial viewpoints." 515 U.S. at 831. In reaching this conclusion, the Court rejected the idea that to constitute viewpoint discrimination, the government's disfavor must be focused on one, specific view. Targeting an entire set of perspectives also crosses the line, for debate is also "skewed" when "multiple voices are silenced." *Rosenberger*, 515 U.S. at 831–32. Most relevant for present purposes, the Supreme Court offered up this example: "If the topic of debate is, for example, racism, then exclusion of several views on that problem is just as offensive to the First Amendment as exclusion of only one." *Id*. at 831.

Indeed, the Ninth Circuit has already applied *Rosenberger*'s reasoning to hold that grant terminations very similar to those at issue here occurred "because of the recipients' perceived . . . *viewpoints*." *Thakur*, 176 F.4th at 1201 (emphasis added). It based that conclusion on two things that are present here as well. First, a recognition that, in the current funding context, the terms "DEI, DEIA, and environmental justice are inherently directional; they reflect 'perspective[s],' rather than neutral topics." *Id*. (quoting *Rosenberger*, 515 U.S. at 829). Second, evidence showing that the government identified grants for termination based on whether they "focused on or promoted (in whole or in part) 'environmental justice,' [DEI], and 'gender ideology'"; that agencies relied on "keyword searches"; and that agencies "targeted grants with words like 'equity,' 'diversity,' 'inclusion,' and 'justice.'" *Id*. That, the Ninth Circuit concluded, was sufficient to show "that the purpose of the grant terminations was to suppress the particular point of view the grant recipients promoted." *Id*.

And, as the Ninth Circuit made clear in an earlier decision in *Thakur*, that Defendants were guided by EOs that smear these and similar viewpoints "reinforces [the] conclusion" of viewpoint bias.

Thakur v. Trump, 163 F.4th 1198, 1206 (9th Cir. 2025). *See also supra* Statement of Facts (describing viewpoint biases of EO 14173, EO 14151, and EO 14168); Heanue, Ex. 4 at 2 (NIH policy is "consistent with" the EOs); Doe 3 ¶ 25 (NIH denied application because it "does not comply with applicable Executive Orders and related policy guidance"). Similarly, the fact that "more than a dozen agencies selected particular grants for termination regardless of the programs through which they were funded, based on their connection to" these same views, as shown by other lawsuits challenging similar policies by other agencies, further evidences the viewpoint bias here. *Thakur*, 163 F.4th at 1205 (considering DEI, DEIA, and environmental justice viewpoints). *See also ACLS*, 2026 WL 1256545, at *44–49 (DEI-based terminations to implement EOs as to NEH grants); *RILA*, 800 F. Supp. 3d at 368 (NEA policy of "disfavor[ing] applications that promote gender ideology"). Thus, the Challenged Policies and Terminations violate the First Amendment's bar on viewpoint discrimination in government facilitation of private speech.

c. The Challenged Policies and Terminations Are Unreasonable in Light of the Purposes of NIH Funding

The Challenged Policies and Terminations separately violate the First Amendment's prohibition on restrictions that are unreasonable in light of the purpose of the funding. *See Thakur*, 176 F.4th at 1201, n.6 (quoting *Martinez*, 561 U.S. at 679). Or, put another way, they impermissibly "distort [the] usual functioning" of the "medium of expression." *Velazquez*, 531 U.S. at 543.

Given NIH's mission of expanding knowledge and encouraging scientific discovery, blocking grants because the resulting speech may express views that, while accurate, are disfavored by the government, is unreasonable and distorts the medium of biomedical speech. *See Schiff*, 784 F. Supp. 3d at 394 (crediting argument that removing language that acknowledges the existence of transgender people from HHS forum designed to promote patient safety "directly contradict[s forum's] purpose"); *People for the Ethical Treatment of Animals v. Tabak*, 109 F.4th 627, 630 (D.C. Cir. 2024) (holding that NIH's practice of removing from its social media posts any comment that contained "the terms 'animal,' 'testing,' and 'cruel'" was not reasonable because, according to NIH, the purpose of the forum was to communicate important public health information and to engage the public on such issues for educational purposes). *See also* Bell ¶ 20 (noting that renegotiation pursuant to the Policies made grant materials less clear and precise); Moseson ¶¶ 24, 36 (forced renegotiation "had nothing to do with the

scientific methods, activities, or rigor of the research—they only served to make the study aims and focus less clear" and "felt designed to obfuscate the intention and aims of our research study"); Green ¶ 20 (limitations on "what demographic groups I can . . . write about . . . will limit the impact of the findings and publications"); Edwards ¶ 18 ("restrictions on the use of the term 'gender' may prevent us from fully examining and reporting [study participants'] experiences").

2. The Policies and Terminations Unconstitutionally Compel Speech

The Challenged Policies and Terminations also violate the "cardinal constitutional command" against "[c]ompelling individuals to mouth support for views they find objectionable[.]" *Janus v. AFSCME, Council 31*, 585 U.S. 878, 892 (2018). Pursuant to the Challenged Policies, Defendants actively compel speech, requiring that researchers not only *avoid* certain terms but affirmatively *use* their opposites to have a hope of retaining or obtaining funding. Through the renegotiation process, researchers have been forced to say, for example, "pregnant women," not "pregnant people," Moseson ¶ 23; "temperature fluctuations," not "climate change," Minor ¶ 22; "reproductive health," not "abortion," Bell Decl. ¶ 19; and "biological sex," not "gender," Edwards ¶¶ 15–17. *See also* Hatcher ¶ 23, Ex. 2 (forbidden terms include "birthing people," "lactating individual," "climate crisis," and "global warming"); Moseson ¶ 23 (directed to change "policy restrictions [arising from *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022) ("*Dobbs*")]" to "policy changes"); Bell ¶¶ 27–29 (instructed to state that foreign research is justified because it will improve Americans' health). Defendants also direct researchers to change language in pending applications. *See, e.g.*, Bell ¶ 31 (directed to change "climate change" to "extreme heat" and "pregnant people" to "pregnant women" in application); Edwards ¶¶ 15–17 (directed to use "biological sex" instead of "gender" in application).

"If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). The government can no more compel people "to utter what is not in [their] mind," *id.* at 634, than it can prohibit them from uttering disfavored messages. *See supra* Section I.A.1.

That the government is compelling speech as a condition of government funding cannot save it. *See, e.g., Agency for Int'l Dev. v. Alliance for Open Society Intern. Inc.*, 570 U.S. 205, 213–14 (2013) (a

funding condition "compel[ling] the endorsement of ideas that [the government] approves" "can result in an unconstitutional burden on First Amendment rights") (citation omitted); *Finley*, 524 U.S. at 587 (government cannot "manipulate[]" a subsidy "to have a coercive effect") (citation modified). The Fifth Circuit has held, for instance, that a Texas law that compelled speech from booksellers as a condition of receiving money from the state—requiring them to rate books according to a government rubric in order to be able to sell to state schools—violated the First Amendment, for it "require[d] Plaintiffs to 'either speak as the State demands' or suffer the consequences." *Book People, Inc. v. Wong*, 91 F.4th 318, 324, 338–39 (5th Cir. 2024) (quoting *303 Creative LLC v. Elenis*, 600 U.S. 570, 589 (2023)). That Defendants compel researchers' speech, while at the same time requiring them to disclose that the speech reflects their own views and not those of NIH, only highlights the injury. *See supra* Section I.A.1.a. *Cf. Rust v. Sullivan,* 500 U.S. 173, 200 (1991) ("the university is a traditional sphere of free expression so fundamental to the functioning of our society that the [First Amendment restricts the] Government's ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds").

Pursuant to the Challenged Policies, language changes compelled through renegotiation "become new terms and conditions of [the] award," with which the recipient "must comply," presumably determining what researchers must say in resulting presentations, publications, press releases, and more. *See* Heanue, Ex. 17. *See also* Moseson Decl. ¶ 38, Ex. 5 at 6–7 (NOA includes "SPECIAL TERM AND CONDITION" stating that "[t]he recipient has revised the Abstract, Public Health Relevance Statement, and Specific Aims" and "[t]he project must be carried out in accordance with . . . the agreed upon updates"). And Defendants track what all grant recipients say with NIH funds. *See* Heanue, Ex. 2 § 8.2.1 (annual progress reports must include a list of "[p]ublications resulting from . . . [the] NIH grant-supported project" to date). The compelled speech requirement thus acts as "an ongoing condition on recipients' speech and activities, a ground for terminating a grant after selection is complete." *Open Society*, 570 U.S. at 218. *See, e.g.*, Moseson ¶ 41 ("I am fearful that NIH will terminate my funding if I speak or write about my work or present my findings in ways that differ from the language that NIH required us to adopt."); Doe 3 ¶ 30 (noting concern that, after having to renegotiate after first year of funding, "publish[ing] or present[ing] . . . findings from the first year . . . could result in NIH terminating

[the] grant again"); Green ¶ 20 ("I am concerned about being able to describe any work funded by this grant in publications, presentations, or other avenues in a manner that is inconsistent with the language that NIH forced me to adopt in my grant materials."); Albarracín ¶ 27 (same).

The condition also "leverage[s] funding to [compel] speech outside the contours of the federal program," separately and additionally violating the First Amendment. *Open Society*, 570 U.S. at 206. It attaches not only to how individuals can describe their NIH research, but also to how they can describe *themselves*—their backgrounds, motivations, and worldviews—in public-facing grant materials. Though the language appears in the grant materials, it defines the researcher, not just the project. *See id.* at 217, 219 (finding that compelled certification regarding organization's policy beliefs violated the First Amendment even though it appeared in award documents). Requiring a scientist to identify as an extreme weather researcher, rather than a climate change researcher, *see* Minor ¶ 23, or a person who studies "pregnant women," not "pregnant people," resounds outside of the scope of the NIH funding. *See also* Decl. of Salles ("Salles") ¶ 19 (describing inability to accurately describe career focused on gender equity due to prohibited terms list). And while defining oneself in a way that appeals to a funder is part of most funding processes, *having to* define in a particular way is not. Moreover, because many of the compelled terms convey a view—for example, that all pregnant people are women—and are required for that very reason, forcing researchers to use the terms in effect pushes them to "avow . . . belief[s]" contrary to their own. *Open Society*, 570 U.S. at 218. *See also Bates v. Pakseresht*, 146 F.4th 772, 785, 789 (9th Cir. 2025) (requiring person to "reinforce the state's perspective of sexuality and gender identity as evolving concepts" to qualify for foster parenthood unconstitutionally compelled speech). Having to use the government's language in NIH-research-related speech—including about themselves—makes it impossible, or at a minimum intellectually suspect, for researchers to "then turn around and assert a contrary belief . . . on [their] own time and dime." *Open Society*, 570 U.S. at 218.

3. The Terminations Constitute Retaliation

Finally, the Terminations separately violate the First Amendment because they constitute retaliation for speech. To succeed on a retaliation claim, the Termination Class must show "(1) [they] engaged in constitutionally protected activity; (2) the defendant's actions would chill a person of ordinary firmness from continuing to engage in the protected activity; and (3) the protected activity was

a substantial motivating factor in the defendant's conduct—i.e., that there was a nexus between the defendant's actions and an intent to chill speech." *Koala*, 931 F.3d at 905 (citation modified).

Courts have consistently held that grant termination constitutes an adverse action. *See, e.g.*, *Nat'l Pub. Radio, Inc. v. Trump*, 827 F. Supp. 3d 48, 84 (D.D.C. 2026) (denying "meaningful access to a grant program" is adverse action); *Am. Acad. of Pediatrics v. HHS*, 816 F. Supp. 3d 27, 54–55 (D.D.C. 2026) (termination of grants constituted adverse action); *President & Fellows of Harvard Coll. v. HHS*, 798 F. Supp. 3d 77, 121 (D. Mass. 2025) (same).

And, as described in detail above, NIH has chosen which grants to terminate based on the protected views of researchers, the views it expected project results, publications, and presentations to express, and/or the speech that in fact resulted from the funding. *See supra* Section I.A.1.b. *See also* Rosso ¶ 26 (project terminated because, among other things, it defined "structural racism" as "residential segregation, inequitable distribution of resources, and community disruption"); Cohen ¶ 22 (project terminated because of grant's "overall hypothesis . . . 'that neighborhood inequity will modify the risk of cognitive decline,'" reflecting a "reliance on racism" as a causal mechanism); Salles ¶¶ 14–15 (though project was "proceeding well," NIH terminated it using stock anti-DEI language); Decl. of Doe 2 ("Doe 2") ¶ 23 (same); Daw ¶¶ 17–18 (same for grant that "support[ed] project's hypothesis that racial/ethnic disparities in kidney disease incidence and mortality are worsened in counties characterized by higher levels of structural racism"). This evidence, along with that described *supra* Section I.A.1.b, demonstrates that the terminations were substantially motivated by researchers' protected speech conveying such viewpoints.

B. The Policies Violate the APA

Plaintiffs and the Policy Class are also likely to succeed on their APA claims because the Challenged Policies are arbitrary and capricious, violate congressional mandates that require IC Directors to make final decisions on grant funding based on set criteria, and violate regulations barring terminations for changes in priorities that postdate the awards.[7]

[7] The APA also requires courts to "hold unlawful and set aside" agency action "found to be . . . contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B). As explained above, the current policies violate the First Amendment, and Plaintiffs are also likely to prevail on their APA claim for that reason.

1. The Challenged Policies Are Final Agency Action

As a threshold matter, the Challenged Policies are final agency action within the meaning of the APA because they (1) "mark the consummation of the agency's decisionmaking process" and (2) are those "by which rights or obligations have been determined or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177 n.15, 178 (1997) (citation modified). The "finality element must be interpreted in a pragmatic and flexible manner," *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560, 562 (9th Cir. 1992) (citation modified), with a focus on "practical and legal effects." *Oregon Nat. Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006).

The Challenged Policies reflect the consummation of Defendants' decision-making. They identify viewpoints that are "out of alignment with NIH priorities" and that NIH will no longer fund, and detail the steps NIH officials must take to execute that policy, including specific steps for flagging, renegotiating, terminating, and denying grants and applications. Heanue, Ex. 18, at 3, 6. They bind NIH and HHS staff, who are tasked with implementation. *See id*. at 2, 5 (IC staff "must" apply the required process to "*all* competing applications . . . and ongoing projects" and flagged research "must be renegotiated . . . or . . . terminated or not awarded") (emphasis in original); Heanue, Ex. 4 at 3 ("This Directive *shall* be implemented by all relevant NIH personnel") (emphasis added). *See also Biden v. Texas*, 597 U.S. 785, 808–09 (2022) (holding agency memoranda were final agency action because they "bound" agency staff from continuing certain programs) (citation modified).

That Defendants have taken concrete steps to implement the Challenged Policies—detailed in the terminations, renegotiations, and denials discussed above, *see supra* Section I.A.1.b.—further evidences their finality. *See, e.g.*, *S.F. Herring Ass'n v. Dep't of the Interior*, 946 F.3d 564, 579–80 (9th Cir. 2019) (agency action final where "enforcement activities confirm[ed] its decision-making process was not only consummated, but operationalized"); *New York v. U.S. Dep't of Energy*, No. 6:25-cv-01458-MTK, 2025 WL 3140578, at *9 (D. Or. Nov. 10, 2025), *appeal dismissed*, No. 26-214, 2026 WL 1049169 (9th Cir. Apr. 13, 2026) (agency action final where it "marks a definitive and specific agency position that [the agency] has subsequently enforced."). This implementation also shows that the Challenged Policies have consequences for researchers.

2. The Challenged Policies Are Arbitrary and Capricious

Under the APA, agency actions are unlawful and must be set aside if they are arbitrary and capricious. 5 U.S.C. § 706(2)(A). A final agency action must be supported by "reasoned decisionmaking," *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020) (citation modified), meaning an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation modified). An agency action is also arbitrary and capricious if it "relied on factors which Congress has not intended it to consider." *Id.* The Challenged Policies fail on all accounts.

First, Defendants have not offered a reasoned justification for purging certain viewpoints from scientific research. They make broad assertions that the disfavored views "do[] not follow the principles of gold-standard science," or are not "promising." *See* Heanue, Ex. 15 at 6–7; *see also* Heanue, Ex. 16 at 5–6. But Defendants have not explained why this is the case nor have they "examine[d] the relevant data and articulate[d] a satisfactory explanation." *State Farm*, 463 U.S. at 43. Characterizing views as "broad," "poorly defined," or "poorly measured," *see* Heanue, Ex. 15 at 6; Heanue, Ex. 16 at 5, is no substitute for a data-based explanation. *See APHA*, 791 F. Supp. 3d at 182 (finding "not a shred of evidence" to back up claims that "research . . . on [diversity and] gender identity [is] often unscientific [and provides] little . . . return on investment.") (citation modified). Why, for example, should measurable impacts of systemic racism be excluded from research relating to determinants of health? Far from reasoned decisionmaking, the Challenged Policies weaken NIH-funded research by taking certain answers to scientific questions off the table. *See, e.g.*, Rosso ¶ 37, Edwards ¶ 18, Green ¶ 20.

Moreover, some of the Policy changes are so nonsensical that it is hard to imagine a reasoned explanation for them. Why, for example, do Defendants permit research into "extreme weather," but not "climate change"; why allow research into the harms of gender-affirming care but not its benefits?

The new and unexplained limitation on research into the public health impacts of policy interventions is perhaps the most perplexing. According to Bhattacharya, research that aims to provide evidence to policymakers rather than healthcare professionals is "not in-scope." Heanue ¶ 25, Ex. 21 at 17. Why, then, is NIH simultaneously seeking "research that informs financing, incentives, workforce challenges, consumer decision making, and efficiency in care delivery" or research relevant to health

outcomes for which "the pathway can be policy, delivery, financing, or behavior"? Heanue ¶ 26, Ex. 22 at 3–4.

In application, it is apparent that expected outcome drives implementation of this unexplained rule: it is used when research is likely to show the negative impacts of favored policies on public health or the positive impacts of disfavored ones. *See* Moseson ¶¶ 16–19, 23–38 (application blocked for trying to "influence" policy, even though research merely documents impact of *Dobbs* on abortion access and health outcomes); Bell ¶ 11, 13–19 (similar); Doe 1 ¶¶ 9, 17 (similar); Ankuda ¶¶ 9–15 (high-scoring application likely to highlight negative clinical impact of Medicare Advantage plans denied for influencing policy, while applications that minimized critiques of Medicare Advantage plans were funded, as were worse-scoring applications focused on different policy areas); Pagkas-Bather ¶¶ 15–18 (research likely to demonstrate that basic income guarantee improves health outcomes for low-income people with HIV is in jeopardy of termination); Albarracín ¶¶ 20–24 (researcher directed to remove "harm reduction" from application to research substance abuse disorders).[8]

Second, by scanning grants for renegotiation or termination based on the use of terms like "minorit[y]," "gender," "racism," "underrepresented," "DEI," "equit[y]," or "LGBT," Doe 1, Ex. 2 at 12–16, the Agency has "relied on factors which Congress has not intended it to consider." *State Farm*, 463 U.S. at 43. *See, e.g.*, 42 U.S.C. §§ 285t(b); 283p; 282(b)(8)(D)(ii) (describing, respectively, congressional mandates to "give priority to . . . supporting minority health disparities research"; "encourage efforts to improve research related to the health of sexual and gender minority populations";

[8] Defendants may attempt to justify the impacting-policy prohibition by stating that such research does not relate to variables that "could be influenced by biomedical research," Heanue, Ex. 21 at 17, but that is illogical—*see, e.g.*, Rosso ¶ 38 (explaining that biomedical and behavioral interventions cannot be successful without considering social conditions, and that interventions targeted at neighborhoods can be incredibly powerful approaches to improve health)—and it ignores NIH's role of supporting research precisely because it can broadly improve public health, including through providing information to policymakers. *See, e.g.*, Moseson ¶¶ 16, 35 (noting that NIH funds research "in a host of areas that impact policies at all levels of governance, from hospital policies to national and international guidelines," and explaining that grant was submitted in response to program announcement for proposals evaluating the impact of sudden legal or policy changes and specifying policymakers as an intended audience); Pagkas-Bather ¶ 16 (noting that NIH still funds some research that could impact future policy decisions).

and "utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities").

Third, NIH has implemented a policy not to fund "vaccine hesitancy," "climate change," and "misinformation," without any public acknowledgment whatsoever. Doe 1, Ex. 2 at 5, 12, 16. Indeed, it has publicly stated that the Memoli Directive enacting these prohibitions is no longer in effect. Heanue, Ex. 18 at 2. Defendants' failure to accurately acknowledge the contours of its policy violates one of the most basic requirements of the APA. *See Washington v. U.S. Dep't of Educ.*, 167 F.4th 1241, 1247 (9th Cir. 2026) (affirming arbitrary and capricious holding where Department did not "give the grantees an opportunity to learn about or address the Department's unpublished change in policy affecting its grant continuation process.").

3. The Challenged Policies Strip IC Directors of Their Authority to Make Final Decisions on Awarding Grants and Are Contrary to Law

Under the APA, a reviewing court may also "hold unlawful and set aside agency action" that is "not in accordance with law," 5 U.S.C. § 706(2)(A), or is in "excess of statutory . . . authority." *Id.* §706(2)(C). Defendants' policy of requiring OER or HHS, rather than IC Directors, to conduct final review of grants flagged for alleged misalignment with agency priorities violates the law in two ways.

First, the policy violates Congress' explicit mandate that it is IC Directors who "shall" "review and make the final decision with respect to making [a research grant] award." 42 U.S.C. § 284(b)(3)(A). The word "shall" is mandatory, meaning that the IC Director—and only the IC Director—must review and make the final decision regarding a new grant application. *See Serv. Emps. Int'l Union v. United States*, 598 F.3d 1110, 1113 (9th Cir. 2010). In a similar vein, the statute provides that it is the "[HHS] Secretary, *acting through the [IC] Director*," who "may make grants . . . for research, training, or demonstrations"—regardless of whether they are new or renewal applications. 42 U.S.C. § 284(b)(2), (B) (emphasis added).

Second, through empowering OER and HHS to make decisions pursuant to the Challenged Policies, Defendants have flouted the standards Congress imposed on final grant application review. Regarding applications for future grants, 42 U.S.C § 284(b)(3) requires that the IC Director "take into consideration, as appropriate," the IC's mission and strategic plan, "programs or projects funded by other agencies on similar research topics," and "advice by [IC] staff, "advisory council or board"—not

the presence of disfavored views. *Id.* § 284(b)(3)(B). Further, 42 U.S.C. § 289 requires that the IC Director base decisions on technical and scientific peer review of applications. *See id.* § 289; *see also id.* § 284(b)(2)(B). Empowering OER and HHS decisionmakers to rely on unwritten priorities and viewpoint-signifying terms supplants the criteria mandated by Congress.

4. Allowing Terminations for Subsequent Changes in Agency Priorities Is Contrary to Law

The Challenged Policies require NIH to terminate grants issued under prior agency priorities if they are purportedly not aligned with the new priorities set forth in the Bhattacharya Directive. *See* Heanue, Ex. 18 at 6. This is also contrary to law. The claimed basis for such terminations—2 C.F.R. § 200.340(a)(4), which allows for termination "if an award no longer effectuates the program goals or agency priorities"—can only be based on priorities in place when the award was issued. *See New Jersey v. OMB*, No. 1:25-cv-11816-IT, 2026 WL 2069832, at *11 (D. Mass. July 17, 2026).

The plain language of Section 200.340(a)(4) compels this conclusion. The provision allows for termination only if an existing grant "no longer effectuates *the* program goals or agency priorities." 2 C.F.R. § 200.340(a)(4) (emphasis added). "[T]he definite article 'the' particularizes the subject which it precedes and is a word of limitation." *Gale v. First Franklin Loan Servs.*, 701 F.3d 1240, 1246 n.3 (9th Cir. 2012). In contrast to "the indefinite or generalizing force of 'a' or 'an,'" use of "the" followed by a particular noun (*i.e.*, *the* program or *the* agency priorities) indicates that the noun's identity is discrete and certain. *Id*. *See also Niz-Chavez v. Garland*, 593 U.S. 155, 166 (2021) ("using a definite article with a singular noun . . . seems to speak of . . . a discrete thing"). To that end, "*the* program goals or agency priorities" must mean the specific goals and priorities in place at the time of the initial award, 2 C.F.R. § 200.340(a)(4) (emphasis added), not just *any* goals or priorities that an agency could later identify.

The phrase "*no longer effectuates* the program goals or agency priorities" further confirms this interpretation. *Id.* (emphasis added). "No longer effectuates" necessarily implies that the award previously effectuated the agency goals or priorities—meaning they must previously have been in place. *See OMB*, 2026 WL 2069832, at *11.

Further, interpreting Section 200.340(a)(4) to permit termination based on program goals or agency priorities that did not exist at the time the award was issued "would render the other grounds" of Section 200.340(a)—non-compliance with the grant's terms and conditions or consent of the grantee—

"superfluous." *Id*. at *12. Relying on those narrower circumstances would never be necessary if NIH could invoke new goals or priorities to terminate grants whenever it wished.

What's more, "[t]he broader regulatory scheme dictates that an agency may not terminate grants pursuant to" Section 200.340(a)(4) "solely because" the program goals or "agency's priorities have changed," because related regulations prioritize "ensuring that grantees are on notice, before applying, as to what the program goals and agency priorities are for any particular award." *Id.* at *13–14 (citing, *e.g.*, 2 C.F.R. §§ 200.202(a), 200.203(b)(1), 200.204(a)(8), 200.204(c)(1)).

The requirement to terminate grants for non-alignment with the priorities set forth in the Bhattacharya Directive thus violates the APA.

II. THE TUCKER ACT DOES NOT DEPRIVE THIS COURT OF JURISDICTION

Defendants may argue that the Tucker Act deprives this Court of jurisdiction over Plaintiffs' APA challenges to the Challenged Policies, and First Amendment challenges to the Terminations. Not so. With respect to the APA claims, the Supreme Court has made clear that the Tucker Act does not preclude APA challenges to forward-looking policies. *See Nat'l Insts. of Health v. Am. Pub. Health Ass'n*, 145 S. Ct. 2658, 2661 (2025) (Barrett, J., concurring); *id*. at 2662–63 (Roberts, C.J., concurring in part and dissenting in part). As Justice Barrett explained, "[t]hat the agency guidance discusses internal policies related to grants does not transform a challenge to that guidance into a claim 'founded . . . upon' contract that only the [Court of Federal Claims] can hear." *Id*. at 2661 (citation omitted). With respect to the First Amendment Terminations claims, as courts in this district have recognized, sovereign immunity—which was the sole basis for the Supreme Court's orders in *APHA,* 145 S. Ct. 2658, and *Department of Education v. California*, 604 U.S. 650 (2025)—is no barrier to "suits alleging that a federal official violated the Constitution." *California v. Wright*, No. 26-cv-01417-RFL, 2026 WL 1915590, at *7 (N.D. Cal. July 2, 2026) (citation modified). Moreover, because Plaintiffs could not assert their First Amendment claims in the Court of Federal Claims, *United States v. Connolly*, 716 F.2d 882, 887 (Fed. Cir. 1983), Congress would have had to clearly state its intent to leave Plaintiffs with no forum for them. *Webster v. Doe*, 486 U.S. 592, 603 (1988); *accord Wright*, 2026 WL 1915590, at *9. It did not. *See Am. Ass'n of Univ. Professors v. Trump*, 815 F. Supp. 3d 907, 958 (N.D. Cal. 2025), *appeal dismissed*, No. 26-263, 2026 WL 1049175 (9th Cir. Feb. 11, 2026) (noting "no evidence," much less a

clear statement). *See also Wright*, 2026 WL 1915590, at *9 (collecting cases from around the country holding that the Tucker Act does not strip district courts of jurisdiction over constitutional challenges to grant terminations).

III. ABSENT A PRELIMINARY INJUNCTION, PLAINTIFFS WILL SUFFER IRREPARABLE HARM

The "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Thakur*, 176 F.4th at 1205 (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). The Ninth Circuit has already applied this rule in the context of viewpoint-based grant terminations. *Id*. The Terminations and Challenged Policies are halting research-related speech every day. *See, e.g.*, Daw ¶ 19; Doe 1 ¶ 19; Doe 2 ¶¶ 25–28. Until the forced renegotiations are enjoined, researchers will continue to reasonably fear they must use the government's preferred script when they speak, write, or present findings. Moseson ¶ 41; Albarracín ¶¶ 14–17, 19, 22-24, 26-27; Edwards ¶¶ 14, 16–18; Bell ¶¶ 17, 19, 32; Green ¶ 20; Doe 3 ¶ 30. That may result in "misattribut[ing]" or "not account[ing] for" important biomedical explanations. Rosso ¶ 37. And, as long as the Challenged Policies are in place, some researchers cannot fairly compete or apply for NIH funding at all. *See, e.g.*, Hatcher ¶¶ 23–29; Moseson ¶ 42; Albarracín ¶¶ 27, 29; Edwards ¶¶ 19–24; Salles ¶ 19; Bell ¶¶ 30–32; Daw ¶ 22; Doe 1 ¶¶ 20–22; Doe 2 ¶¶ 33–34; Doe 4 ¶¶ 12–15, 24, 29; Doe 5 ¶¶ 22–24.

In addition to these impacts on speech (and the related negative effects on public health from failing to accurately describe findings), the Challenged Policies and Terminations are stopping necessary data collection and undermining the relationships on which community research depends. Cohen ¶¶ 24–28 (unless funding is restored in the next few months, "the time gap of our longitudinal data will become too large to continue data collection," and "absence from the community of greater than a year will do tremendous damage to future recruitment efforts for clinical trials"); Salles ¶ 17 (without funding, planned two-year follow-up to assess lasting change cannot happen, sharply limiting the value of work already completed); Rosso ¶¶ 31–35 (cancellation of grant in fifth year "jeopardizes" the ability to analyze already-collected data and undoes "over 10 years" of building community trust); Daw ¶¶ 20–21. As long as the Terminations remain in place, interrupted follow-ups and unfinished analyses also

jeopardize participants' access to information about their health. Rosso ¶ 32 (noting inability to "determine whether participants have dementia" and advise them accordingly); Cohen ¶¶ 24, 26.

NIH's viewpoint-driven terminations and disruptions have also impacted projects, staffing, and career trajectories in ways that, without prompt relief, will never be repaired. *See* Salles ¶ 16 ("[m]y department . . . has given me an extremely short amount of time to find further funding or else lose my job"); Rosso ¶ 38 ("I am now considering whether I will have to pivot my research away from social factors"); Doe 2 ¶¶ 25–29 (describing resulting staffing changes and shortages, running out of bridge funding, and "compounding" "enormous negative consequences for my job security and career development"); Green ¶¶ 19–21 (detailing negative impact of funding disruptions on career trajectory and noting "health insurance coverage gap" and lost income from delays); Doe 3 ¶ 32 (forced redirection "has cost me the specialized expertise I spent my career building"); Jackson ¶ 27 (expecting to have to lay off two employees and possibly having to leave her current research field if funding does not resume soon); Daw ¶ 19 (noting team members had to spend more time on responsibilities outside of research relating to grant to make up for lost funding); Doe 5 ¶¶ 21, 24 (describing loss of staff and repurposing startup funds that will soon run out, after which project cannot continue; consequently "applying for research grants abroad" and "considering moving out of the United States"). *See Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014) ("Plaintiffs' entire careers may be constrained by professional opportunities they are denied today.").

A later judgment cannot restore speech withheld, time-sensitive work abandoned, community trust lost, training forgone, or career opportunities lost. *See id.*; *Doe v. Harris*, 772 F.3d 563, 583 (9th Cir. 2014).

IV. THE EQUITIES AND PUBLIC INTEREST FAVOR AN INJUNCTION

The balance of the equities and public-interest factors—which merge in actions against the government—both strongly favor a preliminary injunction. *Baird*, 81 F.4th at 1040. Initially, "it is always in the public interest to prevent the violation of a party's constitutional rights." *Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 916 F.3d 749, 758 (9th Cir. 2019) (*en banc*) (citation modified); *see Thakur*, 176 F.4th at 1205–06; *E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 677–78 (9th Cir. 2021), *overruled on other grounds by Ariz. All. for Retired Ams. v. Mayes*, 186 F.4th 622 (9th Cir. 2026)

(public has a strong interest in ensuring that federal agencies follow the law). Furthermore, absent an injunction, Defendants' policies will not only continue to harm researchers, *see supra* Section III, but also substantially harm the public, who will lose the benefits of the delayed, distorted, or cancelled research—and who may never recover the knowledge, treatments, and cures that otherwise would have been produced. *See e.g.*, Salles ¶ 17 (termination means public will not learn if intervention has long-term impact on sexual harassment); Rosso ¶¶ 32–33 (data gathered over four-plus years will not be shared with community and planned publications suggesting targets for later-life cognitive protection will not occur); Edwards ¶ 24 (limitations on research will "hinder the development of effective prevention strategies" and "reduce the positive impact of this research on the health of LGBTQ+ youth and/or Indigenous youth"); Albarracín ¶ 29 ("[D]ecades of building trust in science among the communities we serve have been and will continue to be severely disrupted by the NIH dictating which viewpoints are acceptable to study").

On the other side of the scale, the requested injunction would impose no meaningful harm to Defendants. Defendants have no legitimate interest in continuing a likely unlawful practice. *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013). Even with an injunction, NIH would retain its discretion to make lawful funding decisions and adopt lawful scientific and programmatic priorities. Enjoining the Challenged Policies would not disburse funds, and so would create no irreparable fiscal injury. *See Washington v. U.S. Dep't of Educ.*, 161 F.4th 1136, 1141 (9th Cir. 2025). And *Thakur* confirms that any fiscal concerns from reinstating terminated grants do not overcome the constitutional injuries and public interests in favor of addressing the constitutional violations. 176 F.4th at 1205–06.

V. THE COURT SHOULD STAY THE CHALLENGED POLICIES UNDER 5 U.S.C. § 705

The Court should also stay the Challenged Policies under 5 U.S.C. § 705, which authorizes courts to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." "The scope of interim relief under Section 705 is consistent with the scope of final relief under 5 U.S.C. § 706 . . . of the APA, which grants federal courts the authority to 'hold unlawful and set aside agency actions' on a nationwide basis when the challenged action is held unlawful." *Novedades Y Servicios, Inc. v. Fin. Crimes Enf't Network*, 181 F.4th 961, 981 (9th Cir. 2026) (citation modified). Thus, unlike preliminary injunctions, a

§ 705 stay need not be limited to party-specific relief, but "[t]he standard for granting a § 705 stay is essentially the same as the standard for granting a preliminary injunction." *Pablo Sequen v. Albarran*, 810 F. Supp. 3d 1084, 1133 (N.D. Cal. 2025). For the same reasons a preliminary injunction is warranted, the Court should grant a stay of the Challenged Policies.

VI. THE COURT SHOULD WAIVE THE BOND REQUIREMENT

The Court should exercise its discretion to waive a bond under Fed. R. Civ. P. 65(c) because there is no "realistic likelihood of harm to the defendant from enjoining his or her conduct," *City & Cnty. of San Francisco v. U.S. Dep't of Just.*, 822 F. Supp. 3d 1056, 1069 (N.D. Cal. 2026) (quoting *Johnson v. Couturier*, 572 F.3d 1067, 1086 (9th Cir. 2009)), and "requiring a bond would stifle Plaintiffs' enforcement of their rights under the APA and the First Amendment." *Thakur v. Trump*, 800 F. Supp. 3d 1044, 1074 (N.D. Cal. 2025). At most, if the Court is inclined to find some bond is warranted, it should "request mere nominal security" of no more than $100 from Plaintiffs. *See Am. Ass'n of Univ. Professors*, 815 F. Supp. 3d at 977; *Thakur*, 800 F. Supp. 3d at 1074.

CONCLUSION

For all the reasons discussed herein, the Court should grant Plaintiffs' motion for a preliminary injunction and stay the Challenged Policies.

Dated: September 24, 2026

Respectfully submitted,



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Attorneys for Plaintiffs

ATTESTATION

Pursuant to N.D. Cal. Civil Local Rule 5-1(i)(3), I hereby attest that concurrence in the filing of this document has been obtained from each of the other signatories whose signatures are indicated within this e-filed document.

Date: September 24, 2026

Neil K. Sawhney

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES, *et al.*,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, *et al.*,

Defendants.

Case No. 3:26-cv-10510

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR STAY AND PRELIMINARY INJUNCTION

The Court, having considered Plaintiffs' Motion for Stay and Preliminary Injunction, the supporting record, Defendants' response, and Plaintiffs' reply, GRANTS the motion for the reasons stated in the accompanying opinion and ORDERS as follows.

1. This Order applies to and is enforceable by the named Plaintiffs and members of the two provisionally certified classes, namely, (a) the Termination Class, which consists of all principal investigators, multiple-principal investigators, researchers, or project leaders for NIH research grants identified for termination based on the Challenged Policies, whose grants remain terminated; and (b) the Policy Class, which consists of all persons who have an existing NIH grant and/or who applied or will apply for an NIH grant whose grant or application is subject to termination, denial, rephrasing, or renegotiation based on the Challenged Policies; and all persons who would apply for an NIH grant but for the Challenged Policies.

2. For purposes of this Order, the Challenged Policies include requirements described and implemented through the February 21, 2025 Memoli Directive; the March–May 2025 Award Assessments Guidance; the August 15, 2025 and July 2, 2026 Bhattacharya Directives; the November 18, 2025 Compliance Reminder, NOT-OD-26-007; the December 12, 2025 Staff Guidance; and associated unwritten protocols.

3. These Challenged Policies:

a. Terminate, screen, disadvantage, or require alteration of NIH grant applications or funded projects because researchers express, or are perceived or expected to express, disfavored viewpoints concerning diversity, equity, and inclusion; gender identity; climate change; vaccines; misinformation; or the health effects of public policies;

b. Terminate, screen, disadvantage, or require alteration of NIH grant applications or funded projects because of their actual or perceived connection to diversity, equity, and inclusion, including the mention of minorities and diverse study populations; gender identity; climate change; vaccine hesitancy; misinformation; or the health effects of public policies, without any reasoned explanation or, in some instances, any public acknowledgment;

c. Require additional final approval by NIH's Office of Extramural Research and/or HHS under the priority-alignment review process after approval by the relevant Institute or Center Director; and

d. Require termination of existing awards for misalignment with agency priorities adopted after the awards were made.

4. Pursuant to 5 U.S.C. § 705, the operation and implementation of the Challenged Policies are STAYED.

5. Defendants are PRELIMINARILY ENJOINED from applying the Challenged Policies to Plaintiffs or members of either class during the pendency of this litigation. This prohibition includes, but is not limited to: (a) flagging or subjecting applications or awards to additional review pursuant to the Challenged Policies described in paragraph 3(a) of this Order; (b) compelling changes to grant language or resulting speech as a condition of funding pursuant to the Challenged Policies described in paragraph 3(a) of this Order; (c) denying, terminating, suspending, withholding, or delaying funding pursuant to the Challenged Policies described in paragraphs 3(a) and 3(b) of this Order; (d) usurping IC Directors' final decisionmaking authority pursuant to the Challenged Policies described in paragraph

3(c) of this Order; or (e) terminating grants for misalignment with subsequent agency priorities pursuant to the Challenged Policies described in paragraph 3(d) of this Order. Defendants are further PRELIMINARILY ENJOINED from enforcing award conditions resulting from compelled alterations or otherwise penalizing researchers for research-related speech consistent with the original terms of their grants during the pendency of this litigation. Defendants may not take any of the actions described in this paragraph through a renamed, successor, or substitute policy, guidance, or directive.

6. Defendants are PRELIMINARILY ENJOINED from effectuating or maintaining in any way the terminations of NIH grants held by, or supporting, Plaintiffs or members of the Termination Class that were terminated in retaliation for protected speech and/or based on the viewpoint criteria described in paragraph 3(a).This preliminary injunction requires a return to the status quo as it existed just prior to the termination for each award, where the status quo is defined by the amount of time that was remaining on the grant at the moment of the given termination..

7. The parties shall meet and confer to address the situation of any Plaintiffs or members of the Termination Class who need a transfer or No Cost Extension to be returned to the status quo.

8. Within 3 business days of this Order, Defendants shall distribute this Order and implementing instructions to personnel responsible for administering the affected grants and applications.

9. Within 14 days of this Order, Defendants shall file a declaration identifying the actions taken to comply with this Order, the status of all affected awards and applications, any outstanding implementation steps, and the reasons those steps remain incomplete. Defendants shall file supplemental reports every 14 days thereafter until implementation is complete or the Court orders otherwise.

10. This Order binds Defendants and their officers, agents, servants, employees, and attorneys, and other persons in active concert or participation with them, who receive actual notice of this Order, as provided by Federal Rule of Civil Procedure 65(d)(2).

.

11. In the interest of justice and finding good cause shown, the Court waives security under Federal Rule of Civil Procedure 65(c).

12. This Order takes effect immediately and remains in effect until further order of the Court.

IT IS SO ORDERED.

Dated:

_____

Honorable Sallie Kim
United States Magistrate Judge

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF ARGHAVAN SALLES

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Arghavan Salles, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Arghavan Salles. I am a Board-Certified surgeon and a Clinical Associate Professor at the Stanford University Department of Medicine, where I also served as the Special Advisor for Culture and Community Building until July 2026. I have focused my research career on gender equity, implicit bias, diversity, inclusion and physician well-being.

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I earned a B.A. and B.S. from the University of Southern California in 2002, an M.D. from Stanford University School of Medicine in 2006 and a PhD in Social Psychology from Stanford University School of Education in 2014 that was supported by a T32 grant from NIH. I completed my fellowship in minimally invasive surgery at Washington University in St. Louis and served on the faculty there for three years before returning to Stanford in 2019.

5. I have published research papers in top medical journals, including JAMA Internal Medicine, BMJ, JAMA Network Open, JAMA Surgery, and the International Journal of Obesity. I have published opinion pieces in leading journals such as JAMA and The Lancet, and I sit on The Lancet's racial equity board.

6. In 2022 I was awarded an R01 grant, titled Sexual Harassment Training of Principal Investigators (STOP) with a project term of July 1, 2022, through June 30, 2027. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals are lengthy and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money—it indicates a project's scientific importance, methodological rigor, and real-world potential to improve public health.

7. My award focused on sexual harassment in biomedical research—despite high enrollment in biomedical graduate programs, women remain under-represented in the biomedical research workforce. Although anyone can experience sexual harassment, women, especially those with other marginalized aspects of identity, and sexual and gender minorities are disproportionately impacted. NIH T32 training programs are an understudied yet important contributor to the workforce and a key stage for intervention. As such, my project was designed to explore the impact of an intervention on T32 training program Principal Investigators' and mentors' confidence in their ability to intervene when they witness sexual harassment and the impact of the intervention on T32 mentees' experiences with microaggressions and sexual harassment, sense of belonging, well-being, research productivity and persistence in biomedical research careers.

8. To complete the project's research aims, I planned to conduct a randomized, controlled trial of NIH T32 programs to test whether a novel multi-modal virtual intervention incorporating video game elements would address and reduce sexual harassment and allow for a generalizable and easily scalable educational program to improve NIH training environments nationwide which could ultimately increase the diversity of the biomedical research workforce. Attached hereto as **Exhibit 1** is a true and correct copy of this R01 grant's Notice of Award (i.e., NOA).

9. During the first three years of the grant, we 1) developed an evidence-based intervention incorporating novel, custom videos and video games; multimedia content including videos, podcasts, and news articles from external sources; and other interactive exercises; 2) enrolled and randomized T32 training programs into either the treatment condition (where they would receive this intervention) or a control condition (focused on research ethics); and 3) tested the intervention with a cohort of several hundred biomedical research faculty involved in T32 training programs across the country.

10. I emailed the program officer (PO) on February 3, 2025, after a colleague funded through the same mechanism as mine—Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise—had heard from her PO. I asked if there was anything I needed to know that might affect the funding of this grant or the grant application I had submitted in the fall of 2024 (which was withdrawn from study section in spring of 2025 and then reviewed after a settlement in

a prior lawsuit and is not at issue in this case). She did not immediately reply. I followed up again on February 18, and again she did not reply.

11. On April 2, 2025, I received an email from NIGMS stating that, due to a change in NIH/HHS priorities, the program under which my award was funded had been terminated. I was informed that no future years of funding would be available, and NIGMS would not permit ANY no-cost-extensions. Attached hereto as **Exhibit 2** is a true and correct copy of this email.

12. The next day, April 3, my PO emailed to say that my grant would be terminated "no later than the end of the current budget period. However, awards may terminate sooner based on NIH/HHS priorities." This left our project in limbo, unsure whether we would be funded from day to day. I asked the PO how to appeal this decision. She said the appeals process would be outlined when I received an updated Notice of Award.

13. Several months later I received a revised Notice of Award dated June 17, 2025, reflecting my grant's termination. Attached hereto as **Exhibit 3** is a true and correct copy of this revised Notice of Award.

14. Neither the revised Notice of Award nor the termination notice includes any individualized explanation for why the grant was canceled, and both fail to discuss the grant application, progress reports, or other related materials. The project was proceeding well, and the project's annual progress reports had never prompted questioning or reduction in funds from the NIH prior to this termination.

15. Instead, the termination notice contains the following language about its decision:

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

16. The termination of this grant set off a cascade of events that has brought me to a critical juncture in my research career. In the fall of 2024 I had one funded R01, a pending application for a second and ideas for future awards. Today, I have zero NIH grants and dim prospects for obtaining future grants. My department, which had previously enthusiastically supported my work, has given me an extremely short amount of time to find further funding or else lose my job. Unless my grant is reinstated soon, I do not see how my research career can continue.

17. With regard to the STOP project that had been funded by the NIH, I have tried very hard to push that work forward and get our initial data analyzed so we could publish at least preliminary results. Without that, the taxpayer money that supported our work for three years would have been wasted. Unfortunately, due to the grant's termination, I was unable to replace a staff-member who left, and we now have a very small staff which has limited our capacity to continue the work. We had intended to test the intervention we designed on two cohorts, in subsequent years, but since our funding was cut after the first cohort, we had limited capacity to pursue the second cohort. We did so with some modest support from my department. We are doing what we can to try to publish preliminary findings despite being underpowered and understaffed. We will not be able to complete the long-term follow-up that was described in the original proposal, including our planned assessment of the enduring impact of the intervention two years later. Short-term changes in behavior are important and valuable, but the true test of an intervention is whether it results in durable change. Losing the ability to assess the longer-term impact of the intervention limits the utility of the entire project, including the work already completed at taxpayer expense.

18. My position at Stanford is dependent on bringing in additional funding, thus I have continued to submit applications for NIH opportunities. In January of 2026, I submitted an application for an R35 award. R35s are "Investigator-Focused Awards." They provide support to experienced investigators for that investigator's research program or lab rather than a discrete research project. They are only available to investigators with R01s in the previous 12-18 months, which is a relatively small universe of applicants, making me a potentially competitive candidate. Based on my qualifications, a program officer at the NIH encouraged me to apply.

19. Putting together my application was incredibly difficult. Based on public reporting, I understood that if I included words like "woman" or "sexual harassment" in my grant application it would be flagged as non-conforming to NIH priorities. Because these grants are given to investigators, rather than to support specific projects, a critical portion of the application is describing the investigator's previous work in a way that demonstrates "clear intellectual leadership" in the proposed research program. I was unable to accurately describe my work because of the widely known list of banned words. Having studied gender equity for over 15 years, with sexual harassment being a key part of that, I somehow had to describe my work without using "gender," "equity," or "sexual." I therefore had to describe my previous research in vague terms, for example referring to "mistreatment" instead of sexual harassment. I then proposed using our previously established methods of novel multi-modal interventions with video games on civility, bullying, and research misconduct. If not for this sudden and drastic change in the NIH last year, I would have been able to describe my previous work in detail, assessing implicit bias, microaggressions, sexual harassment, and other discriminatory behavior that asymmetrically impacts outcomes for professionals based on their gender and other aspects of identity. I would also have been able to propose interventions more clearly in line with that work rather than having to pivot to civility, bullying, and research misconduct. In short, I would have been able to describe work that would advance the research I have been conducting for over 15 years rather than new areas of research that have tangential relations to my past work. That would, of course, make for a stronger application.

20. I later learned the R35 application was "not discussed" at study section, meaning it was not considered competitive for funding at that time. Although the application could be discussed at a future study section, this is a bad prognostic indicator for the application's chances of success.

21. Importantly, sexual harassment can and does affect people of all genders and remains illegal. When it funded my work, the NIH understood the importance of addressing this critical barrier that impairs our workforce from doing the best possible science as individuals are pushed out of the field after experiencing sexual harassment. We will never know what cures and advances might have been discovered by those pushed out of science because of these experiences. These days, NIH simply does not care.

22. I am at a loss to understand how I will ever again be competitive for an NIH grant if NIH will not consider applications that include the terms that accurately describe my research goals and expertise. Even worse, I will never qualify for an NIH grant if I am forced out of academia due to the sudden politicization of NIH's decision-making.

23. I understand that, as a class representative, I represent the interests of everyone in the class and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Redwood City, California this thirteenth day of September 2026.



Arghavan Salles

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# R01GM147063
Federal Award Date
09-08-2022

Recipient Information

1. Recipient Name
LELAND STANFORD JUNIOR UNIVERSITY, THE
450 JANE STANFORD WAY

STANFORD, 94305

2. Congressional District of Recipient
18

3. Payment System Identifier (ID)
1941156365A1

4. Employer Identification Number (EIN)
941156365

5. Data Universal Numbering System (DUNS)
009214214

6. Recipient's Unique Entity Identifier
HJD6G4D6TJY5

7. Project Director or Principal Investigator
Arghavan Salles, MD

arghavan@alumni.stanford.edu
650-387-5275

8. Authorized Official
Ms. Karen G. Wong

Federal Agency Information

9. Awarding Agency Contact Information
Jennifer M Lynch

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
jennifer.lynch@nih.gov
301-594-3918

10. Program Official Contact Information
Shakira M Nelson

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
shakira.nelson@nih.gov
240-281-1039

Federal Award Information

11. Award Number
1R01GM147063-01

12. Unique Federal Award Identification Number (FAIN)
R01GM147063

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Sexual harassment Training Of Principal investigators (STOP)

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-08-2022 **– End Date** 06-30-2023	
20. Total Amount of Federal Funds Obligated by this Action	$416,252
20 a. Direct Cost Amount	$306,153
20 b. Indirect Cost Amount	$110,099
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$416,252
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$416,252
26. Project Period Start Date 09-08-2022 **– End Date** 06-30-2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$416,252

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Justin Rosenzweig

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30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 1R01GM147063-01

Principal Investigator(s):
Arghavan Salles, MD

Award e-mailed to: NIHAWARDS@lists.stanford.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $416,252 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to STANFORD UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of General Medical Sciences of the National Institutes of Health under Award Number R01GM147063. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Justin Rosenzweig
Grants Management Officer
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	$306,153
Federal F&A Costs	$110,099
Approved Budget	$416,252
Total Amount of Federal Funds Authorized (Federal Share)	$416,252
TOTAL FEDERAL AWARD AMOUNT	$416,252
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$416,252

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$416,252	$416,252
2	$401,679	$401,679
3	$401,907	$401,907
4	$401,788	$401,788
5	$401,874	$401,874

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1941156365A1
Document Number:	RGM147063A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025	2026
OD	8055783	$416,252				
GM	8472185		$401,679	$401,907	$401,788	$401,874

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: T210SN / **OC**: 41021 / **Released**: Rosenzweig, Justin 08-30-2022
Award Processed: 09/08/2022 12:09:12 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01GM147063-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01GM147063-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01GM147063. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 1R01GM147063-01

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

1. None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm

2. As appropriate, the awardee is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of General Medical Sciences.

3. This award is issued in accordance with the NIH fiscal policies described in NIH Guide Notice NOT-OD-22-105.

4. This is a Modular Grant Award without direct cost categorical breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement (December 2021) at: (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_13/13.1_general.htm). Recipients have discretion in determining how to allocate and account for costs related to modular awards within their organizational accounting system. However, institutions are still required to ensure that all costs charged to modular awards are in accordance with applicable costs principles, the NIH GPS, and any legislatively imposed restrictions.

5. The Year -01 budget period is slightly less than 12 months in length (full 12-month level of funds provided) so that the anniversary date for future non-competing awards will be July 1. The Research Performance Progress Report (RPPR) will be due 45 days prior to this date (60 days for non-SNAP awards) each year. Guidance on RPPR submission is documented in the RPPR Instruction Guide found at: http://grants.nih.gov/grants/rppr/index.htm.

This anniversary date may change the receipt date for the next competing continuation (Type 2) application. Consult the submission dates/deadlines on the NIH Office of Extramural Research Grants (OER) Home page at http://grants.nih.gov/grants/dates.htm.

6. This award includes co-funding from the Office of Research on Women's Health (ORWH) ($306,153 direct costs, $110,099 F&A costs).

SECTION V - NIGMS CONTACTS

The NIGMS WWW home page is at http://www.nigms.nih.gov

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01GM147063-01

INSTITUTION: STANFORD UNIVERSITY

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Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	57.4%	57.4%	57.4%	57.4%	57.4%
F&A Cost Base 1	$191,810	$169,019	$166,760	$167,938	$167,091
F&A Costs 1	$110,099	$97,017	$95,720	$96,396	$95,910

Version: 11 - 7/14/2022 8:27 PM | Generated on: 9/8/2022 12:09 AM

Exhibit 2



Arghavan Salles <arghavan@alumni.stanford.edu>

NIGMS Funding Update

Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov> Wed, Apr 2, 2025 at 10:49 AM
To: "arghavan@alumni.stanford.edu" <arghavan@alumni.stanford.edu>

Re: R01GM147063-03

Dear Dr. Salles,

I am writing to let you know that due to changes in NIH/HHS priorities, the **Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

Exhibit 3

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# R01GM147063
Federal Award Date
06/17/2025

Recipient Information

1. Recipient Name
THE LELAND STANFORD JUNIOR UNIVERSITY
450 JANE STANFORD WAY
STANFORD, CA 94305

2. Congressional District of Recipient
16

3. Payment System Identifier (ID)
1941156365A1

4. Employer Identification Number (EIN)
941156365

5. Data Universal Numbering System (DUNS)
009214214

6. Recipient's Unique Entity Identifier
HJD6G4D6TJY5

7. Project Director or Principal Investigator
Arghavan Salles, MD

arghavan@alumni.stanford.edu
650-387-5275

8. Authorized Official
Sharon Collum

Federal Agency Information

9. Awarding Agency Contact Information
Adam S Barnhart

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
adam.barnhart@nih.gov
(301) 451-1942

10. Program Official Contact Information
Shakira M Nelson

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
shakira.nelson@nih.gov
240-281-1039

Federal Award Information

11. Award Number
5R01GM147063-03

SPO 244574

12. Unique Federal Award Identification Number (FAIN)
R01GM147063

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Sexual harassment Training Of Principal investigators (STOP)

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/01/2024 **– End Date** 06/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$401,907
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$401,907
26. Project Period Start Date 09/08/2022 **– End Date** 06/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,219,838

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Justin Rosenzweig

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 5R01GM147063-03 REVISED

Principal Investigator(s):
Arghavan Salles, MD

Award e-mailed to: NIHAWARDS@lists.stanford.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to STANFORD UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of General Medical Sciences of the National Institutes of Health under Award Number R01GM147063. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Justin Rosenzweig
Grants Management Officer
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/17/2025 1:02 PM

Federal Direct Costs	$306,187
Federal F&A Costs	$95,720
Approved Budget	$401,907
Total Amount of Federal Funds Authorized (Federal Share)	$401,907
TOTAL FEDERAL AWARD AMOUNT	$401,907

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$401,907	$401,907

Fiscal Information:
Payment System Identifier: 1941156365A1
Document Number: RGM147063A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8055783	$401,907

NIH Administrative Data:
PCC: T210SN / **OC**: 41025 / **Released**: 06/15/2025
Award Processed: 06/17/2025 01:02:59 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01GM147063-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01GM147063-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01GM147063. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

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Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

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SECTION IV – GM SPECIFIC AWARD CONDITIONS – 5R01GM147063-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

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

Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, STANFORD UNIVERSITY may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to Dr. Jon Lorsch, Director, NIGMS at
nigmsreconsiderations@nigms.nih.gov.

TERMS AND CONDITIONS FROM PREVIOUS AWARD

1. This award is issued in accordance with the NIH fiscal policies described in NIH Guide Notice NOT-OD-24-109.

2. This is a Modular Grant Award without direct cost categorical breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement (April 2024) at: (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_13/13.1_general.htm). Recipients have discretion in determining how to allocate and account for costs related to modular awards within their organizational accounting system. However, institutions are still required to ensure that all costs charged to modular awards are in accordance with applicable costs principles, the NIH GPS, and any legislatively imposed restrictions.

3. This award includes co-funding from the Office of Research on Women's Health (ORWH) ($306,187 direct costs, $95,720 F&A costs).

4. None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL:
http://grants.nih.gov/grants/policy/salcap_summary.htm

5. As appropriate, the awardee is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of General Medical Sciences.

6. Unobligated Balances: As indicated in Section III of this Notice of Award, an unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval; in accord with

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section 8.1.1.1 of the NIH GPS, NIGMS staff reserve the right to make budgetary reductions to award commitments in cases where recipients have accrued excessively large unobligated balances.

NIGMS' OFFICIAL WEBSITE

For more information, please visit: http://www.nigms.nih.gov

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01GM147063-03 REVISED

INSTITUTION: STANFORD UNIVERSITY

Budget	Year 3
TOTAL FEDERAL DC	$306,187
TOTAL FEDERAL F&A	$95,720
TOTAL COST	$401,907

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	57.4%
F&A Cost Base 1	$166,760
F&A Costs 1	$95,720

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF ABIGAIL HATCHER

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Abigail Hatcher, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Abigail Hatcher.

3. I am offering this declaration in my individual capacity and not on behalf of any current or former employer.

4. I am an independent public health researcher and an unpaid adjunct at the University of North Carolina at Chapel Hill Gillings School of Global Public Health.

5. From May 2020 until December 2025, I was a research-track faculty member in the Department of Health Behavior at the University of North Carolina at Chapel Hill. I resigned my position in December 2025.

6. I have worked in violence prevention for 21 years, with a focus on HIV and mental health around the time of pregnancy. I lived in South Africa for 17 years and have conducted research there since 2007. Over the course of my career, I have held investigative roles in approximately ten NIH grants and four European grants.

7. My research examines violence and HIV in pregnancy and the conditions that shape who benefits from health research and who has the opportunity to conduct it. To do this work effectively, I must be able to identify specific populations, pinpoint and address disparities, and design programs and policies to study the social conditions that produce those health outcomes.

8. One example is NIH grant 1R25HD116367, originally titled *Restoring equity to measuring and preventing perinatal intimate partner violence (Remap-IPV),* now titled *Early career researchers mentored around perinatal intimate partner violence (Remap-IPV)*. My institution was awarded the grant for which I was a principal investigator in September 2024 by the National Institute of Child Health and Human Development. That R25 research-education grant focused on training a broad spectrum of early-stage investigators to study violence in pregnancy using rigorous measurement and ethical practices. The project combined in-person and online instruction with mentorship so that trainees could draft a peer-reviewed paper with a scientific writing mentor, which serves as a track record of scientific collaboration to improve their future grant funding.

9. NIH terminated the Remap-IPV grant on March 21, 2025, because it allegedly "no longer effectuates agency priorities," including "amorphous equity objectives," and might qualify as a DEI study. This grant was reinstated on July 4, 2025, as a result of *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787 (D. Mass.). The injuries I describe and relief I am seeking here are separate from that lawsuit.

10. After NIH terminated my grant, I was told by my institution to halt my lines of equitable research. I was also told that if philanthropic grant applications that communicated viewpoints relating to equity were successful, the university would not accept the non-federal award. This prohibition made continued employment as a researcher financially untenable for me. I was a soft-funded scientist, meaning that grant funding was essential to support my salary and my research. I could no longer raise my salary through NIH or non-federal grants, even though obtaining grants was a central condition of my research-track position. I resigned from UNC in December 2025. I am now an independent researcher and retain only an unpaid adjunct appointment at UNC's Gilling School of Global Public Health.

11. When I resigned, and after my grant was reinstated, I relinquished the award so that it could be transferred to a co-investigator at the University of California, San Diego. I continue to work part-time on violence prevention and mental health as an independent contractor.

12. The Remap-IPV grant has undergone repeated high-level political reviews. After reinstatement, I was instructed by my program officer to revise the public-facing sections of the grant, including the title, the health relevance section, and the abstract, or else the grant would be flagged and the transfer to my co-investigator might not go through. They told me to change the original title of the grant to omit the phrase "Restoring equity." We were also told by the program officer to revise specific aims. These proposed line edits removed words and phrases like "underrepresented," "diverse," "health equity," "structural inequity," "sexual gender minority," "pregnant person," and people "marginalized by race, disability, sexuality, and/or poverty." While I had misgivings about recharacterizing my research, in order to ensure the funding continued, I made the requested changes around the public-facing sections (title and abstract) but opted not to alter the specific aims. The transfer to my co-investigator ultimately took place after a months-long delay.

13. Because NIH required us to make these changes, I am fearful that NIH may re-terminate this grant if I speak or write about my work or present my findings in ways that differ from the language that NIH required us to adopt.

14. Apart from this, in an application for a training grant, I, along with a co-investigator, proposed a program that focused on training HIV researchers on scientific writing. The original application, submitted in September 2024 before the "agency priorities" were altered, proposed a two-year scientific-writing fellowship for early-stage HIV researchers, divided evenly between investigators in the United States and Southern Africa. The program would provide mentorship, residential writing retreats, online instruction, professional-development support, and training in manuscripts and NIH grant applications.

15. Our original application focused on investigators from underrepresented minority and low- and middle-income settings and on research concerning gender-based violence and other social determinants of HIV. Our application posited that disparities in scientific funding and mentorship limit whose knowledge is represented in HIV research. For example, if a review panel includes only scientists with a biomedical approach to treating HIV, the review panel may award lower scores for applications that take a social or environmental approach to HIV. Similarly, if a review panel includes only United States investigators working on domestic research, it may award lower scores to applications that expand or translate African clinical advances. Thus, our application proposed to build a pipeline of United States and African scientists to improve the quality, rigor, and breadth of scientific questions examined by the next generation of HIV investigators.

16. After NIH priorities changed, I understood that we would need to change the language and focus of the grant application to have a realistic chance of being awarded funding. As a result, my co-investigator and I substantially recast the application in a revision submitted in September 2025. We removed constructs and terms including "underrepresented minorities," "gender-based violence," "racism," "stigmatized identities," "intersection," "particularly women," "underrepresented," and "minoritized." We also removed the list of countries in the relevant region of Southern Africa.

17. In addition, we asked core faculty on the second grant submission to remove words from their biosketch that might trigger a flag in the NIH review process. For example, in my biosketch I

removed words such as "gender-based violence," "minority," "social and structural," "gendered syndemic," and "determinants of health." To deal with my own university limitations on new proposals I applied as a consultant instead of routing the sub-award through my institution.

18. This second submission fared worse in peer review due to the noted lack of specificity in the grant. For example, one reviewer noted "Some of the mentors' biosketches appear to be not targeted to this application, raising slight concerns about their commitment to this proposal." Naming me as a co-investigator without an institutional home was noted by a reviewer as a weakness in the environment for the training program.

19. These revisions made the application less programmatically distinct from general HIV training. The original premise was that the United States research pipeline trains scholars across race and gender through the postdoctoral stage, but loses many of these investigators during early careers, and that targeted mentorship could help to prevent those losses. Not naming the populations most affected by this research loss obscured both the problem and the reason for the proposed intervention.

20. In my judgment, that lack of precision also made our application less competitive for funding because it obscured our investigative expertise in addressing the intersection of violence and HIV. This is an area that has not yet been adequately addressed by existing medication regimens or clinical programs. Studying this topic and training new researchers to address it offers us a competitive advantage as mentors. By omitting certain terms or constructs in the second revision in order to obscure disfavored viewpoints relating to DEI, we discarded ideas and scientific approaches known to be persistent drivers of HIV-related health.

21. We then resubmitted the grant a third time in May 2026. This final version centered broadly on community-engaged HIV research, communicating with academic and community audiences, and the use of artificial intelligence in scientific writing. It no longer proposed a cohort divided evenly between United States and Southern African investigators. Instead, trainees would be based in the United States.

22. Although the third revised application still refers generally to early-stage investigators, we removed the original application's focus on underrepresented minority and low- and middle-income investigators. In this third revision we omitted additional words from the application including "social

and structural determinants of health," "systemic," and "sexuality." We also removed terms such as "Black," "Brown," and "African." The third revision is under review during the month of September 2026.

23. Several of the words we removed over the course of our multiple revisions were listed in an appendix to a June 26, 2026 article in *Nature*, including "gender," "racism," "minority," and "underrepresented." The article describes the list of 235 terms as tool NIH uses to screen grants for disfavored language that indicates that grants will likely need to be revised for alignment. Attached hereto as **Exhibit 1** is a true and correct copy of this article, and attached hereto as **Exhibit 2** is a true and correct copy of the appendix. This confirmed for me that NIH was censoring grants that used particular language it associated with gender or racial equity and that we were correct to remove such terms to obtain an NIH grant award.

24. Beyond that application, I have chosen not to submit new applications for NIH grants. Preparing a competitive NIH application requires substantial time and effort. I face the sunk costs of writing new grants that may be terminated at any moment, the psychological toll of scrubbing my science of reference to people of color and real inequities, and the moral injury of abandoning ethical principles, including my obligations to participants already enrolled in research that is halted or terminated without notice.

25. Prior to NIH's flagged words lists and censorship policies, I had started developing an R01 application extending findings from my earlier career-development work on reducing violence during pregnancy within primary healthcare clinics. The proposed research planned to test multiple clinical strategies to reduce violence and improve pregnancy outcomes in a clinical trial. It drew upon an efficacious brief intervention to reduce perinatal violence – a social condition that leads to more deaths in pregnancy in the United States than the next three causes of pregnancy-related death (pre-eclampsia, sepsis, and hemorrhage) combined. However, a South African trial is better to test solutions to this particular confluence of health problems due to a relatively higher burden of violence. A South African setting allows for the larger sample sizes required in confirmatory clinical trials. Although this project grows directly out of my longstanding expertise, its South African setting and focus on race, gender, and equity make it especially disfavored under the current policies.

26. I continue mentorship of students through F31, D43, and T32 training grants. Those efforts do not cover my salary and do not replace the grants I would submit to advance my own research program. Converting career-development work into independent R-series funding has become doubly difficult because NIH now disfavors both foreign research and research focused on race or gender.

27. For now, I am concentrating on completing work supported by the grants and subawards that remain, researching the effects of grant terminations, and trying to stay active enough in my field. This activity is important to resume a full research program when I can again describe my scientific portfolio accurately in NIH grant applications. I am also working under a Mellon/Scholars at Risk fellowship to track terminated scientists and their experience of the curbing of academic freedom nationally.

28. NIH is the single-largest funder of public health research in the United States, and R-series NIH grants are career-defining awards for researchers in my field. The monetary value of my Mellon/Scholars at Risk fellowship and the work I do supporting other people's grants is only a fraction of the NIH grant funding I previously received for my research work. My ability to continue my research career is uncertain. Universities prefer to hire candidates with federal research funding to cover a large portion of investigator salary, support salaries of staff, offer training opportunities for students, and provide the university itself with funding in the form of overheads. Without a continued track record of federal research funding, a university job in public health is uncertain. This is personally devastating, as I have devoted over 20 years to public health research and returned to the United States from South Africa for the express purpose of deepening my research career.

29. NIH policies have changed not only the words I use, but the research I am able to propose. They have deterred me from submitting the R01 application described above, narrowed the populations I can target, interrupted the progression of my research career, and deprived the public and students of work directed at ameliorating violence in pregnancy.

30. I do not believe I can prepare a truthful and competitive NIH application while avoiding the terms necessary to explain my expertise, the populations affected, and the scientific basis for my career. Until NIH's current policies change, I will continue to refrain from submitting applications that I otherwise would pursue.

31. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Durham, North Carolina this 18th day of September 2026.

Abigail Hatcher

Exhibit 1

nature

NEWS | 26 June 2026 | Clarification 27 June 2026

Inside the new political screening that's stalling NIH grants

Mandatory reviews by top health officials and checks for 235 disfavoured terms have left hundreds of vetted grant applications in administrative limbo.

By Max Kozlov

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The US National Institutes of Health has seen grant applications held up by extra layers of scrutiny. Credit: Mark Wilson/Newsmakers/Getty

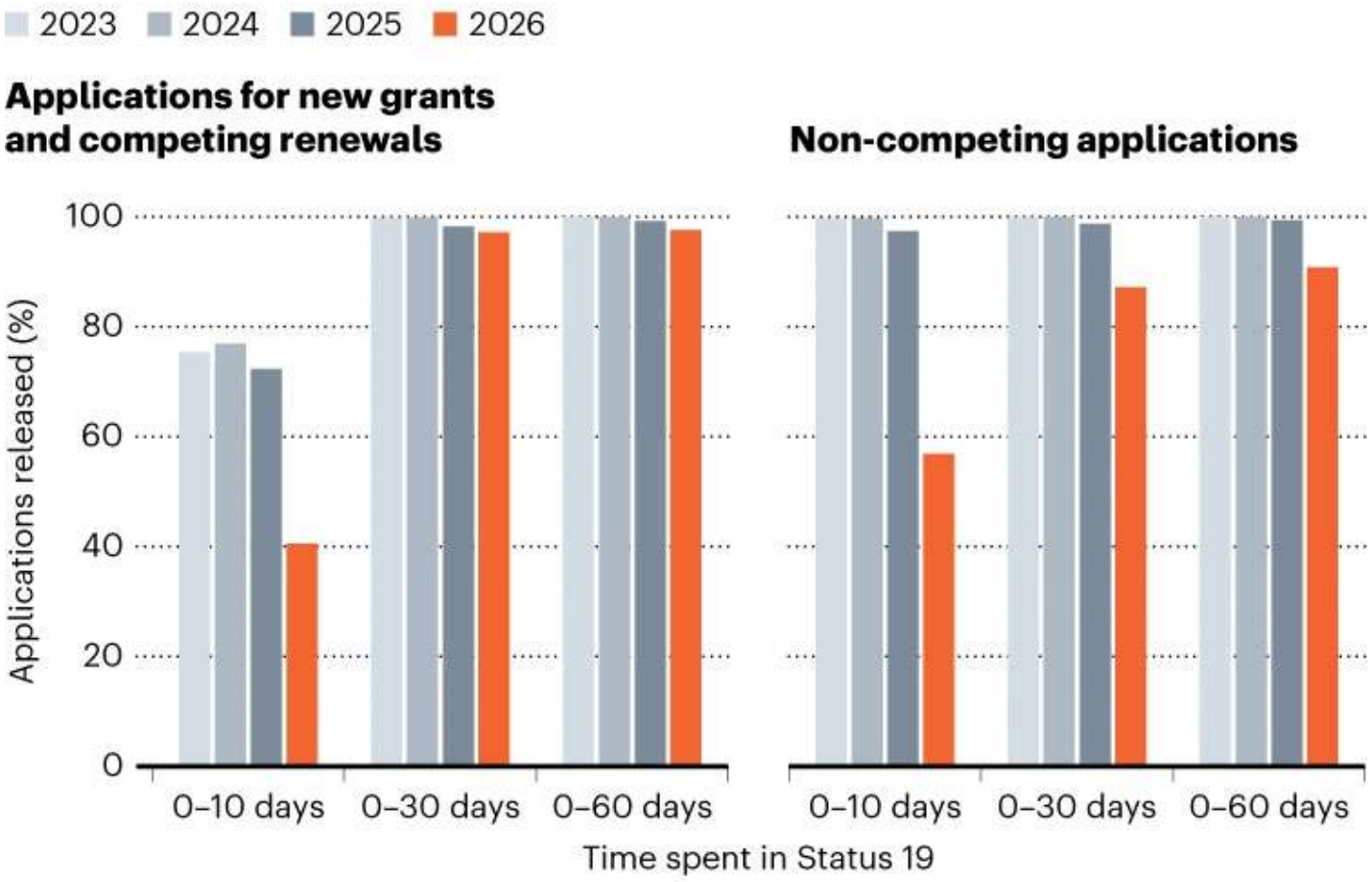
Hundreds of grant applications to the US National Institutes of Health (NIH) are being held up at any given time by unprecedented scrutiny after peer review. Some have been flagged by an algorithm for using terms, such as 'gender' and 'climate change', that have been deemed not to conform with the priorities of the administration of US President Donald Trump.

These new layers of review have delayed delivery of funds to labs and research institutions — and have even resulted in the outright rejection of some applications that had been approved by outside and agency scientists. Before 2025, it was unheard of for grants that had received such approvals to be rejected, says one of six NIH officials who spoke to *Nature* on condition of anonymity. The extra scrutiny ramped up in early 2026 and is conducted by NIH leaders and officials at the NIH's parent agency, the Department of Health and Human Services (HHS).

The extra scrutiny has particularly affected researchers waiting for previously approved projects to be renewed. Most applications clear the supplemental review in two weeks, but 10% of the grant-renewal applications that have entered this phase in the 2026 fiscal year have become stuck for more than seven weeks, and some have been held up indefinitely, according to data and internal e-mails that *Nature* has obtained (see 'Holding pattern').

HOLDING PATTERN

After approval from agency scientists, applications for US National Institutes of Health (NIH) grants move into 'Status 19', the internal designation for an award that has been fully prepared but not yet funded. Over the past year, officials at the NIH and its parent agency have begun additional scrutiny at this stage. Many applications that enter Status 19 are approved after a short delay. But a small fraction — especially applications for 'non-competing renewals' — are still being held back after two months.



Competing renewals undergo peer review alongside applications for new projects. Non-competing applications concern continuations of existing grants that have already been peer reviewed. Data are shown from the start of the fiscal year (1 October the previous calendar year) to early June.

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Source: US National Institutes of Health data obtained by an agency programme officer.

Similar reviews could be coming to other federal agencies. On 29 May, the White House proposed rules that would give political appointees unheard-of control over scientific grant-making.

"We're the test case," says an NIH programme officer. "The new rules would essentially codify the administration's ability to restrict funding on anything because they don't like the topics or the words" used in the applications.

The Trump administration has criticized the federal grant-making process as opaque and unaccountable. Grants have been used "to promote a 'woke' policy agenda that did not reflect the values of the vast majority of the American public", says the 29 May proposal to overhaul grant-making.

In response to *Nature*'s queries about the grant-screening process, an NIH spokesperson said that "there are no 'banned word' lists at NIH, and funding decisions are not based on specific words or phrases." Internal documents suggest that the agency does not ban these words, but projects that use them are much more likely to be scrutinized by programme officers who use the tool and by NIH and HHS officials reviewing the project.

Automated check

Weeks after Trump took office in January 2025, his administration began terminating thousands of grants on disfavoured topics, such as diversity, equity and inclusion, climate change, misinformation, vaccine hesitancy and what it called 'gender ideology'. Billionaire Elon Musk's Department of Government Efficiency (DOGE) directed these terminations, *Nature* previously reported.

As DOGE's influence in government waned, NIH leaders formalized a screening process by creating an algorithm that checks applications for a list of disfavoured terms (see Supplementary information). As of February, the list included 235 terms, which serve as an "indicator that the grant likely needs, at a minimum, a revision to align its terminology with NIH priorities", according to one internal document.

RELATED



NIH grant cuts disproportionately hit minority and female scientists

The tool checks every application's title, abstract and other summary sections for terms including 'racism', 'fossil fuel', 'queer' and 'sexual minorit' (referring to all forms of the phrase 'sexual minority').

This algorithm is applied after applications have passed two rounds of peer review, and after programme officials and the relevant institute director have deemed them worthy of funding and in alignment with institute priorities (see 'How an NIH grant is processed').

If the application contains one of the 235 disfavoured terms, it is classified as "not clean". Programme officers are then instructed to renegotiate the language or scope of the proposed project with the applicant, or to scrap it altogether. Officers must also write a 'decision memo' that describes the actions taken.

Grant limbo

After this step, applications enter a phase called Status 19. Historically, the NIH has used this status to give members of the US Congress advance notice of the projects being funded in their districts.

Now, this designation also gives NIH leaders and the "HHS counselor" an opportunity to review all applications, according to internal documents that *Nature* reviewed.

Feedback from both NIH leaders and HHS officials sometimes questions whether the applications should be funded, according to the documents. "Does [the institute] really want to fund this study? Seems likely to end up in a Congressional waste report," reads one comment, referring to analyses that highlight examples of allegedly improper federal spending.

RELATED



US science after a year of Trump: what has been lost and what remains

In such cases, the application is sent back to the handling NIH programme officer to remedy the issue, often requiring that they renegotiate the scope of the project with the applicant before resubmitting the grant for subsequent rounds of Status 19 review. Sometimes, e-mails reprimand the people who processed the applications: "There were a lot of problematic [National Institute on Aging] grants in the queue this week", says one e-mail from NIH leaders in March. "Many of them had significant problems that should have been caught by your staff."

Applications are often sent back because they include disfavoured topics or have foreign collaborators on projects that do not show a "clear benefit" to the United States. Applications are also bounced back to programme officers for alleged "lobbying activities", a reference to projects that aim to inform policy; or for containing "vague and non-specific language", such as the phrase 'social determinants of health', which is deemed not to include "measurable concepts", according to e-mails that *Nature* obtained.

In rare cases, these extra reviews can prevent applications from being funded. *Nature* learnt of two such applications — they concerned research that was on politically sensitive topics but was not, according to NIH staff, in opposition to the NIH's priorities list, which was published in August 2025. "Just because the topic is something that makes some people uncomfortable doesn't mean we shouldn't research it," says one NIH programme officer, who adds that the studies were deemed scientifically rigorous by multiple panels of scientists before they were shut down.

"It's demoralizing the number of hours we spend working up a grant that they might kill at the last possible moment", the officer says. "It's a tremendous waste of taxpayer dollars."

Heavier workload

Running the text-analysis tool, renegotiating applications and fielding comments from NIH and HHS leaders has tripled the workload of NIH staff members, they say. The extra steps also delay delivery of money to researchers, sometimes by months.

One NIH official analysed non-competing grant-renewal applications (those that have been peer reviewed in the past and are soliciting their next year of funding) that entered Status 19 between the start of the 2026 fiscal year on 1 October 2025 and early June 2026. They found that only 57% were approved within ten days. By comparison, in the same period over the previous three years, more than 95% of non-competing applications were approved within ten days.

Elizabeth Ginexi, who was an NIH programme officer for 22 years before leaving the agency in 2025, says that renewals might be especially scrutinized because they were originally "approved years ago under different criteria" and "are now being re-evaluated against current political requirements".

These delays add to others caused by a staffing shortage, a record-breaking 43-day government shutdown in 2025 and a roughly 40-day delay in the White House's release of the 2026 NIH budget after it was signed into law. As a result, the NIH has allocated about 17% less money so far in 2026 than it did, on average, in the same period in 2021–24.

"NIH leadership is telling staff not to create friction or cause obstruction to get grants out the door, when the reality is, it's the administration creating the barriers," one programme officer says.

How an NIH grant application is processed

It can take more than a year for an application for a US National Institutes of Health (NIH) grant to work its way through the system. Numbers in brackets show roughly how long each step takes

Step 1: Submission and referral. After submission, an application is assigned to a specific NIH institute and a study section (a panel that provides peer review).

Step 2: Study-section peer review (6 months). The panel, made up of independent scientists from all over the United States, reviews the application, scores it and sends feedback to the applicant.

Step 3: Advisory-council review (3 months). Each institute's advisory council, composed of outside scientists, reviews the application to ensure that it broadly aligns with the institute's mission. The council's recommendation is sent to institute staff.

Step 4: Institute staff review and sign-off (4–6 weeks). Staff at the institute's branch and division levels develop a funding plan for the proposal. If the branch and division directors sign off on the application, it is reviewed by the institute director. The applicant is notified that their grant is being considered for funding.

Step 5: Programme and grants-management-specialist review (4–6 weeks). Programme staff members check that the application follows NIH's scientific requirements in areas such as the treatment of human study participants. At the same time, grants-management specialists review the proposed budget details, ensure that prospective grant recipients comply with the NIH's financial policies and prepare the formal notice of award. These steps are delayed if the US Congress and president have not approved an annual spending bill.

As of this year, an application in this phase is also screened for disfavoured terms and concepts. If these are detected, programme officers must draft a "justification memo" to defend the award and work with the applicant to revise the application.

Step 6: "Status 19" administrative hold (typically 1–4 weeks but can be considerably longer). The application is put on hold — a step originally intended to allow time for members of congressional staff to get a preview of grants funded in their districts.

As of this year, every grant at this stage is now reviewed by top NIH officials and then by leading officials at the Department of Health and Human Services, which oversees the NIH. If these officials object to anything in the application, it is sent back to step 5.

Step 7: Award issued. The applicant is notified, and their institution gains access to the funds.

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UPDATES & CORRECTIONS

Clarification 27 June 2026: The role of an NIH employee has been clarified in this version of the article.

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SUPPLEMENTARY INFORMATION

1. Disfavoured words

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Nature (*Nature*) | ISSN 1476-4687 (online) | ISSN 0028-0836 (print)

Exhibit 2

Term	Category
changing climate	Climate Change
climate change	Climate Change
climate crisis	Climate Change
climate justice	Climate Change
environmental justice	Climate Change
fossil fuel	Climate Change
global warming	Climate Change
address diversity	DEI
advance diversity	DEI
advancement diversity	DEI
advances diversity	DEI
advancing diversity	DEI
apartheid	DEI
attendee diversity	DEI
bolster diversity	DEI
broaden diversity	DEI
broadening diversity	DEI
broadens diversity	DEI
campus diversity	DEI
center diversity	DEI
cohort diversity	DEI
commitment diversity	DEI
committed diversity	DEI
criminal justice	DEI
critical race theory	DEI
cultural diversity	DEI
cultural equity	DEI
DEI	DEI
DEIA	DEI
DEIB	DEI
DEIJ	DEI
digital equity	DEI
disadvantaged minorit	DEI
diverse applicant	DEI
diverse audience	DEI
diverse background	DEI
diverse biologist	DEI
diverse candidate	DEI
diverse chemist	DEI
diverse cohort	DEI
diverse collaborator	DEI
diverse communities	DEI
diverse cultur	DEI
diverse faculty	DEI
diverse graduate	DEI
diverse inclusive	DEI
diverse individual	DEI

diverse investigator	DEI
diverse leader	DEI
diverse learner	DEI
diverse people	DEI
diverse personnel	DEI
diverse postdoc	DEI
diverse predoc	DEI
diverse researcher	DEI
diverse respondent	DEI
diverse scholar	DEI
diverse scientist	DEI
diverse stem	DEI
diverse student	DEI
diverse talented	DEI
diverse team	DEI
diverse trainee	DEI
diverse undergraduate	DEI
diverse volunteer	DEI
diverse workforce	DEI
diversification workforce	DEI
diversify workforce	DEI
diversity inclusion	DEI
diversity leader	DEI
diversity program	DEI
diversity recruit	DEI
diversity stem	DEI
diversity supplement	DEI
embrace diversity	DEI
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ethnic equit	DEI
ethnic segregation	DEI

ethnically diverse	DEI
expand diversity	DEI
expanding diversity	DEI
expands diversity	DEI
faculty diversity	DEI
graduate diversity	DEI
graduates diversity	DEI
HBCU	DEI
health equit	DEI
health inequit	DEI
hispanic serving	DEI
historically black	DEI
HSI	DEI
improve diversity	DEI
improved diversity	DEI
improves diversity	DEI
improving diversity	DEI
inclusion diversity	DEI
inclusiv	DEI
increase diversity	DEI
increased diversity	DEI
increases diversity	DEI
increasing diversity	DEI
increasingly diverse	DEI
inequit	DEI
justice	DEI
lack diversity	DEI
latinx	DEI
leadership diversity	DEI
leading diversity	DEI
member diversity	DEI
members diversity	DEI
minorit	DEI
monitor diversity	DEI
need diversity	DEI
office diversity	DEI
openness diversity	DEI
oppression	DEI
PEDP	DEI
postdoc diversity	DEI
postdoctoral diversity	DEI
program diversity	DEI
progress diversity	DEI
promote diversity	DEI
promotes diversity	DEI
promoting diversity	DEI
promotion diversity	DEI
racial discrimination	DEI

racial diversity	DEI
racial equit	DEI
racial segregation	DEI
racially diverse	DEI
racism	DEI
racist	DEI
recruitment diversity	DEI
recruitment plan	DEI
residential segregation	DEI
RPED	DEI
scientists diversity	DEI
staff diversity	DEI
stem diversity	DEI
structural racism	DEI
student diversity	DEI
students diversity	DEI
support diversity	DEI
supported diversity	DEI
supporting diversity	DEI
supportive diversity	DEI
supports diversity	DEI
systemic racism	DEI
talent diversity	DEI
train diverse	DEI
training diverse	DEI
underrepresent	DEI
underrepresented group	DEI
underrepresented minorit	DEI
underrepresented population	DEI
underrepresented student	DEI
URM	DEI
user diversity	DEI
values diversity	DEI
workforce diversification	DEI
workforce diversity	DEI
assigned birth	Gender
assigned female birth	Gender
assigned male birth	Gender
birthing people	Gender
birthing person	Gender
gender	Gender
gender affirm	Gender
gender confirm	Gender
gender confusion	Gender
gender difference	Gender
gender disparity	Gender
gender dysphoria	Gender
gender equit	Gender

gender expression	Gender
gender fluid	Gender
gender identity	Gender
gender minorit	Gender
gender nonbinary	Gender
gender sex	Gender
genderqueer	Gender
lactating individual	Gender
lactating people	Gender
lactating person	Gender
LGB	Gender
LGBT	Gender
neovagina	Gender
phalloplasty	Gender
pregnant individual	Gender
pregnant people	Gender
pregnant person	Gender
puberty blocker	Gender
queer	Gender
sex assigned	Gender
sex gender	Gender
sexual gender	Gender
sexual gender minorit	Gender
sexual minorit	Gender
SGM	Gender
transfeminine	Gender
transgender	Gender
transmasculine	Gender
transphob	Gender
transsexual	Gender
vaginoplasty	Gender
disinform	Misinformation
malinform	Misinformation
misinform	Misinformation
accept vaccin	Vaccine Heistancy
acceptance vaccin	Vaccine Heistancy
refusal vaccin	Vaccine Heistancy
refuse vaccin	Vaccine Heistancy
vaccination acceptance	Vaccine Heistancy
vaccination hesitan	Vaccine Heistancy
vaccination refusal	Vaccine Heistancy
vaccine acceptance	Vaccine Heistancy
vaccine hesitan	Vaccine Heistancy
vaccine refusal	Vaccine Heistancy

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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF ANDREA ROSSO

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Andrea Rosso, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Andrea L. Rosso.

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I am a tenured Associate Professor in the Department of Epidemiology at the University of Pittsburgh, where I also lead the Brain, Environment, Aging, and Mobility (BEAM) lab. My research aims to improve the physical and cognitive function of older adults, reduce disability, and help individuals stay independent in their communities.

5. I earned my MPH (2007) and PhD (2012) in Epidemiology from Drexel University. I completed postdoctoral work from 2012-2014 in Epidemiology of Aging/Neuroepidemiology at the University of Pittsburgh.

6. I have published widely in my field, including over 100 peer-review articles in publications such as *Neurology*; *Alzheimer's & Dementia; American Journal of Epidemiology*; *NeuroImage/NeuroImage: Clinical*; *Journal of Gerontology: Medical Sciences*; and *Journal of the American Geriatrics Society*.

7. I have been recognized with several honors in my field at the national level. I was named a fellow of the Gerontological Society of America in 2024, was inducted as a member of the Delta Omega Honors Society in Public Health in 2022, and was awarded multiple Loan Repayment Program awards from the National Institutes of Health. I have also received awards for research and mentoring from the University of Pittsburgh and for excellence in peer reviewing from the *Journal of Gerontology: Medical Sciences.*

8. I have served as the Principal Investigator, Multiple Principal Investigator, or Program Project Director on multiple grants from the National Institutes of Health, specifically the National Institute on Aging (NIA), including:

- R01 AG057671: *Restoring Central Motor Control to Improve Community Mobility of Older Adults*;

- K01 AG053431: *Environmental Challenges and the Aging Brain: Implications for Community Mobility*;
- R21 AG054666: *Cognitive Decline, Brain Aging, Physical Environment, and Mobility*; and
- KL2 TR000146: *Neural Mechanisms of Community Mobility in Older Adults*.

9. I have been conducting research on neighborhood conditions and aging since my PhD training. Through this work, it became apparent to me that due to the legacies of racist practices such as redlining, White flight, and blockbusting that studies of neighborhood quality in relation to health outcomes in the US are inextricably linked with racial inequities in health. I have been committed to ensuring that my research includes those from under-represented backgrounds, such as those living in lower-income, African American neighborhoods, as this is critical for meeting the principle of justice as outlined in the Belmont report on ethical research involving human subjects and in the validity of research findings as applied to these communities. Without representative samples, we risk producing scientific findings with limited usefulness in the real world. I was approached by a team of other researchers in 2017 to expand an ongoing NIH-funded study in two African American neighborhoods in Pittsburgh to assess cognitive aging and dementia outcomes. I saw this as an important opportunity to expand the scope of cognitive aging research where this population has been underrepresented.

10. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals are lengthy and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money—it indicates a project's scientific importance, methodological rigor, and real-world potential to improve public health. In addition, grant cycles are 5 years long and don't always align with a single administration. It is impossible to predict future agency priorities at the time of grant submission or even earlier at the time of idea conception and development.

11. In 2022, my institution was awarded a five-year R01 NIA grant for which I am a multiple principal investigator, along with two other researchers. The grant is titled *Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods* (5R01AG072652), which had a project term of Feb. 15, 2022 through January 31, 2027, and built upon our research team's previous NIH-funded studies.

12. African Americans (AAs) have significantly higher rates and earlier onset of Alzheimer's Disease and related dementias (ADRD) relative to White Americans; however, we lack a thorough understanding of how the individual lived experience of being AA, including exposures stemming from structural racism, contributes to elevated ADRD risk. This project focused on two predominantly AA neighborhoods in Pittsburgh and included cognitive assessments, additional assessments of blood pressure and sleep, assessments of life and residential history, and qualitative interviews to reveal opportunities and barriers experienced by AAs in achieving optimal cognitive health in late life. This project built upon the team's existing, community-based research infrastructure to examine the impact of changing neighborhood conditions and the role of risk and protective factors, including biomedical factors such as hypertension, poor sleep and depressive symptoms, in the lived experience of AAs and their influence on cognitive function and ADRD risk.

13. Attached hereto as **Exhibit 1 is a true and correct copy of this** R01 grant's initial Notice of Award (i.e., NOA).

14. Based on findings from our early data, we published nearly a dozen articles about our research in journals including *Journal of Racial and Ethnic Health Disparities*, *Journal of Community Psychology*, *Sleep Health*, *Sleep Medicine*, *Housing Policy Debate*, *The Journals of Gerontology: Medical Sciences*, *Alzheimer's & Dementia*, *Journal of Urban Health*, *BMC Public Health*, and *Journal of Alzheimer's Disease*.

15. I have also presented our findings in oral presentations at national and international conferences including the Gerontological Society of America, the Alzheimer's Association International Conference, and an invited plenary session at the Interdisciplinary Association for Population Health Science.

16. In 2025, I became aware of a number of grants terminated by NIH on the basis that they were not aligned with the agency's new priorities insofar as they promoted DEI, gender identity, and other concepts disfavored by the administration. Based on the types of grants that were terminated, I became concerned that NIH might determine that our project—which studied Alzheimer's disease risk in a predominantly African American neighborhood—would be deemed by NIH to promote DEI.

17. As we approached the fifth year of grant funding and had to submit an annual report on the progress of the grant, in order to ensure that funding for our work was not disrupted, we reached out to our NIH program officer to submit revised language as to the aims of the grant to preemptively try to more clearly align with NIH priorities. While we kept language about the elevated risk of Alzheimer's Disease and related dementias for African Americans, we changed the framing from talking about structural racism to talking about socioeconomic disadvantage. We included this revised language in our annual report that was submitted to NIH.

18. We never received a response to the modified aims we proposed.

19. When the funds from NIH for the fifth year of our grant which we were supposed to receive by February 1, 2026 were delayed, we became concerned that our grant was being held up because of the agency's process of re-evaluating grants for alignment with new priorities. When we reached out to our NIH program officer in February and April of 2026, they confirmed that our grant was still under review by the grants management office. We also learned from a conversation with the grants management specialist that the PO and grants management office had already signed off on our grant but that it was nonetheless being held.

20. Then, on May 27, through our institution, we submitted revised language for our title, abstract, and narrative—the public-facing parts of our grant—that we believed would align with NIH's new priorities and survive its censorship screening. Specifically, we removed references to African Americans, discrimination, lived experiences, disinvested communities, neighborhood segregation, racial disparities, and structural racism, replacing these with language about low-socioeconomic status and economic disadvantage. So, for example, we proposed changing our title from *Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk* <u>*in Disinvested, African American Neighborhoods*</u> to *Longitudinal Examination of Neighborhoods,*

Cognitive Aging, and Alzheimer's Disease Risk. And we changed language in the abstract similarly, from "Although prior research has made significant contributions to our understanding of racial disparities in ADRD, we still lack a comprehensive understanding of how the individual lived experience of being AA, including cumulative exposure to structural racism, contributes to elevated ADRD risk and the potential mechanisms underlying those risks" to "Although prior research has made significant contributions to our understanding of socioeconomic differences in ADRD, we still lack a comprehensive understanding of how individual risk factors contribute to elevated ADRD risk and the potential mechanisms underlying those risks." Although we had misgivings about these changes and how they distorted the characterization of what we were actually studying, we proceeded with them in order to ensure our grant funding continued.

21. However, NIH staff never responded substantively to our requests to renegotiate the language of the grant.

22. Instead, we received a response the following day that the award was under administrative review at NIH, that there was no update or timeline for completion, and that there was no further action required from us.

23. The following month, on June 20, 2026, we received a new NOA which included language that had not been in our prior NOAs indicating that the award "may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities." Attached hereto as **Exhibit 2 is a true and correct copy of this** updated NOA.

24. This was alarming as we had the suspicion that NIH would conclude our award was not currently in alignment with agency priorities because of its focus on individuals in disinvested African American neighborhoods and use of terms such as "structural racism" throughout the grant and in the public facing language. We were aware of other grants being terminated in 2025 with similar focus and others being asked to renegotiate language. Indeed, that was why we had made several efforts to update the grant language, without success.

25. Then, on August 4, 2026, we received a letter from the NIH stating that the grant had been terminated "because the project no longer effectuates NIH's priorities, as reflected in the August

15, 2025, Director's Priorities Statement." Attached hereto as **Exhibit 3 is a true and correct copy of this** termination letter.

26. Specifically, the letter highlighted the grant's definition of "structural racism" as "residential segregation, inequitable distribution of resources, and community disruption," as "unclear." Our neighborhood measures which we characterize as a product of historical structural racism are drawn from administrative and historical records—Census tract data, residential composition over time, housing values, and related public records dating to 1940—which are objective, third-party, and independently verifiable.

27. Further, the letter faulted the grant's use of surveys and interviews to measure individual-level discrimination as "subjective." We use standardized, psychometrically validated survey instruments which are an established scientific method for rendering subjective experience into a reliable, quantifiable variable, and are not "amorphous," but rather a critical person-oriented perspective. These subjective experiences are impactful for health outcomes such as cognitive aging specifically because they reflect both the occurrence of an event and the interpretation of that event by the individual. This is standard practice in the field with subjective reporting of individual experiences commonly being used in NIH-funded research on a variety of topics, including, just to name a few, pain, sleep quality, social isolation, perceived cognitive function, and well-being.

28. In addition, the letter concluded that the "neighborhood stressors" assessed in the grant, including "Neighborhood Reinvestment and Revitalization (e.g., housing tax credits), Lifecourse Neighborhood Level Exposures (e.g., unemployment rate, median housing value, neighborhood racial composition), Individual-Level Risk and Protective Factors (e.g., limited education opportunities, perceived safety, neighborhood satisfaction)" "all fall outside of biomedical research's sphere of influence" and thus "will not lead to actionable healthcare interventions." However, this award examines the specific, modifiable, and treatable biobehavioral mechanisms (i.e., sleep and cardiometabolic risk) through which neighborhood conditions are hypothesized to affect cognitive aging and dementia risk.

29. The letter states that the award cannot be renegotiated to bring it into alignment with NIH's priorities.

30. Two days later, on August 6, 2026, we received a new NOA moving up the end date from the grant to August 7, 2026 and quoting extensively from the August 4 letter as the basis for the termination. Attached hereto as **Exhibit 4** is a true and correct copy of this termination NOA.

31. Under the design of the study, the project team conducts two visits with cohort participants: one with a data collector surveying a number of factors (including experiences of discrimination using a validated measure, adverse childhood experiences, depressive symptoms, PTSD, residential and educational history, height, weight, blood pressure, and objectively measured sleep quality) and a second one with a cognitive assessment team testing for cognitive function, medical history, and independence in activities of daily living. Between 2022 and when the grant was terminated in August 2026, we had completed most of these visits. However, we had not yet had our clinical team make a determination of whether each participant has dementia or not. We also have not completed processing our most recent data and disseminating findings in scientific publications and directly to the community.

32. Because we had already collected much of the data for the study, NIH's termination in our fifth year jeopardizes the ability of our clinical team to review the data and determine whether participants have dementia. Consequently, we may be unable to inform particular participants 1:1 whom the data would indicate have dementia that they should follow up with their own physicians. We also may not be able to provide community updates to participants to educate them about our findings. For example, we had planned a community advisory board meeting at the end of September that we will no longer be able to hold.

33. Beyond that, the termination threatens our ability to publish papers about our findings, which seems perverse when NIH had already invested over $8 million in the grant, just to cut off the funding at the stage when we are nearly ready to disseminate our findings. We had planned to publish papers about how mental health consequences of childhood adverse events impacts cognitive function and providing evidence for potential targets for adults who have experienced adverse childhood events to protect later life cognitive function. Another example is understanding how using simple cutoffs on cognitive test scores compares to doing a comprehensive clinical assessment of likely dementia in this sample. We suspect that due to systematic biases in standard cognitive tests that they will overdiagnose

cognitive impairment without considering the full clinical picture, which has important implications for clinical diagnosis.

34. Even if we are able to publish our findings, I am fearful of negative impacts on my ability to secure NIH funding in the future. If I speak or write about my work or present my findings using a title that refers to any of the concepts to which NIH objected, such as discrimination or neighborhood stressors and their impact on health, and list that title on my biosketch for future NIH grant applications, that could well doom the prospects for those applications' success. But omitting such a title would obscure my scholarship, making my application less competitive.

35. Further, members of our team spent over 10 years building trust with our community participant cohort and partnering community organizations to conduct the assessments, which cover sensitive topics, including childhood abuse, PTSD, and experiences of discrimination. The sudden termination of the grant and our inability to follow up with participants is devastating to those in the participant cohort, both for their trust in research generally and in us as researchers in particular.

36. The termination of this grant has impacted the way I approach my work, including both the language I use to describe my research and the substance of my research itself. Because of NIH flagging terms like "African Americans" and "racism" as misaligned with its priorities, I have reframed the language of at least two other grant applications that might similarly communicate the disfavored viewpoint that racial inequality can bear on health outcomes. Both proposed projects would use the same cohort of predominantly African American neighborhoods in Pittsburgh as the terminated grant—I am unsure whether this focus in itself will be disqualifying. One will examine how neighborhood conditions impact mobility trajectories; I omitted reference to how racism might have factored into those neighborhood conditions. The other determines the contributors for becoming homebound across socioeconomic and rural/urban settings; I framed this proposal so that it focuses on socioeconomic divides rather than racial disparities. While I have preemptively tried to structure these proposals to avoid "problematic" language in accordance with NIH's censorship policies, I am concerned that the proposals are not as strong and will not score as highly with peer reviewers as they would have otherwise.

37. If this grant were restored, it would allow me to move forward with completing the research that we had planned and with framing the research in the context of the current scientific understanding, regardless of specific language usage. By focusing language solely on economic disadvantage and not acknowledging the role of structural racism, we lose the context of why the exposures and outcomes we are studying are more common in this population. As a consequence, we may misattribute the reasons for risk or not account for important exposures such as discrimination.

38. NIH funding has and continues to be the primary way that I have funded my research program. I am now considering whether I will have to pivot my research away from social factors to focus exclusively on physiological factors, even though I know that social factors, including access to medical and economic resources, can be incredibly important in determining people's risk for disease outcome. Biomedical and behavioral interventions cannot be successful without considering the social conditions in which those interventions occur. Further, interventions targeted at neighborhoods and social conditions are possible and can have broad impact across populations, making them incredibly powerful approaches to improve health. It is incorrect to say that neighborhood factors are outside of biomedical research's sphere of influence and cannot lead to actionable healthcare interventions.

39. My research has largely focused on identifying how neighborhood characteristics and social factors affect the health of older adults in order to understand how public health and policy interventions could improve aging outcomes for all. Without the funding from this grant specifically or from NIH funding for this area of research in the future, I will lose this direction of research that I have been building for two decades. This will damage my career advancement if I need to pause and pivot my research in a new direction. It may also negatively impact the prospects for my currently pending NIH grant proposals that communicate a similar disfavored viewpoint.

40. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Pittsburgh, Pennsylvania this 18th day of September 2026.

Andrea Rosso

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG072652
Federal Award Date
02/07/2022

Recipient Information

1. Recipient Name
RAND CORPORATION, THE
1776 MAIN ST

SANTA MONICA, CA 90401

2. Congressional District of Recipient
33

3. Payment System Identifier (ID)
1951958142A1

4. Employer Identification Number (EIN)
951958142

5. Data Universal Numbering System (DUNS)
006914071

6. Recipient's Unique Entity Identifier
YY46Q97AEZA8

7. Project Director or Principal Investigator
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8. Authorized Official
Tonya Bordonaro

Federal Agency Information

9. Awarding Agency Contact Information
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301-496-1472

10. Program Official Contact Information
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301-496-3131

Federal Award Information

11. Award Number
1R01AG072652-01A1

12. Unique Federal Award Identification Number (FAIN)
R01AG072652

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 02/15/2022 **– End Date** 01/31/2023	
20. Total Amount of Federal Funds Obligated by this Action	$2,267,650
20 a. Direct Cost Amount	$1,939,885
20 b. Indirect Cost Amount	$327,765
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$2,267,650
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$2,267,650
26. Project Period Start Date 02/15/2022 **– End Date** 01/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,267,650

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Ryan Blakeney

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG072652-01A1

Principal Investigator(s):
Tamara Dubowitz (contact), SCD
Andrea L Rosso, PHD
Wendy M Troxel, PHD

Award e-mailed to: nihnga@rand.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $2,267,650 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RAND CORPORATION in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072652. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Ryan Blakeney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$229,881
Fringe Benefits	$87,568
Personnel Costs (Subtotal)	$317,449
Travel	$2,011
Other	$558,388
Subawards/Consortium/Contractual Costs	$1,035,476
ADP/Computer Services	$26,561
Federal Direct Costs	$1,939,885
Federal F&A Costs	$327,765
Approved Budget	$2,267,650
Total Amount of Federal Funds Authorized (Federal Share)	$2,267,650
TOTAL FEDERAL AWARD AMOUNT	$2,267,650
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$2,267,650

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$2,267,650	$2,267,650
2	$2,000,788	$2,000,788
3	$1,960,993	$1,960,993
4	$2,038,068	$2,038,068
5	$1,328,661	$1,328,661

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1951958142A1
Document Number:	RAG072652A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025	2026
AG	8033157	$2,267,650	$2,000,788	$1,960,993	$2,038,068	$1,328,661

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2CEPIFB / **OC**: 41021 / **Released**: Blakeney, Ryan 01/27/2022
Award Processed: 02/07/2022 12:03:05 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG072652-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AG072652-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as

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those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG072652. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

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Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

This award includes funds awarded for consortium activity with **University of Pittsburgh--Department of Epidemiology** in the amount of $154,888 ($90,095 direct costs + $64,793 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2017 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

This award includes funds awarded for consortium activity with **University of Pittsburgh--Department of Psychiatry** in the amount of $880,588 ($471,586 direct costs + $409,002 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2017 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG072652-01A1

INSTITUTION: RAND CORPORATION

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$229,881	$208,553	$217,959	$208,553	$217,683
Fringe Benefits	$87,568	$77,331	$81,845	$77,331	$81,714
Personnel Costs (Subtotal)	$317,449	$285,884	$299,804	$285,884	$299,397
Travel	$2,011	$2,055	$2,101	$2,148	$4,392
Other	$558,388	$526,812	$379,872	$485,744	$98,495
Subawards/Consortium/Contractual Costs	$1,035,476	$868,040	$944,266	$944,320	$591,077
ADP/Computer Services	$26,561	$24,823	$26,602	$25,940	$27,371
TOTAL FEDERAL DC	$1,939,885	$1,707,614	$1,652,645	$1,744,036	$1,020,732

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TOTAL FEDERAL COST	$317,765	$285,174	$368,348	$294,032	$307,929
TOTAL COST	$2,267,650	$2,000,788	$1,960,993	$2,038,068	$1,328,661

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	69.25%	69.25%	69.25%	69.25%	69.25%
F&A Cost Base 1	$317,449	$285,884	$299,804	$285,884	$299,397
F&A Costs 1	$219,833	$197,975	$207,614	$197,975	$207,332
F&A Cost Rate 2	33%	32%	32%	32%	32%
F&A Cost Base 2	$317,449	$285,884	$299,804	$285,884	$299,397
F&A Costs 2	$104,758	$91,483	$95,937	$91,483	$95,807
F&A Cost Rate 3	1%	1.3%	1.6%	1.6%	1.6%
F&A Cost Base 3	$317,449	$285,884	$299,804	$285,884	$299,397
F&A Costs 3	$3,174	$3,716	$4,797	$4,574	$4,790

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Exhibit 2

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG072652
Federal Award Date
06/20/2026

Recipient Information

1. Recipient Name
UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION
4200 FIFTH AVENUE
PITTSBURGH, PA 15260

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1250965591A6

4. Employer Identification Number (EIN)
250965591

5. Data Universal Numbering System (DUNS)
004514360

6. Recipient's Unique Entity Identifier
MKAGLD59JRL1

7. Project Director or Principal Investigator
Tamara Dubowitz, SCD (Contact)
Senior Policy Researcher
dubowitz@rand.org
310-393-0411

8. Authorized Official
Jennifer E. Woodward
osp@pitt.edu

Federal Agency Information

9. Awarding Agency Contact Information
Maurice Koo
Extramural Support Assistant
NATIONAL INSTITUTE ON AGING
koom@mail.nih.gov
3014351135

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
5R01AG072652-05

12. Unique Federal Award Identification Number (FAIN)
R01AG072652

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/01/2026 **– End Date** 01/31/2027	
20. Total Amount of Federal Funds Obligated by this Action	$1,540,838
20 a. Direct Cost Amount	$1,174,227
20 b. Indirect Cost Amount	$366,611
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,540,838
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,540,838
26. Project Period Start Date 02/15/2022 **– End Date** 01/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,770,641

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jeni Smits

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG072652-05

Principal Investigator(s):
Tamara Dubowitz (contact), SCD
Andrea L Rosso, PHD
Wendy M Troxel, PHD

Award e-mailed to: ornih@offres.pitt.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,540,838 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PITTSBURGH AT PITTSBURGH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072652. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jeni Smits
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$479,662
Fringe Benefits	$138,003
Personnel Costs (Subtotal)	$617,665
Travel	$6,860
Other	$29,377
Subawards/Consortium/Contractual Costs	$520,325
Federal Direct Costs	$1,174,227
Federal F&A Costs	$366,611
Approved Budget	$1,540,838
Total Amount of Federal Funds Authorized (Federal Share)	$1,540,838
TOTAL FEDERAL AWARD AMOUNT	$1,540,838
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,540,838

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$1,540,838	$1,540,838

Fiscal Information:
Payment System Identifier: 1250965591A6
Document Number: RAG072652B
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026
AG	8033157	$1,540,838

NIH Administrative Data:
PCC: 2CEPIFB / **OC**: 41025 / **Released**: 06/17/2026
Award Processed: 06/20/2026 12:01:12 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AG072652-05

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AG072652-05

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report

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the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG072652. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not

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apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5R01AG072652-05

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

This award includes funds awarded for consortium activity with ***RAND Corporation.*** Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2015 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

This award includes funds awarded for consortium activity with ***University of California, San Francisco***. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2015 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

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SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AG072652-05

INSTITUTION: UNIVERSITY OF PITTSBURGH AT PITTSBURGH

Budget	Year 5
Salaries and Wages	$479,662
Fringe Benefits	$138,003
Personnel Costs (Subtotal)	$617,665
Travel	$6,860
Other	$29,377
Subawards/Consortium/Contractual Costs	$520,325
TOTAL FEDERAL DC	$1,174,227
TOTAL FEDERAL F&A	$366,611
TOTAL COST	$1,540,838

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	59%
F&A Cost Base 1	$621,375
F&A Costs 1	$366,611

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Exhibit 3

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

August 4, 2026

Jennifer Woodward, Ph.D.
Vice Chancellor for Sponsored Programs and Research Operations
University of Pittsburgh
osp@pitt.edu

Dear Dr. Woodward:

This letter notifies the University of Pittsburgh that 5R01AG072652-05, "Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods," will be terminated in full through a Notice of Award to be issued shortly because the project no longer effectuates NIH's priorities, as reflected in the August 15, 2025, Director's Priorities Statement. The award is terminated in accordance with the terms of award and 2 CFR 200.340(a)(4), which state that a federal award may be terminated "by the Federal agency…pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities." This is not a termination for failure to comply with the terms and conditions of the federal award.

On August 15, 2025, I published a statement, "Advancing NIH's Mission Through a Unified Strategy"[1] expressing NIH's current research priorities ("Priorities Statement") in furtherance of my responsibility to provide the overall direction of NIH, to establish and implement general policies respecting the management and operation of NIH programs and activities, and to coordinate and oversee the operation of NIH's institutes, centers, and offices. (See 42 U.S.C. § 282(b)(1) & (2)). These priorities include directing agency resources toward research that is focused on clearly defined, scientifically valid, and measurable health outcomes while advancing research that goes beyond measuring health disparities to prioritizing solution-oriented approaches. As a result, NIH is adjusting its extramural research portfolio, which includes terminating grant awards, to prioritize agency resources towards the above-mentioned priorities.

On June 20, 2026, NIH issued the Notice of Award for 5R01AG072652-05, which contains the following term and condition:

> This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds,

[1] https://www.nih.gov/about-nih/nih-director/statements/advancing-nihs-mission-through-unified-strategy.

> recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

The Goals and Specific Aims of this project are:

> **Aim 1:** Examine the impact of dynamic neighborhood socioeconomic conditions reflecting structural racism across the lifecourse on cognitive outcomes of residents living in two predominantly AA, disadvantaged residential communities through a sequential mixed methods design. Hypothesis 1a: Exploratory in-depth interviews (n=60) will reveal lifecourse opportunities and barriers experienced by AAs in achieving optimal cognitive health in late life. Findings will inform quantitative analyses. Hypothesis 1b: Lifecourse exposure to neighborhood-level socioeconomic conditions (e.g., 1940-present change in racial composition) will be associated with poorer cognitive outcomes in quantitative analyses. **Aim 2:** Examine the impact of cumulative exposure to race-relevant risk and protective factors, respectively, measured at the individual level (e.g., discrimination, social cohesion), and their interaction with neighborhood-level conditions, on cognitive function, cognitive decline, and ADRD diagnosis in middle- and late-life AAs. Hypothesis 2a: Cumulative exposure to race-relevant stressors at the individual-level (e.g., discrimination; adverse childhood events) will be related to poorer cognitive outcomes whereas exposure to protective factors (e.g., social cohesion) will be associated with better cognitive outcomes. Hypothesis 2b: Neighborhood-level differences over time (e.g., racial composition; median housing value) will moderate the impact of individual-level exposures on cognitive outcomes. **Aim 3:** Determine how disruptions in biobehavioral mechanisms including objectively measured sleep and cardiometabolic risk (i.e., blood pressure, diabetes) are related to cognitive outcomes in middle- and late-life AAs through a sequential mixed methods design. Hypothesis 3: Sleep disturbances and cardiometabolic risk factors will be associated with poorer cognitive outcomes and ADRD and will mediate observed associations between individual and neighborhood-level exposures with cognitive outcomes.

The grant R01AG072652 “Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods,” is not in alignment with the August 15, 2025, NIH Priorities Statement as it relates to “Promoting research focused on scientifically valid, measurable health outcomes” and “Shifting to solution-oriented approaches in health disparities research.” (*See* Priorities Statement). The grant supports research to study the effects of “neighborhood stressors” on cognitive outcomes in African Americans: “The scientific premise for this proposal is that cumulative exposure to stress, disruption of the social fabric of the community, and limited access to high quality educational and social resources stemming from neighborhood disinvestment diminish cognitive reserve and foster psychological and physiological vigilance in residents. In turn, such vigilance manifests in heightened autonomic activity (i.e., high blood pressure) and sleep disruption, which serve as putative biobehavioral

mechanisms between neighborhood disadvantage and cognitive and ADRD risk." All these neighborhood stressors fall under the general umbrella of "structural racism" (Figure 1 in the application), which is defined as residential segregation, inequitable distribution of resources, and community disruption. Although residential segregation is potentially measurable, the other parts of the definition are not clear. Individual-level racism/discrimination will be measured using surveys and interviews, which will produce subjective responses; one person's experience and interpretation of the same event can differ from another's, which will introduce significant confounders into the data. The lack of concrete, objective, and measurable variables is not in alignment with NIH's priorities related to "promoting research focused on scientifically valid, measurable health outcomes." "Investigators must employ specific and measurable concepts in health disparities research. For example, redlining and housing discrimination are clearly defined practices that can measurably impact the health of minority populations. NIH will support scientifically rigorous research programs that explore such causes as one reason among many for poor health outcomes for Americans. However, broad or subjective claims—such as attributing worse health outcomes in a particular population to poorly measured factors like systemic racism—should not be presented as established background facts without clearly defining measurable variables that are part of the research question." (*See* Priorities Statement).

In addition, most of the underlying variables comprising "neighborhood stressors" do not fall within biomedical research's sphere of influence: Neighborhood Reinvestment and Revitalization (e.g., housing tax credits), Lifecourse Neighborhood Level Exposures (e.g., unemployment rate, median housing value, neighborhood racial composition), Individual-Level Risk and Protective Factors (e.g., limited education opportunities, perceived safety, neighborhood satisfaction). Because these variables all fall outside of biomedical research's sphere of influence, the results of the work will not lead to actionable healthcare interventions. Thus, the studies are not aligned with NIH's priorities related to shifting to solution-oriented approaches in health disparities research: "Going forward, the NIH will prioritize research that goes beyond measuring health disparities to focusing on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative evidence-based interventions and treatments that address poor health outcomes." (*See* Priorities Statement).

NIH has considered whether a modification or partial termination of the award could bring it into alignment with agency priorities. NIH feels that this award could not be renegotiated to bring it into alignment with priorities because the variables that make up "neighborhood stressors" and "structural racism" are not actionable within biomedical research's sphere of influence. As the study is about these variables, there is no way to change them to bring the grant into alignment with agency priorities without completely changing the work, which would require a new application and peer review.

Costs resulting from financial obligations incurred after termination are not allowable other than in accordance with 2 CFR § 200.472 or as may be provided in further instruction from the agency. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 200.344-200.345. Consistent with 2 C.F.R. 200.344, you will have 120 days

from the effective date of termination to liquidate all allowable financial obligations incurred prior to termination of this award. NIH will issue a final Notice of Award that will provide details related to closeout requirements.

Sincerely,



Jay Bhattacharya, M.D, Ph.D.
Director, NIH

Exhibit 4

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG072652
Federal Award Date
08/06/2026

Recipient Information

1. Recipient Name
UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION
4200 FIFTH AVENUE
PITTSBURGH, PA 15260

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1250965591A6

4. Employer Identification Number (EIN)
250965591

5. Data Universal Numbering System (DUNS)
004514360

6. Recipient's Unique Entity Identifier
MKAGLD59JRL1

7. Project Director or Principal Investigator
Tamara Dubowitz, SCD (Contact)
Senior Policy Researcher
dubowitz@rand.org
310-393-0411

8. Authorized Official
Jennifer E. Woodward
osp@pitt.edu

Federal Agency Information

9. Awarding Agency Contact Information
Maurice Koo
Extramural Support Assistant
NATIONAL INSTITUTE ON AGING
koom@mail.nih.gov
3014351135

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
5R01AG072652-05

12. Unique Federal Award Identification Number (FAIN)
R01AG072652

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/01/2026 **– End Date** 08/07/2026	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,540,838
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,540,838
26. Project Period Start Date 02/15/2022 **– End Date** 08/07/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,770,641

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jeni Smits

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG072652-05 REVISED

Principal Investigator(s):
Tamara Dubowitz (contact), SCD
Andrea L Rosso, PHD
Wendy M Troxel, PHD

Award e-mailed to: ornih@offres.pitt.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PITTSBURGH AT PITTSBURGH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072652. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jeni Smits
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$479,662
Fringe Benefits	$138,003
Personnel Costs (Subtotal)	$617,665
Travel	$6,860
Other	$29,377
Subawards/Consortium/Contractual Costs	$520,325
Federal Direct Costs	$1,174,227
Federal F&A Costs	$366,611
Approved Budget	$1,540,838
Total Amount of Federal Funds Authorized (Federal Share)	$1,540,838
TOTAL FEDERAL AWARD AMOUNT	$1,540,838
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$1,540,838	$1,540,838

Fiscal Information:
Payment System Identifier: 1250965591A6
Document Number: RAG072652B
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026
AG	8033157	$1,540,838

NIH Administrative Data:
PCC: 2CEPIFB / **OC**: 41025 / **Released**: 08/05/2026
Award Processed: 08/07/2026 12:07:33 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AG072652-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AG072652-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report

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the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG072652. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not

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apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5R01AG072652-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revision #1:
This award is revised to reflect a project period end of August 7, 2026, and is hereby terminated in full, because the grant, 5R01AG072652-05, “Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods”, is not in alignment with the August 15, 2025, NIH Priorities Statement, as it relates to “Promoting research focused on scientifically valid, measurable health outcomes”. The award is terminated in accordance with the terms of award and 2 CFR 200.340(a)(4), which states that a federal award may be terminated “by the Federal agency….pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities.” This is not a termination for failure to comply with the terms and conditions of the federal award.

In accordance with the termination letter issued from Dr. Jay Bhattacharya, dated August 4, 2026:

"The grant R01AG072652 "Longitudinal Examination of Neighborhood Disadvantage, Cognitive Aging, and Alzheimer's Disease Risk in Disinvested, African American Neighborhoods," is not in alignment with the August 15, 2025, NIH Priorities Statement as it relates to "Promoting research focused on scientifically valid, measurable health outcomes" and "Shifting to solution-oriented approaches in health disparities research." (See Priorities Statement). The grant supports research to study the effects of "neighborhood stressors" on cognitive outcomes in African Americans: "The scientific premise for this proposal is that cumulative exposure to stress, disruption of the social fabric of the community, and limited access to high quality educational and social resources stemming from neighborhood disinvestment diminish cognitive reserve and foster psychological and physiological vigilance in residents. In turn, such vigilance manifests in heightened autonomic activity (i.e., high blood pressure) and sleep disruption, which serve as putative biobehavioral mechanisms between neighborhood disadvantage and cognitive and ADRD risk." All these neighborhood stressors fall under the general umbrella of "structural racism" (Figure 1 in the application), which is defined as residential segregation, inequitable distribution of resources, and community disruption. Although residential segregation is potentially measurable, the other parts of the definition are not clear. Individual-level racism/discrimination will be measured using surveys and interviews, which will produce subjective responses; one person's experience and interpretation of the same event can differ from another's, which will introduce significant confounders into the data. The lack of concrete, objective, and measurable variables is not in alignment with NIH's priorities related to "promoting research focused on scientifically valid, measurable health outcomes." "Investigators must employ specific and measurable concepts in health disparities research. For example, redlining and housing discrimination are clearly defined practices that can

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measurably impact the health of minority populations. NIH will support scientifically rigorous research programs that explore such causes as one reason among many for poor health outcomes for Americans. However, broad or subjective claims-such as attributing worse health outcomes in a particular population to poorly measured factors like systemic racism-should not be presented as established background facts without clearly defining measurable variables that are part of the research question." (See Priorities Statement).

In addition, most of the underlying variables comprising "neighborhood stressors" do not fall within biomedical research's sphere of influence: Neighborhood Reinvestment and Revitalization (e.g., housing tax credits), Lifecourse Neighborhood Level Exposures (e.g., unemployment rate, median housing value, neighborhood racial composition), Individual-Level Risk and Protective Factors (e.g., limited education opportunities, perceived safety, neighborhood satisfaction). Because these variables all fall outside of biomedical research's sphere of influence, the results of the work will not lead to actionable healthcare interventions. Thus, the studies are not aligned with NIH's priorities related to shifting to solution-oriented approaches in health disparities research: "Going forward, the NIH will prioritize research that goes beyond measuring health disparities to focusing on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative evidence-based interventions and treatments that address poor health outcomes." (See Priorities Statement).

NIH has considered whether a modification or partial termination of the award could bring it into alignment with agency priorities. NIH feels that this award could not be renegotiated to bring it into alignment with priorities because the variables that make up "neighborhood stressors" and "structural racism" are not actionable within biomedical research's sphere of influence. As the study is about these variables, there is no way to change them to bring the grant into alignment with agency priorities without completely changing the work, which would require a new application and peer review.

Costs resulting from financial obligations incurred after termination are not allowable other than in accordance with 2 CFR § 200.472 or as may be provided in further instruction from the agency. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 200.344-200.345. Consistent with 2 C.F.R. 200.344, you will have 120 days from the effective date of termination to liquidate all allowable financial obligations incurred prior to termination of this award.

Supersedes Notice of Award issued June 20, 2026. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer’s Disease Initiative funds.

In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

In accordance with the Notice: NOT-OD-02-017 entitled, “GRADUATE STUDENT COMPENSATION” published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of

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compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

This award includes funds awarded for consortium activity with ***RAND Corporation.*** Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2015 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

This award includes funds awarded for consortium activity with ***University of California, San Francisco***. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2015 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AG072652-05 REVISED

INSTITUTION: UNIVERSITY OF PITTSBURGH AT PITTSBURGH

Budget	Year 5
Salaries and Wages	$479,662
Fringe Benefits	$138,003
Personnel Costs (Subtotal)	$617,665
Travel	$6,860
Other	$29,377
Subawards/Consortium/Contractual Costs	$520,325
TOTAL FEDERAL DC	$1,174,227
TOTAL FEDERAL F&A	$366,611
TOTAL COST	$1,540,838

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	59%
F&A Cost Base 1	$621,375
F&A Costs 1	$366,611

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF ANN D. COHEN-WILSON

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Ann D. Cohen-Wilson, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I am employed by the University of Pittsburgh where I am a tenured Associate Professor and Co-Director of the Molecular Biomarkers in Psychiatry Program in the Department of Psychiatry, the Director of the Neuroimaging Core in the Alzheimer's Disease Research Center, the Director of Collaborative Clinical Studies in Alzheimer's Disease and Related Dementias in the Department of Psychiatry, and the Co-Director of the Alzheimer's Disease Research Center. My research interests are early detection of Alzheimer's disease, neuroimaging and biomarkers of neurodegeneration, and the social determinants of health.

4. I earned my PhD in Neuroscience from the University of Pittsburgh in 2006, and completed my postdoctoral work in Geriatric Psychiatry at the Western Psychiatric Institute and Clinic of the University of Pittsburgh Medical Center in Pittsburgh, PA.

5. I have published widely in my field, including nearly 150 original peer reviewed articles in publications including *Annals of Neurology*, *Alzheimer's & Dementia*, *Journal of Neuroscience*, *NeuroImage*, *Archives of Neurology*, *Journal of Neurochemistry*, *JAMA Neurology*, and *Brain*.

6. In 2025, I received the Christopher Clark Award from Human Amyloid Imaging as well as the Diversity Equity and Inclusion Award from the Department of Psychiatry at the University of Pittsburgh School of Medicine. I have also served in elected leadership roles on national committees including as Chair of the Steering Committee for Neuroimaging Cores of the Alzheimer's disease Research Centers and the Advisory Committee of the International Society to Advance Alzheimer's Disease Research and Treatment.

7. I have been a continuously funded National Institute of Health Researcher for over 25 years and have served as the Principal Investigator, Multiple Principal Investigator, or Co-Investigator on 10 grants from the National Institutes of Health, specifically from the National Institute on Aging and National Institute of Neurological Disorders and Stroke. These grants include:

- R01 AG072641: *Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework*;
- R01 AG052446: *Role of Midlife Cardiovascular Disease on Alzheimer's Pathology and Cerebrovascular Reactivity in the Young-Old*; and
- RF1 AG052525: *Subclinical Vascular Disease and AD Pathology in the Transition from Midlife to Old Age*

8. Health equity is important in my work ethically and especially important scientifically. The different experiences that people have impact the brain in different ways. If scientific research does not recruit participants across different demographics, especially including those demographics who have a higher incidence of the disease being studied, such that not all people have access to biomarker studies, scientists will not have the information necessary to treat members of all communities effectively. This issue has been one that has consistently challenged the Alzheimer's disease and brain aging fields, particularly in relation to biomarker studies. Frequently, individuals at highest risk for Alzheimer's disease are those who are the most understudied, particularly individuals from racial and ethnic minorities and those from underprivileged backgrounds. Indeed, the National Alzheimer's Project Act (NAPA) (Public Law 111- 375) mandated that NIH continue to establish new cohorts that include participants across diverse racial, ethnic and socioeconomic backgrounds (milestone 1c) and reduce disparities in individuals at greatest risk for Alzheimer's disease, including racial and ethnic minorities. Finally, as the Alzheimer's disease field has entered a new era of biological detection of the disease and disease modifying treatments, the necessity of understanding such differences in pathology and treatment response is even more critical. Without research data that is representative of the population at large, a significant group of individuals will be left without the ability to trust that approved biomarkers or therapies will work in their communities.

9. In 2022, my institution was awarded a five-year R01 NIH grant from the NIA for which I am the principal investigator titled *Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework*. This grant was supposed to run through November 30, 2027.

10. This grant is a longitudinal study that continues a broader project I launched years ago to investigate the role of structural and social determinants of health in the development of Alzheimer's

disease. The project proposes that racial inequities in the development of cognitive impairments in the context of Alzheimer's disease are driven by structural inequities. The underlying premise is that there is heterogeneity in the pathology of Alzheimer's disease, and that the expression of cognitive dysfunction in the elderly is the result of two independent processes—neuropathology associated with Alzheimer's disease, and also what we have historically considered modifiable individual risk factors, which may be environmental, behavioral, and sociocultural. The project examines a group of White participants and a group of Black participants, using blood tests and imaging to detect brain changes, and documenting neighborhood factors that may be stressors to determine which factors confer a risk for Alzheimer's disease. The research links socioeconomic factors with cognitive decline.

11. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals are lengthy and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money—it indicates a project's scientific importance, methodological rigor, and real-world potential to improve public health.

12. In the case of this application, after approximately 12 months of planning, analysis, and drafting, the initial application was submitted in July 2020 and underwent peer review but was not accepted. After extensive review of the suggestions made by peer reviewers, discussions with our program officer, and significant revision, the grant was resubmitted in March of 2021. These changes included improvements to the scientific rigor and adjustments of the descriptions of our measures and statistical analyses. After another round of now favorable peer review, the application was awarded in February of 2022. The overall time investment of this award prior to funding was nearly 3 years.

13. Attached hereto as **Exhibit 1 is a tru**e and correct copy of this grant's initial Notice of Award (i.e., NOA).

14. We have published over 40 articles both funded by and related to this research in scholarly journals including *Journal of Neurochemistry*, *Journal of Cerebral Blood Flow and*

Metabolism, *The American Journal of Geriatric Psychiatry*, and *Journal of Neurochemistry*. The data from this project have also been shared with the scientific community around the world and uploaded to the National Alzheimer's Coordinating Center data repository and has provided data for training of PhD students, postdoctoral researchers, industry partners, and junior faculty.

15. Data from this study have also been presented at a variety of prestigious research conferences in the fields of brain aging and Alzheimer's disease, these include the American Academy of Neurology, the Alzheimer's Association International Conference, Human Amyloid Imaging, and the Gerontological Society of America.

16. On December 4, 2025, we received a renegotiation request from my NIH program officer (PO), who informed me that "NIH funds may not be used to support any Diversity Equity and Inclusion (DEI) related activities that were proposed in the application, or for any other DEI-related research or training activities, or programs." I was further advised that I would need to revise the current annual progress report to remove any aims not aligned with new priorities and adjust the budget of the program to ensure that no NIH funds would be used to support these types of activities. Our PO told us that a notice of grant award for year 4 would not be issued until these modifications were made.

17. I spoke to my PO on the phone about this on December 5, 2025. At this time, we discussed the need to revise the aims and whether those revisions would be feasible and meet the necessary and expected thresholds for scientific rigor in our field while still meeting the mandate from leadership at NIH.

18. Although I had misgivings about making the language changes required by NIH, because I wanted my research to continue given both its timeliness and importance, I modified the language. Specifically, I removed language regarding structural racism and health inequity (such as the statements that Black communities experience racism and more adverse social determinants of health, that I would use a health disparities research framework, or that I would collect information about measures of inequity including poverty, neighborhood segregation, and mortgage redlining) and instead focused on the idea that different people have different risks of a variety of stressors both psychological and biological that can be caused by individual experiences and that this may be the result of neighborhood disadvantage.

19. On December 15, 2025, I sent modified aims and narrative for the project, and I sent a modified abstract on December 17, 2025.

20. Even after I modified the language of my grant, I did not receive a NOA for months until late June 2026. Attached hereto as **Exhibit 2** is a true and correct copy of this grant's updated NOA. In the interim, I repeatedly asked my PO about the status of the NOA and if further changes were needed, and they would invariably tell me it was "in progress."

21. On August 7, 2026, I was formally notified through a new NOA that the grant had been terminated on the following basis:

> This award is revised to reflect a project period end of August 7, 2026, and is hereby terminated in full, because the grant, 5R01AG072641-04, "Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework", is not in alignment with the August 15, 2025, NIH Priorities Statement, as it relates to "Promoting research focused on scientifically valid, measurable health outcomes". The award is terminated in accordance with the terms of award and 2 CFR 200.340(a)(4), which states that a federal award may be terminated "by the Federal agency….pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

Attached hereto as **Exhibit 3** is a true and correct copy of this termination NOA.

22. The termination NOA references a letter from Dr. Jay Bhattacharya dated August 4, 2026, that neither I nor my institution ever received. The termination NOA does quote this apparent letter to argue that my grant could not be brought into alignment with agency priorities:

> NIH feels that this award cannot be renegotiated to bring it into alignment with agency priorities. The overall hypothesis of the grant is "that neighborhood inequity will modify the risk of cognitive decline and AD risk." As described above, the reliance on racism and other imprecisely measured and non-actionable factors as key drivers of the hypothesized effects does not align with the NIH's priorities. Removing this central hypothesis and its underlying concepts from the grant, would remove the entire

framework for the study and would not be a viable approach. Because of this, NIH does not believe that the grant can be renegotiated to bring it into alignment with agency priorities.

23. NIH's assertions do not make sense to me as a scientist. It is incorrect to argue that neighborhood inequity is "imprecisely measured and non-actionable." Indeed, the Area Deprivation Index used in the proposal is a rigorous measure of neighborhood inequity utilized broadly in my field. Similarly, the termination NOA's focus on "Figure 1 of the application" as a reason for terminating the grant (purportedly because of its focus on individual and institutional racism as drivers of AD inequities) is nonsensical because Figure 1 describes the factors that NIH itself uses for the National Institute on Aging's (NIA) Health Disparities Framework. The application includes Figure 1 to explain how the research will fit within the framework published by NIA; structural racism was never a proposed measure in this grant. It strains credulity that use of a framework published by NIA no longer effectuates agency priorities. Taken together, these inconsistencies, particularly rejecting a well validated, gold-standard measure as "imprecise," and mischaracterizing a figure drawn directly from NIA's own published framework as evidence of an improper focus on racism, suggest that the stated rationale is not a genuine scientific or methodological concern, but a pretext for terminating research perceived to communicate a viewpoint that structural racial inequities can contribute to disparities in health outcomes.

24. The grant termination has had an enormous negative impact. Without this funding, my team has had to suddenly cancel imaging appointments for our participants. Our team has spent years building trusted relationships with the community—these relationships are now at risk. The termination also means that our scientific work is unlikely to continue, and that may mean our prior work is weakened, too. We have spent over a decade building relationships in communities that do not traditionally participate in research. And we have learned from our research during the COVID pandemic that this trust is lost much more rapidly than it is gained. This means that as we endeavor to engage these communities in other clinical trials and research studies, we will have great difficulty in ensuring our research cohorts are appropriately diverse to ensure our findings can be generalizable to the population writ large. Our longitudinal study built upon a previous study from eight years ago and our

participants came back every 18-24 months for follow up testing. Because I can no longer conduct those follow-ups, we will be unable to track changes for those individuals or disclose results to participants (such as biomarker results and cognitive test results). Additionally, the chaos and scientific loss from this disruption cannot be understated, since science relies on careful and thoughtful timing and collection of data, and these delays will result in a tremendous loss of data and knowledge.

25. The termination of the grant also raises ethical issues. For example, participants gave their time, effort, and specimens (including brain images, blood samples, and DNA), making a calculation that the risks they were exposing themselves to were worth the benefits resulting from the study. Terminating the research midstream has meant that participants had unnecessary exposure to radiation and blood draws without the expected benefits of their participation. In addition, the funding termination could put the samples we have collected at risk, as we may ultimately no longer be able to maintain the freezers or the staff.

26. My team and I have already done a huge component of the baseline analyses for the project. Further, after submission of the grant, new biomarkers for Alzheimer's disease became available and FDA approved but many of these markers have not been examined in diverse, more generalizable populations representing an urgent need in the field. Our study had begun to examine these biomarkers in the last two years but given the termination, we will likely not be able to complete this analysis of additional biomarkers, a huge loss of important data that would have immediate impacts on research and clinical practice. My staff members, including 7 individuals in my lab and 5 individuals supported from this grant from collaborators' labs slated to conduct data analysis will now have to shift to other projects or be laid off.

27. Even if we are able to complete our analysis and publish our findings, I am fearful of negative impacts on my ability to secure NIH funding in the future. If I speak or write about my work or present my findings using a title that refers to any of the concepts to which NIH objected, such as neighborhood inequity or health disparities for racial and ethnic minorities, and list that title on my biosketch for future NIH grant applications, that could well doom the prospects for those applications' success. Indeed, I have previously removed publications from my biosketch that NIH found problematic

because of references to racism. But omitting such a title would obscure my scholarship and make my application less competitive.

28. Additionally, if we were unable to reinstate funding in the next few months, the time gap of our longitudinal data will become too large to continue data collection. At some point, the time gap will become so large that the research field will have moved on. Further, based on our experiences with Covid, I know that a sustained absence from the community of greater than a year will do tremendous damage to future recruitment efforts for clinical trials and other studies.

29. To date, I have spent over $5.2 million on this research. Without the rest of the funding, I will have wasted millions of dollars without being able to finish the study. Further, the time and effort of world leaders in dementia research on these projects now has to be shifted to focusing on closeout of a grant in a chaotic and unscientific manner, a tremendous waste of time and intellectual resources during a time where advances in the field are still desperately needed. Finally, the loss of support for trainees and staff undercuts the ability of our large and successful research program to continue its work into the future.

30. Sustained NIH funding has been the lifeblood of my research program and has contributed substantially to our understanding of early detection of Alzheimer's disease pathology and how risk factors shape the relation between this pathology and cognitive decline in those at highest risk for the dementia. NIH policies of disfavoring research that addresses health disparities will prevent me from applying for future NIH funding to expand our work and findings from this grant to understand how to identify strategies to reduce risk of dementia in these communities that could be quickly integrated into clinical practice. Our plans for a renewal of this research program in 2027 have largely been scrapped given this termination, a loss to not only our research program and community but also to the field.

31. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Clairton, Pennsylvania this 18th day of September 2026.



Ann D. Cohen-Wilson

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG072641
Federal Award Date
02/08/2022

Recipient Information

1. Recipient Name
UNIVERSITY OF PITTSBURGH, THE
4200 5TH AVE

PITTSBURGH, PA 15260

2. Congressional District of Recipient
18

3. Payment System Identifier (ID)
1250965591A6

4. Employer Identification Number (EIN)
250965591

5. Data Universal Numbering System (DUNS)
004514360

6. Recipient's Unique Entity Identifier
MKAGLD59JRL1

7. Project Director or Principal Investigator
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8. Authorized Official
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10. Program Official Contact Information
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301 496-9350

Federal Award Information

11. Award Number
1R01AG072641-01A1

12. Unique Federal Award Identification Number (FAIN)
R01AG072641

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 02/15/2022 **– End Date** 11/30/2022	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$2,416,844
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$2,416,844
26. Project Period Start Date 02/15/2022 **– End Date** 11/30/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,416,844

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Robin Laney

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG072641-01A1 REVISED

Principal Investigator(s):
Ann D. Cohen, PHD

Award e-mailed to: ornih@offres.pitt.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PITTSBURGH AT PITTSBURGH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072641. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$556,286
Fringe Benefits	$180,401
Personnel Costs (Subtotal)	$736,687
Materials & Supplies	$29,376
Travel	$2,500
Other	$1,121,198
Subawards/Consortium/Contractual Costs	$31,343
Federal Direct Costs	$1,921,104
Federal F&A Costs	$495,740
Approved Budget	$2,416,844
Total Amount of Federal Funds Authorized (Federal Share)	$2,416,844
TOTAL FEDERAL AWARD AMOUNT	$2,416,844
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$2,416,844	$2,416,844
2	$2,371,452	$2,371,452
3	$2,614,246	$2,614,246
4	$2,274,144	$2,274,144
5	$1,901,877	$1,901,877

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1250965591A6
Document Number: RAG072641A
PMS Account Type: P (Subaccount)
Fiscal Year: 2022

IC	CAN	2022	2023	2024	2025	2026
AG	8033159	$2,416,844	$2,371,452	$2,614,246	$2,274,144	$1,901,877

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 3CPHDCE / **OC**: 41021 / **Released**: Laney, Robin 02/07/2022
Award Processed: 02/08/2022 12:04:19 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG072641-01A1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AG072641-01A1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

d. National Policy Requirements and all other requirements described in the NIH Publication Publication Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG072641. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1R01AG072641-01A1 REVISED

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Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This revised award corrects the budget period and project period ends dates to 11/30/2022 and 11/30/2026 respectively.

Supersedes Notice of Award issued 02/02/2022. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

This award includes funds awarded for consortium activity with University of Georgia Research Foundation in the amount of $31,343 ($20,757 direct costs + $10,586 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on December 1. The Research Performance Progress Report (RPPR) is due 45 days prior to this date for SNAP awards or 60 days prior for non-SNAP awards.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG072641-01A1 REVISED

INSTITUTION: UNIVERSITY OF PITTSBURGH AT PITTSBURGH

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$556,286	$556,286	$556,286	$556,286	$568,976
Fringe Benefits	$180,401	$180,401	$180,401	$180,401	$184,056
Personnel Costs (Subtotal)	$736,687	$736,687	$736,687	$736,687	$753,032
Materials & Supplies	$29,376	$4,500	$9,206	$4,500	$4,500
Travel	$2,500	$2,500	$2,500	$3,000	$3,000
Other	$1,121,198	$1,121,198	$1,280,185	$959,810	$465,915
Subawards/Consortium/Contractual Costs	$31,343	$31,343	$101,856	$101,856	$101,856
TOTAL FEDERAL DC	$1,921,104	$1,896,228	$2,130,434	$1,805,853	$1,328,303
TOTAL FEDERAL F&A	$495,740	$475,224	$483,812	$468,291	$573,574
TOTAL COST	$2,416,844	$2,371,452	$2,614,246	$2,274,144	$1,901,877

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	56.5%	59%	59%	59%	59%

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F&A Cost Base 1	$396,392	$865,464	$821,860	$796,714	$1,072,179
F&A Costs 1	$201,361	$475,224	$483,812	$468,291	$573,574
F&A Cost Rate 2	59%				
F&A Cost Base 2	$498,948				
F&A Costs 2	$294,379				

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Exhibit 2

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG072641
Federal Award Date
06/20/2026

Recipient Information

1. Recipient Name
UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION
4200 FIFTH AVENUE
PITTSBURGH, PA 15260

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1250965591A6

4. Employer Identification Number (EIN)
250965591

5. Data Universal Numbering System (DUNS)
004514360

6. Recipient's Unique Entity Identifier
MKAGLD59JRL1

7. Project Director or Principal Investigator
Ann D. Cohen, PHD
Associate Professor
cohenad@upmc.edu
412-512-5006

8. Authorized Official
Jordan Myers
jcm271@pitt.edu
412-648-5905

Federal Agency Information

9. Awarding Agency Contact Information
John Bladen
Grants Technical Assistant
NATIONAL INSTITUTE ON AGING
bladenj@nia.nih.gov
301-496-1472

10. Program Official Contact Information
Cerise Elliott
Program Analyst
NATIONAL INSTITUTE ON AGING
elliottce@mail.nih.gov
301 496-9350

Federal Award Information

11. Award Number
5R01AG072641-04

12. Unique Federal Award Identification Number (FAIN)
R01AG072641

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 12/01/2025 **– End Date** 11/30/2026	
20. Total Amount of Federal Funds Obligated by this Action	$2,274,144
20 a. Direct Cost Amount	$1,805,853
20 b. Indirect Cost Amount	$468,291
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$2,274,144
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$2,274,144
26. Project Period Start Date 02/15/2022 **– End Date** 11/30/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$9,624,401

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jeni Smits

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG072641-04

Principal Investigator(s):
Ann D. Cohen, PHD

Award e-mailed to: ornih@offres.pitt.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $2,274,144 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PITTSBURGH AT PITTSBURGH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072641. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jeni Smits
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$556,286

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Fringe Benefits	$180,401
Personnel Costs (Subtotal)	$736,687
Materials & Supplies	$4,500
Travel	$3,000
Other	$959,810
Subawards/Consortium/Contractual Costs	$101,856
Federal Direct Costs	$1,805,853
Federal F&A Costs	$468,291
Approved Budget	$2,274,144
Total Amount of Federal Funds Authorized (Federal Share)	$2,274,144
TOTAL FEDERAL AWARD AMOUNT	$2,274,144
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$2,274,144

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$2,274,144	$2,274,144
5	$1,901,877	$1,901,877

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1250965591A6
Document Number: RAG072641A
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026	2027
AG	8033159	$2,274,144	$1,901,877

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 3CPHDCE / **OC**: 41025 / **Released**: 06/17/2026
Award Processed: 06/20/2026 12:01:27 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AG072641-04

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AG072641-04

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards

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as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG072641. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of

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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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5R01AG072641-04

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Funding for this award has been provided by Alzheimer's Disease Initiative funds

The requested budget was considered and determined not to represent significant re-budgeting. Therefore, categorical amounts reflect the direct and facilities and administrative cost (F&A) levels previously recommended for the current year. Funds may be re-budgeted between direct costs and F&A costs, consistent with applicable cost principles and institutional and policy requirements for prior approval.

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This award includes funds awarded for consortium activity with **University of Georgia Research Foundation**. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

As appropriate, the awardee is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of Aging (NIA).

In accordance with the Notice: NOT-OD-02-017 entitled, “GRADUATE STUDENT COMPENSATION” published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AG072641-04

INSTITUTION: UNIVERSITY OF PITTSBURGH AT PITTSBURGH

Budget	Year 4	Year 5
Salaries and Wages	$556,286	$568,976
Fringe Benefits	$180,401	$184,056
Personnel Costs (Subtotal)	$736,687	$753,032
Materials & Supplies	$4,500	$4,500
Travel	$3,000	$3,000
Other	$959,810	$465,915
Subawards/Consortium/Contractual Costs	$101,856	$101,856
TOTAL FEDERAL DC	$1,805,853	$1,328,303
TOTAL FEDERAL F&A	$468,291	$573,574
TOTAL COST	$2,274,144	$1,901,877

Facilities and Administrative Costs	Year 4	Year 5
F&A Cost Rate 1	59%	59%
F&A Cost Base 1	$793,714	$972,159
F&A Costs 1	$468,291	$573,574

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Exhibit 3

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG072641
Federal Award Date
08/06/2026

Recipient Information

1. Recipient Name
UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION
4200 FIFTH AVENUE
PITTSBURGH, PA 15260

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1250965591A6

4. Employer Identification Number (EIN)
250965591

5. Data Universal Numbering System (DUNS)
004514360

6. Recipient's Unique Entity Identifier
MKAGLD59JRL1

7. Project Director or Principal Investigator
Ann D. Cohen, PHD
Associate Professor
cohenad@upmc.edu
412-512-5006

8. Authorized Official
Jordan Myers
jcm271@pitt.edu
412-648-5905

Federal Agency Information

9. Awarding Agency Contact Information
John Bladen
Grants Technical Assistant
NATIONAL INSTITUTE ON AGING
bladenj@nia.nih.gov
301-496-1472

10. Program Official Contact Information
Cerise Elliott
Program Analyst
NATIONAL INSTITUTE ON AGING
elliottce@mail.nih.gov
301 496-9350

Federal Award Information

11. Award Number
5R01AG072641-04

12. Unique Federal Award Identification Number (FAIN)
R01AG072641

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 12/01/2025 **– End Date** 08/07/2026	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$2,274,144
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$2,274,144
26. Project Period Start Date 02/15/2022 **– End Date** 08/07/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$9,624,401

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jeni Smits

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:25 - 2/15/2024 9:51 AM | Generated on: 8/7/2026 12:15 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG072641-04 REVISED

Principal Investigator(s):
Ann D. Cohen, PHD

Award e-mailed to: ornih@offres.pitt.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PITTSBURGH AT PITTSBURGH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072641. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jeni Smits
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$556,286

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/7/2026 12:15 AM

Fringe Benefits	$180,401
Personnel Costs (Subtotal)	$736,687
Materials & Supplies	$4,500
Travel	$3,000
Other	$959,810
Subawards/Consortium/Contractual Costs	$101,856
Federal Direct Costs	$1,805,853
Federal F&A Costs	$468,291
Approved Budget	$2,274,144
Total Amount of Federal Funds Authorized (Federal Share)	$2,274,144
TOTAL FEDERAL AWARD AMOUNT	$2,274,144
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$2,274,144	$2,274,144

Fiscal Information:
Payment System Identifier: 1250965591A6
Document Number: RAG072641A
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026
AG	8033159	$2,274,144

NIH Administrative Data:
PCC: 3CPHDCE / **OC**: 41025 / **Released**: 08/05/2026
Award Processed: 08/07/2026 12:15:32 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AG072641-04 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AG072641-04 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research

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for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG072641. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards,

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Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5R01AG072641-04 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revision #1:

This award is revised to reflect a project period end of August 7, 2026, and is hereby terminated in full, because the grant, 5R01AG072641-04, “Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework”, is not in alignment with the August 15, 2025, NIH Priorities Statement, as it relates to “Promoting research focused on scientifically valid, measurable health outcomes”. The award is terminated in accordance with the terms of award and 2 CFR 200.340(a)(4), which states that a federal award may be terminated “by the Federal agency….pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities.” This is not a termination for failure to comply with the terms and conditions of the federal award.

In accordance with the termination letter issued from Dr. Jay Bhattacharya, dated August 4, 2026:

The grant 5R01AG072641-04 "Predictors of Altered CNS Structure, Function, and Connectomics in the Elderly using a Health Disparities Framework," is not in alignment with the August 15, 2025, NIH Priorities Statement. The grant supports a research study to look for associations between "neighborhood inequity" and Alzheimer's Disease (AD) risk and cognitive decline. The researchers use a "health equity framework" in which they "propose that racial inequities in the development of cognitive impairments in the context of AD are driven by pervasive structural and institutionalized inequities that shape risk and disadvantage at multiple levels, including biological, environmental, behavioral, sociocultural ... " The work relies heavily on the premise that individual and institutional racism are major drivers of the inequities they hypothesize influence AD risk and progression. In Figure 1 of the application, they show Institutional and Personally-Mediated Racism as the major influencers of physical, social, and healthcare context as well as of individual health and social factors. They use as a proxy measure for Institutional Racism (which they admit is "difficult to define") residential segregation and redlining. Personally mediated racism does not appear to have a measure in the study. An additional issue is that racism and neighborhood disadvantage/inequity, while manifestly negative, are not within biomedical research's sphere of influence. Thus even if it can be demonstrated that they do have direct effects on a particular health outcome, such as Alzheimer's disease, the result would not lead to an actionable biomedical intervention. The fact that the research is not solution-oriented also puts it out of alignment with the NIH's priorities: "Going forward, the NIH will prioritize research that goes beyond measuring health disparities to focusing on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative

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evidence-based interventions and treatments that address poor health outcomes." (See Priorities Statement.)

NIH has considered whether a modification or partial termination of the award could bring it into alignment with agency priorities. NIH feels that this award cannot be renegotiated to bring it into alignment with agency priorities. The overall hypothesis of the grant is "that neighborhood inequity will modify the risk of cognitive decline and AD risk." As described above, the reliance on racism and other imprecisely measured and non-actionable factors as key drivers of the hypothesized effects does not align with the NIH's priorities. Removing this central hypothesis and its underlying concepts from the grant, would remove the entire framework for the study and would not be a viable approach. Because of this, NIH does not believe that the grant can be renegotiated to bring it into alignment with agency priorities."

Costs resulting from financial obligations incurred after termination are not allowable other than in accordance with 2 CFR § 200.472 or as may be provided in further instruction from the agency. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 200.344-200.345. Consistent with 2 C.F.R. 200.344, you will have 120 days from the effective date of termination to liquidate all allowable financial obligations incurred prior to termination of this award.

Supersedes Notice of Award issued June 20, 2026. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer's Disease Initiative funds

The requested budget was considered and determined not to represent significant re-budgeting. Therefore, categorical amounts reflect the direct and facilities and administrative cost (F&A) levels previously recommended for the current year. Funds may be re-budgeted between direct costs and F&A costs, consistent with applicable cost principles and institutional and policy requirements for prior approval.

This award includes funds awarded for consortium activity with **University of Georgia Research Foundation**. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15
consortium_agreements.htm

As appropriate, the awardee is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of Aging (NIA).

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

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SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AG072641-04 REVISED

INSTITUTION: UNIVERSITY OF PITTSBURGH AT PITTSBURGH

Budget	Year 4
Salaries and Wages	$556,286
Fringe Benefits	$180,401
Personnel Costs (Subtotal)	$736,687
Materials & Supplies	$4,500
Travel	$3,000
Other	$959,810
Subawards/Consortium/Contractual Costs	$101,856
TOTAL FEDERAL DC	$1,805,853
TOTAL FEDERAL F&A	$468,291
TOTAL COST	$2,274,144

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	59%
F&A Cost Base 1	$793,714
F&A Costs 1	$468,291

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF DOLORES ALBARRACÍN

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Dolores Albarracín, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. I am the Amy Gutmann University Professor at the University of Pennsylvania. I am also the Director of the Annenberg Public Policy Center at the University of Pennsylvania. My research focuses on attitudes and persuasion as well as behavioral change. My work seeks to understand how people respond to persuasive communications, the dynamics of misinformation and conspiracy theories, and how to develop effective interventions to change behaviors that are detrimental for individuals and society at large. My research has direct impacts on health including how health risk behaviors can be discouraged, how health and other policies affect behavior, when emotions and past behavioral commitments drive persuasion and beliefs, and whether communities can be brought together to mitigate health threats.

3. I offer this declaration in my individual capacity and not on behalf of my employer.

4. My research career has been motivated by a lifelong interest in understanding the human mind and behavior, as well as an enjoyment of thinking, solving problems, writing, and conducting statistical data analysis. My academic pursuits around attitudes stemmed in part from growing up during a military dictatorship in Argentina, which limited citizen's expression and the freedom to research particular topics, even firing academics and closing university majors such as psychology. I came to the United States as a Ph.D. student in 1992. Thus, for more than three decades, the United States provided the academic freedom to perform research and write scientific discoveries without the political interference that I had perceived in Argentina during and after the dictatorship.

5. Before working at the University of Pennsylvania, I was a professor at the University of Illinois at Urbana-Champaign, where I remain a professor emerita. Prior to that, I was promoted through the ranks from assistant to endowed full professor at the University of Florida.

6. I received my B.A. in Psychology from Universidad Católica de La Plata and my Professor in Letters from Universidad Nacional de La Plata, both in La Plata, Argentina. I completed a Ph.D. in Clinical Psychology at Universidad de Belgrano in Buenos Aires, Argentina. I then completed a M.A. and another Ph.D. in Psychology (specializing in social psychology) at the University of Illinois at Urbana-Champaign.

7. To date, I am the author of six books and approximately 250 publications in peer-reviewed journals. I am a member of the American Academy of Arts and Sciences, the American Association for the Advancement of Science, and the American Academy for Political and Social Science. I have been recognized with several scientific awards, including mid-career and senior awards in the discipline of Social Psychology, and the BBVA Frontiers of Knowledge Award in Social Science. I was also president of the Society for Personality and Social Psychology. My career has been greatly facilitated by NIH funding, which has allowed me to pursue my research on basic social psychological issues and applications to health, while training many generations of students and postdocs who are now faculty members at other universities or contribute to public health or industry.

8. Institutional grantees are the entities that host the research and receive the award and funding from the National Institutes of Health (NIH), and are generally universities, hospitals, and sometimes non-profits and other entities. Awards also name one or more Principal Investigators, who are researchers directly responsible for proposing the projects, overseeing the design and implementation of studies, and managing the research from the application stage through the end of a grant. I have applied for federal grants since I was a doctoral student at the University of Illinois and NIH has awarded 15 grants for which I was or am the Principal Investigator over the course of my career. I have been involved in approximately 13 additional federal grants as co-investigator and mentor. One of the grants for which I am a Principal Investigator—R01MH132415—was included on the spreadsheet in Exhibit A of the June 23, 2025 partial final judgment in *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787 (D. Mass.). The other grants discussed in this declaration are separate from that grant.

9. At least two of my grant applications—both R01 grant applications—have been subjected to NIH's policies targeting disfavored viewpoints.

10. The goal of the first of those grants—titled *Adaptive, Regionally and Individually Tailored AI Based Intervention to Increase HIV Testing and Prevention in Philadelphia*, with a grant number of R01MH140783—is to test the effectiveness and dissemination of a digital intervention to promote HIV testing and linkage to pre-exposure prophylaxis (or "PrEP"). The research project seeks to transform how health promotion campaigns are conducted by combining large language models and

community outreach to engage participants in HIV prevention programs. The project is conducted in collaboration with the Philadelphia Department of Public Health. The original plan was to recruit as participants men who have sex with men and transgender women from priority zip codes of Philadelphia country. The sample would be 50% ethnic minorities to reflect the segment with the most risk and public health relevance, and we would develop and test an innovative artificial intelligence (AI) and community consultation process to elevate the effectiveness of the campaigns and programs designed to promote HIV testing and prevention in Philadelphia. In its final form, the project involves randomizing 1,000 participants to a standard of care or an experimental condition, testing effects on HIV testing and prevention, gauging implementation outcomes, and performing an economic assessment of cost-effectiveness. The AI component involves automating tailoring to individuals and zip codes, adapts to public health changes in the region, and incorporates the opinions of a community advisory board. The project is based on well-established theory about behavioral change and persuasion.

11. I submitted the application for this grant to NIH in January 2025. Developing this project and the application materials for it took years, with my team and I working through multiple iterations of the application to respond to feedback and refine our proposal. Over that time, we spent thousands of hours working on this grant application, including reviewing literature, analyzing data, conducting pilot studies, and drafting and revising the application materials themselves.

12. As noted above, originally, the grant application included transgender women as a population to be studied. However, early in January of 2025, I learned that the incoming administration was intending to issue an executive order that would enforce sex-based distinctions across federal policies (which is consistent with Executive Order 14168). In light of this information and my understanding that grants studying transgender women would not be funded, my team and I made the decision to remove transgender women from our sampling plan, despite the fact that the science of HIV prevention identifies transgender women as a priority group affected by new diagnoses. Promoting behavior change and service use in priority populations is central to the evidence-based approach to intervening to curb the epidemic.

13. In April 2025, I contacted the program officer assigned to this grant application because the project had received a good score. I met with the program officer virtually, and she informed me that

the application was of interest and that she believed it would receive funding. However, during the rest of the year, I received no updates from NIH regarding the status of the application.

14. On April 25, 2026, I received an email from the program officer assigned to this grant application. Attached hereto as Exhibit 1 is a true and correct copy of that email. In that email, the program officer stated: "Revisions to the application will be needed to align the study with current agency priorities," linking to NIH's August 15, 2025 statement titled "Advancing NIH's Mission Through a Unified Strategy." Ex. 1 at 1. The program officer also stated in that email that "[i]t would be best if we could meet to discuss these changes." *Id.*

15. On May 4, 2026, I met with the program officer to discuss potential revisions to my application. During that conversation, the program officer informed me that my application was flagged by the agency because of the substance of my application. More specifically, the program officer indicated that there was specific language that had been flagged in my application, as well as concern over our approach to sampling participants. The program officer informed me that I could make revisions and send an amended application to align with the agency's priorities.

16. Based on this conversation, as well as my concern about topics that were disfavored in light of NIH's August 2025 and December 2025 policy statements, I proceeded to make the changes that had been recommended by the program officer. Regarding our approach to sampling participants, we had planned to oversample—that is, included proportionally more of these individuals in the dataset than in the general population—ethnic minority men as study participants because they are at a higher risk for contracting the disease and not receiving treatment and, consistent with the science of HIV prevention, focusing on them was an evidence-based approach to intervening to curb the HIV epidemic. However, language relating to our ethnic minority oversampling was objectionable to NIH.

17. The changes our team made included removing terms like "health disparities," "gender," "LGBT," "ethnic minority," "Black [person]," "culturally diverse," "racial and ethnic minorities," "vulnerable," "diverse backgrounds," and "transgender." The program officer also told me to remove the term "Hispanic/Latino" and instead use "Latin American." This was surprising because "Latin American" denotes someone born in Latin America rather than the very large and heterogeneous group of U.S. Americans who identify as culturally or ethnically "Latinx."

18. On July 7, 2026, I received a notice of award (NOA) for this project, titled *Adaptive, Regionally and Individually Tailored, AI Based Intervention to Increase HIV Testing and Prevention in Philadelphia* with a grant number R01MH140783. Attached hereto as Exhibit 2 is a true and correct copy of the NOA for this R01 grant.

19. Although we made these revisions to maintain funding for our team and ensure we could still conduct at least some of the research contemplated under the original application, I am concerned that the revisions to the application will limit the benefit to public health from work on this grant. Because I felt compelled to remove transgender women as a population to be studied, the public health benefit that demographic would get from the findings of the research is diminished. Deemphasizing populations at risk for HIV work undermines the research's scientific value and impact. That, of course, reduces the benefit to those specific demographic populations, but it also reduces the opportunities for publications given the limited scope of the research. Particularly concerning is the ability to train the next generation of psychologists, communication scholars, and college students to scientifically intervene in the health area when terms associated with "ethnic minorities" and "health disparities" must be removed from our grant applications and projects, as those individuals will have much more limited exposure to how these concepts and terms operate in academic research.

20. The goal of a second grant application that was subjected to NIH's policies targeting research perceived as reflecting disfavored viewpoints was to increase HIV and Hepatitis diagnosis, prevention, and treatment in rural areas affected by the substance use epidemic (e.g., the "opioid" epidemic). The project also seeks to increase substance use harm reduction, including the use of naloxone—the antidote for an opioid overdose—medication treatment for addictions, and syringe service programs. Moreover, it brings together the community at large and individuals with a history of substance use, seeking to reduce drug stigma and its detrimental effects on disease treatment and prevention. This project builds off work that had been previously focused on some Appalachian and Midwest counties, with the goal of expanding to all rural counties at the highest risk for these diseases in the U.S., testing an intervention and involving local authorities. Our data from the previous eight years provided the basis for the development of this program, which we planned to extend nation-wide incorporating AI for the training of facilitators.

21. On January 7, 2026, I submitted this grant application to NIH. As with the other R01 grant discussed in the paragraphs above, our team spent thousands of hours conducting work to prepare this application.

22. The application received a good score. However, around April 2026, the program officer assigned to this grant and I met to discuss it. During that conversation, the program officer recommended that I delete certain terms—such as "harm reduction" and "substance use stigma"—from the application to have it move forward. As a result of this conversation, as well as my concern about words and topics that were disfavored in light of NIH's August 2025 and December 2025 policy statements, I removed the following terms from my grant application prior to resubmission: "harm reduction" and "substance use stigma." This was surprising because my team had gone to great lengths to sanitize the terminology based on the NIH prior directives and my experience with other recent grants. However, we made the changes suggested by the agency so that our team and the training of future scientists would remain viable.

23. On June 25, 2026, NIH issued an NOA for this grant, titled *Testing the Effectiveness of a Remote Intervention to Reduce Infection Risk in Rural Areas of the United States*, with a grant number of R01DA064602. Attached hereto as Exhibit 3 is a true and correct copy of this R01 grant's NOA.

24. Although I made these revisions because I was concerned about maintaining funding for our research team and ensuring we could still conduct at least some of the research contemplated under the original application, I am troubled that this censorship by NIH will negatively impact this grant and my work. For example, removing "harm reduction" for a study on substance abuse disorders makes the research much less effective, because harm reduction—which includes interventions like syringe service programs and buprenorphine or methadone—is one of the primary interventions used to save lives. The scientific perspective on these measures is that they must be incorporated into evidence-based approaches. This hindrance to studying or even discussing harm reduction thus reduces the ability for our research to have a sizable impact on preventing HIV and Hepatitis C transmission. What's more, the substance use and harm reduction components of our work would be among the most innovative components of our research. Removing these concepts thus reduces our potential to produce meaningful and impactful publications based on this research. As another example, removing "stigma" limits our

ability to implement the project as designed. Specifically, the intervention involves participants from different rural counties in the United States gathering on Zoom to plan improvements to their social lives and health. We include people with a history of substance use and the community at large to increase social support for health behaviors and decrease stigma among all. The removal of the stigma-reduction component of the program substantially diminishes the innovation and potential public health impact of our initiative.

25. Beyond just these two grant applications, given the prohibited terms and research perspectives targeted by NIH, as well NIH's August 2025 and December 2025 policy statements, I am also unsure of what to expect for my future grant applications, including because my work also focuses on vaccine hesitancy and understanding misinformation and disinformation. I am especially concerned about funding for those areas of research given that NIH previously terminated one of my grants (R01MH132415, mentioned in Paragraph 8 above). That grant—originally titled *Understanding the Regional Ecology of a Future HIV Vaccine*—examined the ecology of vaccination on a future HIV vaccine (as well as the uptake of other vaccines), following over three years a nationwide group of approximately 1500 men who have sex with men to determine how vaccine characteristics, community information and misinformation, social media, vaccination norms, and public health and HIV policies predict intentions to receive a future HIV (or other) vaccines. The grant also included a subsequent experimental component, with the goal of testing the effects of these factors on vaccine choices and intentions. Broadly, a goal of this project was to see how policy—at the local, state, and federal level—interacts with misinformation to affect attitudes towards vaccination (including COVID-19). The grant was reinstated because of the *APHA v. NIH* litigation.

26. Even after NIH reinstated this grant because of that litigation, NIH still censored my research. Around the end of July 2025, I spoke with the program officer who was assigned to this grant. During that conversation, the program officer advised me to revise my grant materials to avoid the risk of a second termination of the grant. The program officer also informed me that my grant—which was originally titled *Understanding the Regional Ecology of a Future HIV Vaccine*—had been listed on around 5 or 6 different lists created by NIH in its mass terminations earlier that year, and that some of those lists had been generated even after my grant had already been terminated. The program officer

further noted that this grant had been included on these different lists because it related to various topics targeted by NIH, including COVID-19, misinformation, and vaccine hesitancy. In light of this conversation, and aware of waves of NIH grant terminations earlier that year, I revised the grant materials for this grant, including by removing words like "misinformation," "information circulating in the community," "reluctance to vaccinate," "intentions to vaccinate," "vaccination norms," "vaccine and HIV policy," "vaccine," "vaccinate," "vaccination," "public health policies," "HIV policy," "LGBT," and "COVID-19." The removal of policies included coverage of PrEP, PrEP and HIV testing sites, pharmacy-based PrEP delivery, Medicaid program's benefits, protection of health care for transgender persons, and syringe possession and distribution laws. The grant materials were also modified to eliminate measures of health behavior and intentions. The elimination of behavior and intention measures was troubling because the grant shifted from studying a consequential outcome to studying knowledge as a way of not appearing to try to "promote" health behavior, which the program officer explained was objectionable. I even changed the title of my grant, further scrubbing the concepts targeted by NIH, to *The Ecology of Health Knowledge in the United States*.

27. In light of the above, I am deeply worried about the prospect of future grants in my area of expertise, including work that focuses on vaccine hesitancy and understanding misinformation and disinformation. For example, we would normally be preparing to follow up on our work on the impact of policies, public health information, and public health communication on vaccination, an area where we had worked extensively since 2018. We would also be preparing to continue to study the health impact of government and nongovernment communication on social media, another area that appears to be targeted by NIH. In that sense, potential new research in these areas will be delayed or perhaps never get off the ground because of NIH's recent censorship policies, and efforts to publish our data collected in these domains are at risk as well. Further, I am concerned about being able to describe any work funded by the grants discussed here in publications or presentations in a manner that is inconsistent with the language that NIH forced me to adopt in my application materials.

28. I am among a small group of psychologists in the world who have built a career around making basic research contributions, along with applied discoveries, particularly in the area of health. However, for the duration of my career, this combination was facilitated by academic and funding

environments that enabled me to study HIV prevention, healthy lifestyles, and vaccination, along with the mechanisms of belief, attitude, and behavior change. Therefore, the changes in NIH policy affect future prospects of continuing to do what I have freely done for three decades. The changes also affect the prospects of postdoctoral researchers, graduate students, undergraduate research assistants, and postbaccalaureate research specialists for training in my group. And most of all, it affects the quality of our research in these research areas that are critical to public health.

29. My work in these areas has also been impacted as grants on these topics have been targeted and no new grant opportunities have arisen. In fact, I have not submitted any new grants associated with misinformation or conspiracy theories, avoiding also the study of the impacts of health policies, which has also been questioned. As another example, I have stopped submitting grants about LGBT populations as a lead Principal Investigator to NIH. Further, I am worried that our graduate and undergraduate students and other early career researchers (e.g., postdoctoral fellows) on our team will miss out on training or work around essential concepts in our field—like harm reduction—at this critical stage of their academic career, given that these concepts have been removed from our grant. Finally, decades of building trust in science among the communities we serve have been and will continue to be severely disrupted by the NIH dictating which viewpoints are acceptable to study and intervene on.

30. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Philadelphia, Pennsylvania this 20th day of September 2026.



Dolores Albarracín

Exhibit 1

Tuesday, September 8, 2026 at 04:39:40 Eastern Daylight Time

Subject: RE: 1R01MH140783 -01A1 (Albarracin & Bauermeister)
Date: Saturday, April 25, 2026 at 9:17:57 PM Eastern Daylight Time
From: Scott-Sheldon, Lori (NIH/NIMH) [E]
To: Albarracin, Dolores
CC: Bauermeister, Jose A
Attachments: Data Safety and Monitoring Plan Checklist.docx

Hello Dolores,

There are several documents that will need revisions: (1) Data Safety and Monitoring Plan, (2) Data Management and Sharing Plan, and (3) application.

1. Data Safety and Monitoring Plan: Please update to the DSMP (application pg. 103-104) to align with the NIMH Guidance for Developing a Data and Safety Monitoring Plan for Clinical Trials. A checklist to help guide your revisions is attached. Please have your signing official submit the revised DSMP via the JIT module.
2. Data Management and Sharing Plan: The DMS Plan requires the following changes in alignment with the NIMH Data Sharing Policy:
    a. Element 3: The NIMH requires all human-subjects research to collect HIV-relevant common data elements such as age, sex, HIV, ART, and/or PrEP information, and mental health (PHQ-9, GAD-7). Please identify the CDEs applicable to this study in Element 3.
    b. Element 4A: All NIMH funded human subjects research must submit the data to the NIMH Data Archives (NDA); please update Element 4A.
    c. Element 4C: Data must be submitted to the NDA every 6 months throughout the duration of the award (i.e., every January and July after data collection has commenced). Please update the timeline for data sharing as well as a sentence stating that there are no current limits to the length of time in which data will be archived.

    The revised DMS Plan should also be uploaded via the JIT module, but I have one recommendation before the final document is submitted by the signing official (re: agency alignment).
3. Application: Revisions to the application will be needed to align the study with current agency priorities (see: https://www.nih.gov/about-nih/nih-director/statements/advancing-nihs-mission-through-unified-strategy). It would be best if we could meet to discuss these changes. Feel free to use my bookings link below to schedule a meeting. My schedule is nearly full this week, but I do have 30 minutes available at 10:30 am and 12:30 pm on Monday, April 27.

In addition to these three documents, please upload the response to reviewer letter that was emailed to me on May 27, 2025, also via the JIT module.

Best,
Lori

Lori A. J. Scott-Sheldon, PhD
Chief of Data Science and Emerging Methodology in HIV
National Institute of Mental Health
National Institutes of Health
Phone: 301-792-2309
Email: lori.scott-sheldon@nih.gov

To schedule a meeting: Book time with Scott-Sheldon, Lori (NIH/NIMH) [E]

From: Albarracin, Dolores <dalba@upenn.edu>
Sent: Thursday, April 23, 2026 7:29 PM
To: Scott-Sheldon, Lori (NIH/NIMH) [E] <lori.scott-sheldon@nih.gov>
Cc: Bauermeister, Jose A <bjose@nursing.upenn.edu>
Subject: [EXTERNAL] MH140783

Dear Lori,

I hope you're doing well.

We submitted the JIT and wonder if anything else is needed at this time.

Best,
Dolores

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Exhibit 2

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R01MH140783
Federal Award Date
07/07/2026

Recipient Information

1. Recipient Name
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, THE
3451 WALNUT ST
PHILADELPHIA, PA 19104

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
1231352685A1

4. Employer Identification Number (EIN)
231352685

5. Data Universal Numbering System (DUNS)
042250712

6. Recipient's Unique Entity Identifier
GM1XX56LEP58

7. Project Director or Principal Investigator
DOLORES ALBARRACIN, PHD (Contact)
Professor
dalba@upenn.edu
215-898-7041

8. Authorized Official
ELIZABETH D PELOSO
PennAORs@lists.upenn.edu
215-746-0234

Federal Agency Information

9. Awarding Agency Contact Information
Carla Sue Bridge
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
carla.bridge@nih.gov

10. Program Official Contact Information
Lori Ann Jennifer Scott-Sheldon

NATIONAL INSTITUTE OF MENTAL HEALTH
lori.scott-sheldon@nih.gov

Federal Award Information

11. Award Number
1R01MH140783-01A1

12. Unique Federal Award Identification Number (FAIN)
R01MH140783

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Adaptive, Regionally- and Individually-Tailored, AI-Based Intervention to Increase HIV Testing and Prevention in Philadelphia

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/01/2026 **– End Date** 05/31/2027	
20. Total Amount of Federal Funds Obligated by this Action	$812,484
20 a. Direct Cost Amount	$499,990
20 b. Indirect Cost Amount	$312,494
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$812,484
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$812,484
26. Project Period Start Date 08/01/2026 **– End Date** 05/31/2031	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$812,484

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Heather A Weiss

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R01MH140783-01A1

Principal Investigator(s):
DOLORES ALBARRACIN (contact), PHD
Jose Arturo Bauermeister, PHD

Award e-mailed to: rs-award@lists.upenn.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $812,484 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PENNSYLVANIA in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R01MH140783. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Heather A Weiss
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$266,912
Fringe Benefits	$84,078
Personnel Costs (Subtotal)	$350,990
Other	$149,000
Federal Direct Costs	$499,990
Federal F&A Costs	$312,494
Approved Budget	$812,484
Total Amount of Federal Funds Authorized (Federal Share)	$812,484
TOTAL FEDERAL AWARD AMOUNT	$812,484
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$812,484

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$812,484	$812,484
2	$788,861	$788,861
3	$780,736	$780,736
4	$767,574	$767,574
5	$733,431	$733,431

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1231352685A1
Document Number:	RMH140783A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2026

IC	CAN	2026	2027	2028	2029	2030
MH	8472592	$812,484	$788,861	$780,736	$767,574	$733,431

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 9A-ASPI / **OC**: 41021 / **Released**: 06/25/2026
Award Processed: 07/07/2026 12:33:18 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MH140783-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MH140783-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MH140783. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-

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discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

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Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R01MH140783-01A1

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:
This award has been made in response to the application submitted under the Notice of Funding Opportunity Announcement PA-24-091 which can be referenced at: Expired PAR-24-091: Multidisciplinary Studies of HIV/AIDS and Aging (R01 Clinical Trial Optional).

BUDGET/PROJECT PERIOD ADJUSTMENT:
This grant has been selected under the NIMH plan to redistribute grant workloads more evenly throughout the year. Consequently, the initial budget period reflects a 05/31/2027 end date. Subsequent budget periods will begin on 06/01 and will be for a 12-month duration. Although this grant will have a slightly shorter budget period this year, it is awarded the full 12-month level of funds for the budget period. If needed, additional time may be requested at the end of the project period for a first no-cost extension through eRA Commons.

SPECIAL TERM AND CONDITION:
NIMH has approved the renegotiation of the Abstract and Specific Aims to ensure alignment with Advancing NIH's Mission Through a Unified Strategy | National Institutes of Health (NIH), including the NIH Priority of promoting research focused on scientifically valid, measurable health outcomes. The project must be carried out in accordance with the revised award objectives submitted via the AOR on 05/11/2026.

HUMAN SUBJECTS RESEARCH:
This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 02/09/2026. It is expected that 300 of the 1,000 total projected participants will be recruited by 04/01/2028. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical

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Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

GCP TRAINING:
NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:
The clinical trial(s) supported by this award is subject to the plan within the competing application dated [DATE] submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. It's required that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:
This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

DATA AND SAFETY MONITORING:
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

Each RPPR submitted is expected to include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and a summary of any safety recommendations from the IRB reviews and any actions taken based on the recommendations.

DATA SHARING PLAN:
The data sharing plan submitted 05/05/2026 is approved. **Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5.c "Data Management and Sharing."**

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OTHER SUPPORT TIME COMMITMENT:
Commitment overlap is not permitted and occurs when an individual's time commitment exceeds 100 percent (I.e., 12 person months), whether or not salary is requested. Therefore, no individual's time commitment may exceed 100 percent. Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$16,450	$20,500	$20,500	$17,400	$24,000

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01MH140783-01A1

INSTITUTION: UNIVERSITY OF PENNSYLVANIA

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$266,912	$294,412	$294,412	$294,412	$266,912
Fringe Benefits	$84,078	$92,741	$92,741	$92,741	$84,078
Personnel Costs (Subtotal)	$350,990	$387,153	$387,153	$387,153	$350,990
Travel					$10,302
Other	$149,000	$98,300	$93,300	$85,200	$82,050
Publication Costs					$8,000
TOTAL FEDERAL DC	$499,990	$485,453	$480,453	$472,353	$451,342
TOTAL FEDERAL F&A	$312,494	$303,408	$300,283	$295,221	$282,089
TOTAL COST	$812,484	$788,861	$780,736	$767,574	$733,431

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	62.5%	62.5%	62.5%	62.5%	62.5%
F&A Cost Base 1	$499,990	$485,453	$480,453	$472,353	$451,342
F&A Costs 1	$312,494	$303,408	$300,283	$295,221	$282,089

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Exhibit 3

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Notice of Award
FAIN# R01DA064602
Federal Award Date
06/25/2026

Recipient Information

1. Recipient Name
TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, THE
3451 WALNUT ST
PHILADELPHIA, PA 19104

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
1231352685A1

4. Employer Identification Number (EIN)
231352685

5. Data Universal Numbering System (DUNS)
042250712

6. Recipient's Unique Entity Identifier
GM1XX56LEP58

7. Project Director or Principal Investigator
DOLORES ALBARRACIN, PHD
Professor
dalba@upenn.edu
215-898-7041

8. Authorized Official
Kyle Wolfe
PennAORs@lists.upenn.edu
215-746-2812

Federal Agency Information

9. Awarding Agency Contact Information
Lennin F. Greenwood
Grants Management Specialist
NATIONAL INSTITUTE ON DRUG ABUSE
lennin.greenwood@nih.gov
3018270478

10. Program Official Contact Information
Richard A Jenkins
Health Scientist Administrator
NATIONAL INSTITUTE ON DRUG ABUSE
jenkinsri@mail.nih.gov
301-443-6504

Federal Award Information

11. Award Number
1R01DA064602-01A1

12. Unique Federal Award Identification Number (FAIN)
R01DA064602

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Testing the Effectiveness of a Remote Intervention to Reduce Infection Risk in Rural Areas of the United States

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Use and Addiction Research Programs

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/01/2026 **– End Date** 05/31/2027	
20. Total Amount of Federal Funds Obligated by this Action	$885,939
20 a. Direct Cost Amount	$635,760
20 b. Indirect Cost Amount	$250,179
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$885,939
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$885,939
26. Project Period Start Date 07/01/2026 **– End Date** 05/31/2031	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$885,939

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Garlin R Hallas

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 1R01DA064602-01A1

Principal Investigator(s):
DOLORES ALBARRACIN, PHD

Award e-mailed to: rs-award@lists.upenn.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $885,939 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF PENNSYLVANIA in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R01DA064602. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Garlin R Hallas
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$238,608

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Fringe Benefits	$70,179
Personnel Costs (Subtotal)	$308,787
Materials & Supplies	$17,500
Travel	$4,000
Other	$41,500
Subawards/Consortium/Contractual Costs	$260,473
Publication Costs	$3,500
Federal Direct Costs	$635,760
Federal F&A Costs	$250,179
Approved Budget	$885,939
Total Amount of Federal Funds Authorized (Federal Share)	$885,939
TOTAL FEDERAL AWARD AMOUNT	$885,939
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$885,939

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$885,939	$885,939
2	$1,073,528	$1,073,528
3	$1,061,341	$1,061,341
4	$1,065,400	$1,065,400
5	$943,759	$943,759

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1231352685A1
Document Number: RDA064602A
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026	2027	2028	2029	2030
DA	8073961	$885,939	$1,073,528	$1,061,341	$1,065,400	$943,759

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CV/RJP / **OC**: 41021 / **Released**: 06/12/2026
Award Processed: 06/25/2026 12:14:29 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01DA064602-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01DA064602-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain

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references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01DA064602. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see

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https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the

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False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – DA SPECIFIC AWARD CONDITIONS – 1R01DA064602-01A1

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

CHANGE OF SCOPE – RENEGOTIATION
This award approves the revised aims, abstract, and PHR as submitted in the document dated **05/01/2026 via the Just-in-Time information.** The revised aims, abstract, and PHR are incorporated as terms and conditions of the award and the recipient must comply with these changes. See reminder – NOT-OD-26-007.

FY2026 FUNDING
The award amount for the current year is based upon IRG/Council recommendations, cost analysis, program priorities and availability of funds.

BUDGET PERIOD
Future year anniversary dates for this grant will be June 1 and the Research Performance Progress Report (RPPR) is due on April 15.

NOFO REQUIREMENTS
This award is subject to the requirements detailed in RFA-DA-25-024, entitled High Priority HIV and Substance Use Research (R01 Clinical Trial Optional), posted on 08/02/2024, which are incorporated by reference as terms and conditions of this award.

The NOFO is available here: RFA-DA-25-024: High Priority HIV and Substance Use Research (R01 Clinical Trial Optional)

DATA MANAGEMENT AND SHARING PLAN
This award is subject to the Data Management and Sharing (DMS) plan submitted and approved by NIDA via JIT dated 06/05/2026. Any changes in the DMS plan must be reviewed and approved by the NIDA Program Official. If changes are approved, the approval will be reflected on the Notice of Award (NoA) via revision. If changes are not approved, the Principal Investigator must revise the DMS plan to the satisfaction of the NIDA Program Official.

DATA AND SAFETY MONITORING PLAN
This award is subject to the Data and Safety Monitoring Plan (DSMP) submitted via JIT dated 6/05/2026 and approved by NIDA. Any changes in the DSMP must be reviewed and approved by the NIDA Program Official. If changes are approved, the approval will be reflected on the Notice of Award (NoA) via revision. If changes are not approved, the Principal Investigator must revise the DSMP to the satisfaction of the NIDA Program Official. The Principal Investigator must provide a DSMP for any new trial that is to be conducted under this grant.

DATA AND SAFETY MONITORING BOARD (DSMB)
This award is subject to the NIDA Guidelines for Establishing and Operating a Data and Safety Monitoring Board.

CONSORTIUM ACTIVITY

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This award includes funds awarded for consortium activities. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS), Section on Consortium Agreements - http://grants.nih.gov/policy/nihgps/index.htm.

The recipient is reminded of the *NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements* as published in the NIH Guide notice NOT-OD-23-182 on September 15, 2023 with an effective date of January 1, 2024. The notice can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-182.html

GRADUATE STUDENT CAP
The maximum amount NIH will award for the support of a graduate student on a research grant or a cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend in effect at the time the grant award is issued on the Federal award date. The schedule for NRSA stipends can be found at http://grants.nih.gov/training/nrsa.htm. Consistent with cost principles for Institutions of Higher Education (IHEs) described in 45 CFR 75.431 and 45 CFR 75.466, the compensation of graduate students supported by research grants must be reasonable. These operating principles associated with the compensation of students performing necessary work on NIH funded research projects are described in detail in the *NIH Grants Policy Statement* at http://grants.nih.gov/policy/nihgps/index.htm. The amount provided for compensation includes salary or wages, fringe benefits, and tuition remission.

NIDA TERMS
In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates http://grants.nih.gov/policy/nihgps/index.htm), in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01DA064602-01A1

INSTITUTION: UNIVERSITY OF PENNSYLVANIA

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$238,608	$325,109	$325,109	$325,109	$325,109
Fringe Benefits	$70,179	$98,294	$98,294	$98,294	$98,294
Personnel Costs (Subtotal)	$308,787	$423,403	$423,403	$423,403	$423,403
Materials & Supplies	$17,500	$17,500	$17,500	$17,500	$17,500
Travel	$4,000	$4,000	$4,000	$4,000	$4,000
Other	$41,500	$160,215	$152,715	$155,213	$80,357

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Subawards/Consortium/Contractual Costs	$260,473	$84,524	$84,524	$84,524	$84,524
Publication Costs	$3,500	$3,500	$3,500	$3,500	$3,500
TOTAL FEDERAL DC	$635,760	$693,142	$685,642	$688,140	$613,284
TOTAL FEDERAL F&A	$250,179	$380,386	$375,699	$377,260	$330,475
TOTAL COST	$885,939	$1,073,528	$1,061,341	$1,065,400	$943,759

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	62.5%	62.5%	62.5%	62.5%	62.5%
F&A Cost Base 1	$400,287	$608,618	$601,118	$603,616	$528,760
F&A Costs 1	$250,179	$380,386	$375,699	$377,260	$330,475

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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF HEIDI MOSESON

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Heidi Moseson, declare:

1. My name is Heidi Moseson.

2. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

3. I am an Epidemiologist and Senior Research Scientist at Ibis Reproductive Health ("Ibis") in Oakland, California. I have extensive experience in clinical and social science research and have led a clinical trial, National Institutes of Health ("NIH") funded studies as Principal Investigator ("PI"), and other quantitative and qualitative research for more than 15 years. Ibis is a global research organization whose mission is to drive change through bold, rigorous research and principled partnerships that advance sexual and reproductive autonomy, choices, and health worldwide. I have been a Senior Research Scientist at Ibis since 2020, and previously served as an Associate at Ibis.

4. I am offering this declaration in my individual capacity and not on behalf of my employer.

5. As a Senior Research Scientist, I lead grant-writing, study design, implementation, statistical analysis, and dissemination for research on abortion, contraception, gender-affirming care, and family building. I design and lead research that identifies barriers and facilitators to reproductive health care, particularly abortion and contraception, in the context of shifting policies in the United States. I also lead research on the safety and effectiveness of various models of medication abortion care (abortion with pills), including an ongoing randomized clinical trial in the United States. Additionally, I design and lead research on the family planning needs and experiences of sexual and gender minority people, including development of survey methods and other research measures that are more accurate for sexual and reproductive health experiences. Public health research is core to my and Ibis's work, which is informed by relationships and collaboration with community partners, including organizations and individuals representing pregnant people seeking abortion care and transgender and gender diverse community members, to identify key gaps in information and resources concerning reproductive health, autonomy, and health care access for these populations.

6. I earned a PhD in Epidemiology & Translational Science from the University of California, San Francisco, a Masters of Public Health in Epidemiology & Biostatistics from the

University of California, Berkeley, and a Bachelor of Arts in International Relations & Human Biology from Stanford University.

7. I am widely published in top journals in my field, including in *Lancet*, *Journal of the National Cancer Institute*, *New England Journal of Medicine*, *American Journal of Epidemiology*, *American Journal of Public Health*, *JAMA Network Open*, *Contraception*, and *Perspectives in Sexual and Reproductive Health*, among many others.

8. I am the recipient of numerous honors, including the Vittinghoff Innovation Award for Methodological Innovation and Excellence from the University of California, San Francisco, the Outstanding Young Investigator Award from the North American Forum on Family Planning, and the Soroptimist Award for Women in Science.

9. I have been funded on multiple NIH awards as a PI, and my research has also been funded through grants from the American College of Obstetrics and Gynecology (ACOG) Foundation, the Society of Family Planning, the David & Lucile Packard Foundation, among others organizations.

10. The process for applying for an NIH grant is laborious and preparation of the application can take years and almost universally requires extensive evening and weekend hours. I first began preparation for the grant at issue in September 2022, and it took 13 months from that point to draft the full grant application which we submitted on October 31, 2024. To develop the grant application, we had to have a full study design in place with contingencies, a detailed budget projected over five years, and letters of support from over a dozen community partners who pledged to work with us on the grant—with funding agreements worked out in advance for each of them as well. This experience is consistent with typical NIH application development, which involves conceptualization, relationship building, study design, drafting, multiple expert consultation, and an iterative process of review and revision. Proposals often exceed 200 pages and must make a compelling case that the health issue being studied is urgent and scientifically significant. As applicants, we must prove that our proposed methods are the best possible approach to address the research question. We must also demonstrate that our team is uniquely qualified to achieve the proposed aims. Every application undergoes rigorous peer review by experts, and funding rates are low.

11. Ibis is a plaintiff in the lawsuit *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787 (D. Mass.). In March 2025, NIH terminated two grants on which I served as the PI, a research grant entitled "*Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality*" and a grant providing supplemental funding for that award. Both terminations were vacated as a result of that lawsuit. The grant discussed in this declaration is separate from the grants that were at issue in that lawsuit.

12. I am currently a Multiple PI ("MPI") on an NIH grant from the National Institute of Child Health and Human Development ("NICHD") entitled "*Time Sensitive Research on Barriers to Pregnancy Care*." Under an MPI model, two or more individuals are listed as co-equal PIs on a grant, with equal scientific authority, fiscal accountability, and administrative responsibility for the project. I conceptualized, designed, and drafted this grant application with my MPI at Indiana University. We pursued this model because we recognized that the research project's success hinges upon the blend of distinct and complementary epidemiological and clinical expertise and experience that we bring. Further, we had a history of co-leadership of research in the Midwest on abortion access that prepared us well for this next study.

13. The primary institutional grantee for the award is Indiana University, and Ibis is a sub-awardee. Institutional grantees are the entities that host the research and receive the NIH award and funding, and are generally universities, hospitals, and sometimes non-profits and other entities. Awards also name one or more PIs, who are researchers directly responsible for proposing the projects, overseeing the design and implementation of studies, and managing the research from the application stage through the end of a grant. Under this arrangement, Indiana University transfers a pre-specified amount of the award to Ibis for research staff time, participant remuneration, and other costs detailed in the NIH-reviewed grant application. On a day-to-day basis, I work closely with my MPI at Indiana University through weekly meetings with the full team, as well as multiple 1:1 meetings between the two of us to move the work forward. We work closely together, with frequent communication—similar to if we were at the same institution.

14. The grant number was originally funded as a one-year research project under grant number R61HD116143, with a project term of August 20, 2024–July 31, 2025.

15. Attached hereto as **Exhibit 1** is a true and correct copy of the R61 grant's Notice of Award (i.e., "NOA").

16. The R61 mechanism is a bi-phased grant award that is milestone-driven, and combines two distinct phases of funding into a single application and review cycle to accelerate time sensitive research. The initial R61 phase lasts for 12 months, and if the milestones are successfully met and funds are available, the grant transitions to the R33 phase for an additional four years. The specific call for proposals under which this grant was awarded was PAR-22-233 that aimed to fund research designed to evaluate the impact of unexpected or sudden legal/policy changes, large-scale infrastructure shifts, or major environmental/public health events.

17. The grant awarded was originally titled "*Conducting time-sensitive research on barriers to pregnancy care following policy shifts in the Midwest: The Pathways Study.*" A panel of expert reviewers scored the proposal in the top 5 percent of all submitted grants during that application review cycle, and provided feedback that the research was likely to have a "high impact on the field of reproductive health science and likely to inform geography-specific interventions to address urgent access challenges in the Midwest." Additionally, reviewers noted "the critical nature of the data being collected to identify the impact of bans on millions of Americans" and "the outstanding multidisciplinary team, excellent pilot data to support feasibility of approach, and rigorous mixed methods approach to answering the research objectives."

18. As originally awarded, the project involved a mixed-methods study to examine the barriers to abortion care faced by pregnant Midwesterners following the June 2022 Supreme Court opinion in *Dobbs v. Jackson Women's Health* and the passage of abortion bans in multiple Midwestern states, and the longitudinal impact of those barriers on pregnancy and other physical, mental, and financial health outcomes. To understand the barriers faced by pregnant people seeking abortion in the Midwest amidst these rapidly changing political shocks and to quantify the impact of these restrictions on their health and lives, unbiased, locally relevant data were urgently needed. Yet, most abortion access research had recruited participants from clinics—participants who, by virtue of having gotten to an abortion clinic, represent a population that was able to overcome many barriers to care, and further, excludes people who use telemedicine or self-manage their abortions, and those who continue their

pregnancies. A clinic-based sampling mechanism thus induces selection bias, resulting in research that misses or underestimates barriers to care. To address these methodological limitations, our research sought to (1) expand recruitment to the full population of people seeking abortion, not just those who make it to a clinic, (2) sensitively measure barriers and facilitators to abortion care, (3) capture the full set of possible pregnancy pathways (including miscarriage, birth, clinical abortion, telemedicine abortion, self-managed abortion) and their sequelae over time, and (4) ensure data were sufficiently powered to answer nuanced questions at the regional level. To address this time-sensitive need in an underserved region, we proposed four linked aims in a two-phase study. In the first six months of the R61, we would recruit 500 pregnant people searching for information about abortion online to identify via surveys and characterize via in-depth interviews the barriers people face while seeking abortion in all 12 Midwest states. In the second (R33) phase of the study, we would follow these participants forward in time with additional surveys at 4 and 10 months to measure who succeeded in obtaining abortion and who did not, and the implications of their pregnancy outcome on broader physical, mental, and socioeconomic health outcomes across restrictive versus permissive states. Finally, we would implement a human-centered design approach to engage abortion fund leaders and Midwesterners who had sought abortions to develop and test messages to address knowledge barriers or belief gaps identified in the R61 phase that limit access to abortion. Findings from this study would drive more informed, geography-specific interventions to address urgent access challenges in the Midwest.

19. On May 30, 2025, at the requested date of two months before the end of our R61 award year, we submitted a progress report to the NICHD to document the activities during the award year and progress toward our R61 goals and milestones. This progress report was a necessary step to transition the grant from the R61 phase to the R33 phase. In the report, we detailed grant activities and noted that we had met or exceeded all R61 phase milestones. To transition from the R61 to R33 phase, the NIH staff must determine that the awardees achieved the R61 goals and milestones, review and approve the transition application package, and confirm availability of funds. My understanding is that the approval process for transitioning the grant from an R61 to an R33 historically does not involve renegotiation of the aims or language describing the research.

20. In that first year of the grant, we met and exceeded all the goals and milestones we set out for the R61 year. Specifically, our goals were: (1) to collect baseline survey data from 500 pregnant Midwesterners about experiences seeking abortion care (at the time of the progress report, we had data from 582 pregnant Midwesterners); (2) to conduct 30 in-depth interviews with abortion-seekers to characterize barriers to pregnancy-related care (at the time of the progress report, we had 38 in-depth interviews complete); (3) to have professionally transcribed all interview audio recordings and have developed a codebook for analysis of the interviews (both completed); and (4) to have conducted preliminary quantitative analysis of barriers to pregnancy-related care in the Midwest. Each of these goals was achieved and clearly detailed in the progress report.

21. Presenting at conferences and publishing articles are both core activities for scientists and necessary for the fulfillment of the aims of a research grant. Both are standard ways that researchers share their work with subject matter experts and obtain peer review and feedback, allowing for an iterative process to refine analyses and findings, address gaps, and ensure scientific rigor. Given the focus of the award on rapid research in the wake of time-sensitive changes, we focused particularly intensely throughout the award in identifying opportunities to share findings, even if preliminary, with relevant audiences.

22. In October 2024, myself and one other member of the research team presented preliminary learnings from the study regarding online survey recruitment to a large, national conference. Topics included sharing best practices for implementing our online recruitment methodology in a shifting and uncertain policy environment, with implications for other researchers studying policy shifts. Additionally, the research team submitted four research abstracts and one workshop session to the Society of Family Planning Annual Meeting to share key findings from the surveys and interviews collected in the R61 phase. We were selected for the workshop, and were able to host an entire 75-minute session on preliminary findings from the study to an audience of several hundred family planning researchers, clinicians, and advocates. We continue to work with our advisory board partners to identify the most impactful ways of safely sharing study data with pregnant Midwesterners as well, as they navigate their options for care. Four peer-reviewed publications from the full study dataset are now underway.

23. Instead of the process that—to my understanding—would historically have occurred to transition us from the R61 to R33 phase focusing only on the progress we made towards the aims of our grant and availability of funds, we were requested to make "clarifications" to the public facing language in our aims and abstract. On August 28, 2025, almost two months after funding had lapsed on the R61, NIH notified us that it had finished reviewing our transition application and was requesting clarifications to the public facing language "to eliminate any confusion about our project's alignment with priorities." The suggested clarifications included removing the word "abortion", changing "policy restrictions" to "policy changes", as well as changing "pregnant people" to "pregnant women", among other suggestions. We were told we could accept or reject the suggested edits, but that our final revisions were needed by the next day, and my understanding was that if we did not comply with the requested changes the grant would not be funded. At the time these changes were requested, the NIH had already terminated an R01 on which I was PI – hence, the threat of termination did not feel abstract, but very real and present.

24. Changing the language in our grant in the manner required by NIH was not an easy decision. It felt clear that this was an attempt to censor the word "abortion" from active NIH grants, to diminish the harm of abortion-related restrictions, and to minimize or erase the existence of pregnant people who identify as transgender men or other gender diverse identities other than "pregnant women". The requests had nothing to do with the scientific methods, activities, or rigor of the research – they only served to make the study aims and focus less clear. However, given the delay in approval of our R33 transition application, and that we were already almost two months into unfunded territory with nowhere to charge staff salaries for their time on this study, we felt pressured to accept the changes, or risk not being awarded the R33. After much discussion as a team, we decided a greater harm would be to lose the funding and not be able to complete the research we and hundreds of study subjects had already put so much into—so we accepted the suggested edits and submitted it back to the NIH the following day, as requested, in the hopes it would protect our grant from being terminated. This decision process required multiple conversations, much confusion, uncertainty, and anxiety, and ultimately many hours of staff time that could have instead been devoted to the research.

25. Nevertheless, on September 2, 2025 (about 4 business days after submitting the revised public facing documents), the transition to the R33 phase of the project was finally approved with the first year of the R33 running until May 31, 2026.

26. Attached hereto as **Exhibit 2** is a true and correct copy of the R33 grant's NOA.

27. Since the budget period for the second year of the grant was truncated and set to run from September 10, 2025 to May 31, 2026, on April 15, 2026, Indiana University submitted our required Research Performance Progress Report ("RPPR") necessary for non-competitive renewal. The RPPR is a standardized progress report that NIH grantees must submit every year, six weeks prior to the end of the grant period, to document project accomplishments (milestones, publications, presentations, etc.), challenges, compliance, and financial status, as well as plans for the year ahead. Additionally, RPPRs include a section to report on the project participants—both the study team, as well as research subjects. My understanding, informed by my prior experience as well as conversations and guidance from colleagues, is that the RPPR is used to help the investigator(s) communicate to the program officer and larger NIH staff how the research project is progressing against stated goals. For a grant governed by the Standard Noncompeting Award Process ("SNAP") as mine is, my understanding is that the annual review is never grounds for termination or non-renewal, except for the extremely rare event when an investigator fails to comply with the terms of the award, is guilty of scientific misconduct, or when a project is no longer viable. None of those conditions were true for our grant. All to say, we did not expect to be asked to censor the language in our peer-reviewed, highly scored, and funded grant for which we had met and exceeded all milestones.

28. Instead of receiving the NOA for the third year of the grant in a timely fashion (the second year of the R33 phase), the budget end date passed without word from NIH on renewal. For weeks, we received no NOA and no explanation for the delay.

29. However, upon inquiring in July 2026 about the approximately 2 month delay in our grant, we received an email from the program officer stating that the award "appears to have been stopped after release by the Office of Extramural Research, but we have not yet received information as to why."

30. Attached hereto as **Exhibit 3** is a true and correct copy of the email we received.

31. Two weeks later, the program officer emailed us to say that the Office of Extramural Research provided feedback stating "This grant's public-facing documents were clearly written to obscure what it is about. Please work with the grantee to clarify what the researchers are studying and what interventions could be informed by the work that could be conducted by the healthcare system, as opposed to through legislative changes. If the only possible impactful intervention would be legislation, it is not in the mission of the NIH." (emphasis in original).

32. Attached hereto as **Exhibit 4** is a true and correct copy of the follow up email we received.

33. I was confused that NIH would object to language in my grant as being too vague after having pressured me to adopt the vaguer language months prior. I immediately felt nervous that we were caught in some form of procedural trap, but that if we failed to comply, the NIH might terminate our grant. Again, this fear of termination was very real for me, as the NIH had terminated another of my grants just last year.

34. I was also perplexed and confused about the language in the email regarding legislative changes. The call for proposals to which I applied specifically requested research documenting the impact of policy or legislative changes, so I did not understand how or why I was meant to describe our research project without using the words from the funding mechanism. I spoke with my program officer, who informed me that NIH was raising new objections to research that was thought to relate to public policy. She expressed concern that if I did not revise my grant description and aims to remove references to public policy, the grant would likely be terminated.

35. While researchers cannot control the uses of their research findings once published, and thus any research may ultimately have legislative impact, my work is fundamentally about public health and public health interventions. In addition, I am aware that NIH funds many R01s in a host of areas that impact policies at all levels of governance, from hospital policies to national and international guidelines, so my sense is that NIH is selectively applying this new objection to grants thought to influence public policy to research that it otherwise disfavors. Indeed, the very program announcement (PA-22-233) that funded my award specifically identified policymakers as a target audience – stating

that the findings from the research should maximize "learning opportunities to better inform health care and public health efforts, as well as policymakers."

36. Yet again, it was a difficult decision to decide if and how to comply with the requests from the NIH/OER regarding the public facing language of our grant. The requests were not based on scientific value, integrity, or clarity. Instead, the NIH requests felt designed to obfuscate the intention and aims of our research study—particularly to diminish the centrality of abortion policy and its impact on public health—to serve agency censorship policies while adding no value or rigor to the research itself. The NIH had not identified any limitations or critiques of our scientific methods, and is instead censoring how we described the goals and focus. Myself, my colleagues at Ibis and Indiana University, and others exhausted much staff time on deliberating these changes, making them, and proceeding in an iterative process until the changes were deemed acceptable. This was distressing, confusing, and overshadowed throughout by a fear of termination if we failed to comply—and at the same time, concern that by complying we may also somehow be making our grant more vulnerable, all for a grant that is noncompeting and should not have been renegotiated at all.

37. After weeks of uncertainty and fear that the grant would be terminated, on September 2, 2026, NIH issued the NOA for the third year of our award.

38. Attached hereto as **Exhibit 5** is a true and correct copy of the R33 grant's NOA for the third year.

39. While the award was issued, I continue to fear that the grant will be terminated. Since NIH has now forced us to go through multiple rounds of revision on this grant, each time threatening to terminate the grant if we do not comply, I am worried that NIH will initiate yet another forced revision process or even suddenly summarily terminate the grant as they did in 2025 with another Ibis grant on which I am PI and as I know has happened to many other researchers. The constant threat of termination has enormous repercussions for the research. My research team and I feel constant stress and anxiety about whether the funds for our salaries will be suddenly and capriciously terminated, and uncertain how to advise my existing research team members, for fear that there will be a termination and I will have to suddenly let them go. We feel unable to plan for future team meetings and conference presentations due

to the uncertainty imposed by the threat of termination, and we are worried that speaking up about this experience will threaten our ability to conduct research in the future.

40. In addition, the third year NOA included a term that states, "SPECIAL TERM AND CONDITION: The recipient has revised the Abstract, Public Health Relevance Statement, and Specific Aims to ensure alignment with current agency priorities in [Training future biomedical scientists and/or Promoting research focused on scientifically valid, measurable health outcomes]. The project must be carried out in accordance with the revised plan/section submitted on DATE, which reflects the agreed upon updates. In accordance with this renegotiation, NIH funds may only be used to support activities within the revised scope of the award as described in the documents dated 08/10/2026. NIH funds may not be used to support activities that are not consistent with the revised scope of the award."

41. I am fearful that NIH will terminate my funding if I speak or write about my work or present my findings in ways that differ from the language that NIH required us to adopt.

42. NIH funding is critical to my ability to conduct research at Ibis. But in light of NIH's current censorship policies requiring me to obfuscate my research, and given my recent prior experiences with grant termination and the constant ongoing threat of termination over the last year and a half, I have for now halted putting together new applications to NIH that I would otherwise have pursued. Preparing an NIH application is a laborious process, and NIH's actions have led me to believe that the applications to NIH would likely be denied irrespective of scientific merit or would require me to describe my research in ways that are vague and inaccurate in order to pass through NIH's screens for disfavored research. That has an enormous impact on my ability to move forward with critical research or to build on the findings of this research in the most impactful way, which ultimately has a detrimental impact on public health.

43. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

44. I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at San Francisco California this 15 day of September 2026.



Heidi Moseson

Exhibit 1

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R61HD116143
Federal Award Date
08/19/2024

Recipient Information

1. Recipient Name
TRUSTEES OF INDIANA UNIVERSITY
980 INDIANA AVE RM 2232
INDIANAPOLIS, IN 46202

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1356001673A1

4. Employer Identification Number (EIN)
356001673

5. Data Universal Numbering System (DUNS)
603007902

6. Recipient's Unique Entity Identifier
SHHBRBAPSM35

7. Project Director or Principal Investigator
Tracey Wilkinson, MD (Contact)

tracwilk@iu.edu
317-278-0552

8. Authorized Official
Mr. Steven Allen Martin

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(201) 780-0309

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
1R61HD116143-01

12. Unique Federal Award Identification Number (FAIN)
R61HD116143

13. Statutory Authority
42 USC 241 42 CFR PART 52

14. Federal Award Project Title
Time sensitive research on barriers to pregnancy care

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/20/2024 **– End Date** 07/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$436,905
20 a. Direct Cost Amount	$360,681
20 b. Indirect Cost Amount	$76,224
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$436,905
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$436,905
26. Project Period Start Date 08/20/2024 **– End Date** 07/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$436,905

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Mahasin Ingram

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:25 - 2/15/2024 9:51 AM | Generated on: 8/19/2024 12:16 AM

Notice of Award

Phase 1 Exploratory/Developmental Grant
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R61HD116143-01

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD
Tracey Wilkinson (contact), MD

Award e-mailed to: iuaward+iui@iu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $436,905 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Trustees of Indiana University in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R61HD116143. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Mahasin Ingram
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$58,274
Fringe Benefits	$12,839
Personnel Costs (Subtotal)	$71,113
Travel	$3,225
Other	$30,960
Subawards/Consortium/Contractual Costs	$255,383
Federal Direct Costs	$360,681
Federal F&A Costs	$76,224
Approved Budget	$436,905
Total Amount of Federal Funds Authorized (Federal Share)	$436,905
TOTAL FEDERAL AWARD AMOUNT	$436,905
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$436,905

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$436,905	$436,905

Fiscal Information:
Payment System Identifier: 1356001673A1
Document Number: RHD116143A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	$436,905

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41021 / **Released**: 08/15/2024
Award Processed: 08/19/2024 12:16:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R61HD116143-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R61HD116143-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to

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report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R61HD116143. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R61HD116143-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: This award is being made without a currently valid certification of Institutional Review Board (IRB) approval consistent with 45 CFR Part 46 and is issued with the following restriction [for these studies]: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of IRB approval certification. No funds may be drawn down from the Payment Management System and no obligations may be made against Federal funds for any research involving human subjects prior to issuance of a revised Notice of Award rescinding this restriction.

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IRB approval verification must be submitted within **60 days** of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

REDUCTION: In order to meet NICHD program objectives within FY2024 budget constraints, this grant is reduced **14** percent below the level recommended by the Integrated Review Group. Future year levels of support are determined by applying the same administrative reduction.

DELAYED START DATE: This award includes funds for twelve months of support but is awarded for less than twelve months.

DATA MANAGEMENT AND SHARING: Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the application dated 10/312023.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

SUBPROJECT: Subproject funding information is available via the NIH RePORTER System.

TRANSITION: In accordance with PAR-22-233**,** funding for the **R33** phase of this award will be is contingent upon (1) determination that the **R61** goals and milestones were achieved; (2) review and approval of the transition application package; and (3) availability of funds.

The following documentation/information must be provided in the **R33** transition application:

1. Detailed categorical budget and justification for each year of the **R33** phase. Total direct costs cannot exceed the competing application requested amounts or the Integrated Review Group recommended funding levels, if applicable.
2. Milestones section identifying the approved **R61** milestones and the progress towards meetings those milestones.
3. One-page abstract describing the **R33** phase research plan. State if the originally approved aims have been modified or remain the same. If modified, provide a justification for the modifications.

These components are required two months prior to the anticipated start of the **R33** phase. The report should be sent as a single pdf attachment to the Grants Management Specialist and Program Official indicated on this Notice of Award using the PHS 2590 format. The report must be approved by the institutional Signing Official.

The appropriate NICHD Grants Management and Program staff will review the **R33** transition application. If the transition request is not approved, written notification will be sent to the applicant.

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1
DMS Costs	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R61HD116143-01

INSTITUTION: Trustees of Indiana University

Budget	Year 1
Salaries and Wages	$58,274
Fringe Benefits	$12,839
Personnel Costs (Subtotal)	$71,113
Travel	$3,225
Other	$30,960
Subawards/Consortium/Contractual Costs	$255,383
TOTAL FEDERAL DC	$360,681
TOTAL FEDERAL F&A	$76,224
TOTAL COST	$436,905

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	58.5%
F&A Cost Base 1	$130,298
F&A Costs 1	$76,224

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Exhibit 2

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R33HD116143
Federal Award Date
09/10/2025

Recipient Information

1. Recipient Name
TRUSTEES OF INDIANA UNIVERSITY
980 INDIANA AVE RM 2232
INDIANAPOLIS, IN 46202

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1356001673A1

4. Employer Identification Number (EIN)
356001673

5. Data Universal Numbering System (DUNS)
603007902

6. Recipient's Unique Entity Identifier
SHHBRBAPSM35

7. Project Director or Principal Investigator
Tracey Wilkinson, MD (Contact)

tracwilk@iu.edu
317-278-0552

8. Authorized Official
Mr. Steven Allen Martin

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(201) 780-0309

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
4R33HD116143-02

12. Unique Federal Award Identification Number (FAIN)
R33HD116143

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Time sensitive research on barriers to pregnancy care

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Extension with or without funds

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/10/2025 **– End Date** 05/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$481,641
20 a. Direct Cost Amount	$381,714
20 b. Indirect Cost Amount	$99,927
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$481,641
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$481,641
26. Project Period Start Date 08/20/2024 **– End Date** 05/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$481,641

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Mahasin Ingram

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

EXPLORATORY DEVELOPMENT AWARD
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 4R33HD116143-02

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD
Tracey Wilkinson (contact), MD

Award e-mailed to: iuaward+iui@iu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $481,641 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Trustees of Indiana University in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R33HD116143. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Mahasin Ingram
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$65,337
Fringe Benefits	$15,379
Personnel Costs (Subtotal)	$80,716
Travel	$23,865
Other	$62,734
Subawards/Consortium/Contractual Costs	$214,399
Federal Direct Costs	$381,714
Federal F&A Costs	$99,927
Approved Budget	$481,641
Total Amount of Federal Funds Authorized (Federal Share)	$481,641
TOTAL FEDERAL AWARD AMOUNT	$481,641
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$481,641

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$481,641	$481,641
3	$427,161	$427,161
4	$498,724	$498,724
5	$448,362	$448,362

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1356001673A1
Document Number:	RHD116143B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025	2026	2027	2028
HD	8014702	$481,641	$427,161	$498,724	$448,362

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41025 / **Released**: 09/09/2025
Award Processed: 09/15/2025 05:21:06 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 4R33HD116143-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 4R33HD116143-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R33HD116143. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-

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discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 4R33HD116143-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

ESCALATION: In accordance with FY2025 NICHD fiscal policy, escalation on recurring costs has been removed.

RECYCLING: This award includes funds for twelve months of support but is awarded for less than twelve months. Noncompeting Continuation awards will cycle on **06/01.** NICHD is taking this action to redistribute start dates more evenly throughout the fiscal year.

FUNDING: In order to meet NICHD program objectives within FY2025 budget constraints, this grant is reduced **14** percent below the level recommended by the Integrated Review Group. Future year levels of support are determined by applying the same administrative reduction.

DATA MANAGEMENT AND SHARING: Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the application dated 10/312023.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

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SUBPROJECT: Subproject funding information is available via the NIH RePORTER System.

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 10/31/2023, and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 4R33HD116143-02

INSTITUTION: Trustees of Indiana University

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$65,337	$65,337	$65,337	$65,337
Fringe Benefits	$15,379	$15,379	$15,379	$15,379
Personnel Costs (Subtotal)	$80,716	$80,716	$80,716	$80,716
Travel	$23,865	$3,225	$3,225	$3,225
Other	$62,734	$62,734	$105,734	$73,960
Subawards/Consortium/Contractual Costs	$214,399	$194,681	$194,681	$194,681
Publication Costs			$2,150	$2,150
TOTAL FEDERAL DC	$381,714	$341,356	$386,506	$354,732
TOTAL FEDERAL F&A	$99,927	$85,805	$112,218	$93,630
TOTAL COST	$481,641	$427,161	$498,724	$448,362

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	58.5%	58.5%	58.5%	58.5%
F&A Cost Base 1	$170,815	$146,675	$191,825	$160,051
F&A Costs 1	$99,927	$85,805	$112,218	$93,630

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Exhibit 3

Outlook

Fw: Checking-In

From Heidi Moseson <hmoseson@ibisreproductivehealth.org>
Date Fri 9/18/2026 4:41 PM
To Olga Akselrod <oakselrod@aclu.org>

This Message Is From an External Sender
This message came from outside your organization.

From: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>
Sent: Wednesday, July 15, 2026 2:58 PM
To: tracwilk@iu.edu <tracwilk@iu.edu>
Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>; McCall, Mahasin (NIH/NICHD) [E] <mahasin.ingram@nih.gov>
Subject: RE: Checking-In

Hi Tracey and Heidi,

We are looking into this. It appears to have been stopped after release by the Office of Extramural Research, but we have not yet received information as to why.

Thanks for your patience,

Ronna

Ronna Popkin, PhD
Program Officer, Population Dynamics Branch
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6710B Rockledge/Rm 2209B
Office Phone: 301-827-5121
Mobile Phone: 301-646-8379
ronna.popkin@nih.gov

From: Wilkinson, Tracey Allyson <tracwilk@iu.edu>
Sent: Wednesday, July 15, 2026 1:47 PM
To: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>
Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>; McCall, Mahasin (NIH/NICHD) [E] <mahasin.ingram@nih.gov>
Subject: [EXTERNAL] Re: Checking-In

Dear Ronna-

Hello from Indiana—where it is HOT today! I am currently digging out of my InBox after being OOO for a bit and wanted to quickly reach out and see if you had any updates with regard to our R33 grant. I logged into eRA recently and saw that there was a "pending" listed under Application Status from 6/23 and so was hoping you may have an update on your end! Looking forward to hearing from you!

Sincerely
Tracey

Tracey A. Wilkinson, MD, MPH | Indiana University School of Medicine
Associate Professor of Pediatrics and Obstetrics & Gynecology
317-278-0552 | tracwilk@iu.edu | Schedule a virtual meeting

From: Wilkinson, Tracey Allyson <tracwilk@iu.edu>
Date: Thursday, June 25, 2026 at 3:00 PM
To: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>
Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>
Subject: Re: Checking-In

Dear Ronna-

Hello! I hope you are having a wonderful summer so far! I wanted to quickly reach out to you regarding our RPPR and see if you had any updates from your end! I know my previous email landed when you were out-of-office, so I wanted to quickly send another with the hope you may have recovered from a deep, deep InBox 😊

Sincerely
Tracey

Tracey A. Wilkinson, MD, MPH | Indiana University School of Medicine
Associate Professor of Pediatrics and Obstetrics & Gynecology
317-278-0552 | tracwilk@iu.edu | Schedule a virtual meeting

From: Wilkinson, Tracey Allyson <tracwilk@iu.edu>
Date: Wednesday, June 3, 2026 at 12:58 PM
To: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>
Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>
Subject: Checking-In

Dear Ronna-

Hello! I hope this email finds you doing well! We wanted to quickly email you to see if you had any updates on our recent RPPR that was submitted for R33HD116143-03. We realize that this is an incredibly busy time of year, but would love any updates you may have as the fiscal year started on 6/1/26. Thanks and hope to see you at SFP this fall in-person if not sooner!

Sincerely
Tracey & Heidi

Tracey A. Wilkinson, MD, MPH | Indiana University School of Medicine
Associate Professor of Pediatrics and Obstetrics & Gynecology
317-278-0552 | tracwilk@iu.edu | Schedule a virtual meeting

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Exhibit 4

Outlook

Fw: Clarifications to the Abstract, Aims, and Narrative for 5R33HD116143-03 (PI: Wilkinson)

From Heidi Moseson <hmoseson@ibisreproductivehealth.org>
Date Fri 9/18/2026 4:41 PM
To Olga Akselrod <oakselrod@aclu.org>

This Message Is From an External Sender
This message came from outside your organization.

From: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>
Sent: Friday, July 31, 2026 3:06 PM
To: tracwilk@iu.edu <tracwilk@iu.edu>; Heidi Moseson <hmoseson@ibisreproductivehealth.org>
Cc: jambecke@iu.edu <jambecke@iu.edu>; NICHD HD eRA Notifications (NIH/NICHD) <hderanotifications@mail.nih.gov>; McCall, Mahasin (NIH/NICHD) [E] <mahasin.ingram@nih.gov>
Subject: Clarifications to the Abstract, Aims, and Narrative for 5R33HD116143-03 (PI: Wilkinson)

Dear Tracey and Heidi,

The NIH Office of Extramural Research returned this project to us with the following feedback:

> "This grant's public-facing documents were clearly written to obscure what it is about. Please work with the grantee to clarify what the researchers are studying and what interventions could be informed by the work that could be conducted by the healthcare system, as opposed to through legislative changes. If the only possible impactful intervention would be legislation, it is not in the mission of the NIH."

My suggestion is to revise your Aims, Abstract, and Public Health Relevance/Project Narrative to more clearly convey that the project is investigating how changes in access to abortion care have impacted the health of pregnant women, to include a hard-to-reach and relatively understudied population of pregnant women (women seeking medication abortion outside of the clinic), and that the goal in Aim 3 is quite clearly NOT to change laws/policies but rather to optimize care for women across the Midwest regardless of their policy environment. Also, I have approved some changes to the approach given the issues you all faced in data collection. Please revise the documents to reflect those changes—you do not need to refer to the original design. Describe what you actually did in the R61 and what you are doing now in the R33, and be sure to underscore how the findings from this project will be able to inform and impact future *clinical care and interventions*. Thanks!

Please have your signing official email to Mahasin revised versions of your summary documents (NO tracked changes or references, please!) using the attached Word document template, cc'ing you and me. Please be sure it is emailed as a Word attachment and not a PDF.

Once the revisions are emailed to Mahasin, I will review and either approve or recommend additional clarifications. Thanks for your patience as we awaited feedback from OER on your project and thanks in advance for addressing these comments promptly. I will be out of the office Monday 8/3 – Wednesday 8/5, but if you complete the changes before then, please have your SO email them so I can review as soon as I'm back.

Thanks!

Ronna

Ronna Popkin, PhD
Program Officer, Population Dynamics Branch
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6710B Rockledge/Rm 2209B
Office Phone: 301-827-5121
Mobile Phone: 301-646-8379
ronna.popkin@nih.gov

Exhibit 5

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R33HD116143
Federal Award Date
09/02/2026

Recipient Information

1. Recipient Name
TRUSTEES OF INDIANA UNIVERSITY
980 INDIANA AVE RM 2232
INDIANAPOLIS, IN 46202

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1356001673A1

4. Employer Identification Number (EIN)
356001673

5. Data Universal Numbering System (DUNS)
603007902

6. Recipient's Unique Entity Identifier
SHHBRBAPSM35

7. Project Director or Principal Investigator
Tracey Wilkinson, MD (Contact)
Associate Professor
tracwilk@iu.edu
317-278-0552

8. Authorized Official
James P Becker

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(301) 480-7460

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
5R33HD116143-03

12. Unique Federal Award Identification Number (FAIN)
R33HD116143

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Time sensitive research on barriers to pregnancy care

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2026 **– End Date** 05/31/2027	
20. Total Amount of Federal Funds Obligated by this Action	$427,161
20 a. Direct Cost Amount	$341,356
20 b. Indirect Cost Amount	$85,805
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$427,161
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$427,161
26. Project Period Start Date 08/20/2024 **– End Date** 05/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$908,802

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Mahasin Ingram

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

EXPLORATORY DEVELOPMENT AWARD
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R33HD116143-03

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD
Tracey Wilkinson (contact), MD

Award e-mailed to: iuaward@iu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $427,161 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Trustees of Indiana University in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R33HD116143. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Mahasin Ingram
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$65,337
Fringe Benefits	$15,379
Personnel Costs (Subtotal)	$80,716
Travel	$3,225
Other	$62,734
Subawards/Consortium/Contractual Costs	$194,681
Federal Direct Costs	$341,356
Federal F&A Costs	$85,805
Approved Budget	$427,161
Total Amount of Federal Funds Authorized (Federal Share)	$427,161
TOTAL FEDERAL AWARD AMOUNT	$427,161
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$427,161

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$427,161	$427,161
4	$498,724	$498,724
5	$448,362	$448,362

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1356001673A1
Document Number:	RHD116143B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2026

IC	CAN	2026	2027	2028
HD	8014702	$427,161	$498,724	$448,362

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41025 / **Released**: 08/24/2026
Award Processed: 09/02/2026 12:18:54 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R33HD116143-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R33HD116143-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R33HD116143. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R33HD116143-03

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

SPECIAL TERM AND CONDITION: The recipient has revised the Abstract, Public Health Relevance Statement, and Specific Aims to ensure alignment with current agency priorities in [Training future biomedical scientists and/or Promoting research focused on scientifically valid, measurable health outcomes]. The project must be carried out in accordance with the revised plan/section submitted on DATE, which reflects the agreed upon updates. In accordance with this renegotiation, NIH funds may only be used

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to support activities within the revised scope of the award as described in the documents dated 08/10/2026. NIH funds may not be used to support activities that are not consistent with the revised scope of the award.

DATA MANAGEMENT AND SHARING: Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the application dated 10/312023.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single-site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

CONSORTIUM: This award includes funds awarded for consortium activity with Ibis Reproductive Health, INC.

SUBPROJECT: Subproject funding information is available via the NIH RePORTER System**.**

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 10/31/2023, and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R33HD116143-03

INSTITUTION: Trustees of Indiana University

Budget	Year 3	Year 4	Year 5
Salaries and Wages	$65,337	$65,337	$65,337
Fringe Benefits	$15,379	$15,379	$15,379
Personnel Costs (Subtotal)	$80,716	$80,716	$80,716
Travel	$3,225	$3,225	$3,225
Other	$62,734	$105,734	$73,960
Subawards/Consortium/Contractual Costs	$194,681	$194,681	$194,681
Publication Costs		$2,150	$2,150
TOTAL FEDERAL DC	$341,356	$386,506	$354,732
TOTAL FEDERAL F&A	$85,805	$112,218	$93,630
TOTAL COST	$427,161	$498,724	$448,362

Facilities and Administrative	Year 3	Year 4	Year 5

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/2/2026 12:18 AM

Costs			
F&A Cost Rate 1	58.5%	58.5%	58.5%
F&A Cost Base 1	$146,675	$191,825	$160,051
F&A Costs 1	$85,805	$112,218	$93,630

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/2/2026 12:18 AM

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF JADE PAGKAS-BATHER

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Jade Pagkas-Bather, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Jade Pagkas-Bather. I am an Assistant Professor in the Infectious Disease and Global Health section of the Department of Medicine at the University of Chicago. I also serve as the Director of the Mother and Child Alliance at the University of Chicago.

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I am an infectious disease specialist and HIV preventionist. Specifically, my work examines novel HIV prevention methods among sexual and gender minorities, people who are low income, as well as structural interventions for HIV treatment and prevention.

5. I earned my B.A. from Yale University in Anthropology and M.D. from the University of Illinois College of Medicine. Additionally, I completed my residency in internal medicine at MacNeal Hospital and a fellowship in infectious disease at the University of Washington and earned my M.P.H. in epidemiology from the University of Washington School of Public Health.

6. I have published widely in my field, including in: *Lancet HIV, Nature Mental Health, Journal of Acquired Immune Deficiency Syndromes*, *International Journal of STD & AIDS*, and *Current HIV/AIDS Reports*.

7. Throughout my career I have earned multiple awards including: a Third Coast Center for AIDS Research (TC-CFAR) pilot award, a Bucksbaum pilot award, and a Gilead HIV Research Scholars award. I have also been inaugurated as the first recipient of the EmpowerMED award at The University of Chicago, and been a faculty fellow at the Neubauer Collegium for Culture & Society.

8. My institutions have received multiple NIH grants for which I am the principal or multiple principal investigator including:

- Basic Income Guarantee Chicago: A Trial of Basic Income Guarantee for Young People Living with HIV (R01MH140688).
- Chicago One Step PrEP: Examining the Acceptability, Feasibility, and Appropriateness of Pharmacy-led PrEP (P30AI117943).

- Examining the association between sleep quality and PrEP adherence among Black MSM (1L60MD015518-01).
- Determine acceptability of Black and Latinx MSM towards a PrEP peer navigator in western Washington (5T32AI007044-42).

9. I work at the nexus of social and structural determinants of health for people with HIV or those vulnerable to HIV who have been multiply marginalized (racially, sexually, socially). My clinical work and research indicate that people who are racially/and or sexually minoritized are more vulnerable to infectious diseases such as HIV and other STIs, as well as poor overall health, given their poor social determinants of health. People who are multiply minoritized are more likely to experience poverty and have less access to healthy food, transportation, a safe built environment, and other health-promoting resources.

10. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals are lengthy and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money—it indicates a project's scientific importance, methodological rigor, and real-world potential to improve public health.

11. In 2024, I submitted a NIH grant application to the National Institute of Mental Health as a multiple principal investigator for an R01 grant seeking to examine the impact of basic income guarantee (BIG) on young people with HIV. The hypothesis was that by providing a basic income, we could potentially improve people with HIV's social determinants of health. Young people with HIV experience many social determinants of health such as poverty, racism, and homophobia, that may be obstacles to clinical care engagement and viral suppression. Concomitantly, I spearheaded a pilot program doing this type of work on a smaller scale. We submitted our proposal in September 2024 and scored at the 15th percentile, which was near the cutoff for funding.

12. In the summer of 2025, at the instruction of my NIH program officer, I removed terminology relating to race and gender from the specific aims page, narrative, abstract, and approach section of the grant. This language included a clause about how Black and Latinx people with HIV experience higher rates of poverty. Also, at the instruction of my program officer, I removed language from the Approach section of the grant focusing on sexual and gender minorities, noting that individuals of all gender identities would be included in the study. And throughout the grant, I removed references to the project as a dignity-affirming intervention.

13. On August 6, 2025, we secured the grant, R01MH140688, which has a project term of August 6, 2025 through May 31, 2030.

14. Attached hereto as **Exhibit 1 is a tru**e and correct copy of this R01 grant's Notice of Award (i.e., NOA).

15. In June 2026, my program officer reached out to me again with additional concerns about the language used in the grant documents. Specifically, my program officer informed me that the public-facing language about my grant should not contain references to basic income guarantee. Apart from that, I was instructed to remove all mentions of policy or suggestions that the research could have any impact on policy decisions in the future.

16. Despite NIH officials' newly raised objections to research grants influencing policy, many R01s that the agency still funds do, indeed, impact policies at all levels of governance, from hospital policies to national and international guidelines. Given that NIH still funds research grants that could have an impact on future policy decisions, I understood the objection to my research having a potential policy impact as an objection to the viewpoint expressed in my work—that participants in my research grant—low income people with HIV—might experience health benefits from basic income guarantee, or that such an intervention is worthwhile for this population.

17. In August, my program officer met with me again and informed me that I would need to find alternative funding for the basic income portion of my grant. I proposed retooling the aims to support participants' food or transportation or otherwise rebudgeting such that my institution would cover the cost of the basic income portion. The program officer took this suggestion back to her superior, who eventually allowed me to submit revisions to the grant.

18. On September 2, 2026, I submitted a revised version of the Specific Aims, Narrative, Abstract, Budget, and Budget Justification to align with the new intervention supporting food and transportation support instead of basic income guarantee. On September 17, 2026, NIH issued a Notice of Award for the revised grant.

19. Because of all the back-and-forth with NIH about the nature of the grant, I am fearful the grant may still be terminated for perceived misalignment with agency priorities. Because NIH required us to make these changes to the language of the grant, I am concerned NIH may decide to terminate this grant if I speak or write about my work or present my findings in ways that differ from the language NIH required us to adopt.

20. If this grant is terminated, that would be devastating. First and foremost, this will harm participants and violate their trust in the research team. There are research participants who will not receive the funds they were told they would receive during the period they expected to receive them. Participants in my pilot used their basic income guarantee to support basic needs as well as members of their families and social networks. These basic needs will go unmet. It will also mean my team, which consists of a co-PI, research coordinator, research assistants, data analysts, and a medical student, will not be paid. Additionally, any information generated from the trial will be lost given that we will not be able to carry out the aims of the project as written, and will not have robust data on the impact of basic income on the care engagement and viral load of low income people with HIV. Lastly, an R01 is a career-defining award that allows for the generation of a clear path for research that builds on itself. Research generated from an R01 often leads to manuscripts, abstracts, and promotions, in addition to more R01s and other types of grants. This R01 covers 22.5% of my full-time equivalent. A termination will be a setback for my career and my finances.

21. I recently applied for a R01 NIH grant focused on HPV prevention that seeks to educate people on how to self-screen for anal cancer and other HPV prevention methodologies through use of a warmline or hotline that links participants to resources and care. This submission scored at the 12th percentile, close to the payline, and was ultimately not funded. Our NIH program officer later instructed us to change the language of our resubmission application to remove references to sexual and gender minorities (even though prior reviewers wanted us to focus on transgender women, and the federally

approved HPV screening guidelines reference transgender women, who have an elevated incidence of HPV). My MPI and I decided also to remove the word "vaccine" because we knew that this word was on a list of banned words at the NIH, even though HPV is best prevented through vaccination. This was remarked upon by a reviewer in one of the rounds of peer review organized by NIH—the reviewer clearly did not know that "vaccine" was on the banned words list, despite public reporting and circulation of the list. The resubmission remains pending.

22. If NIH were no longer screening grants for priorities alignment, I would continue my work on the basic income guarantee grant as originally submitted when it was awarded, without the revisions I proposed in response to objections from NIH. Likewise, I would resubmit my grant application on HPV screening and keep in references to vaccines and sexual and gender minorities.

23. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Chicago, Illinois this 18th day of September 2026.

Jade Pagkas-Bather

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R01MH140688
Federal Award Date
08/06/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CHICAGO
5801 S ELLIS AVE
CHICAGO, IL 60637

2. Congressional District of Recipient
01

3. Payment System Identifier (ID)
1362177139A1

4. Employer Identification Number (EIN)
362177139

5. Data Universal Numbering System (DUNS)
005421136

6. Recipient's Unique Entity Identifier
ZUE9HKT2CLC9

7. Project Director or Principal Investigator
Jade Pagkas-Bather, MD (Contact)

jpagkasbather@bsd.uchicago.edu
773-834-3207

8. Authorized Official
Ryan O'Connell
oconnellr@uchicago.edu

Federal Agency Information

9. Awarding Agency Contact Information
Maggie Campbell Paolini
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
maggie.paolini@nih.gov
301-443-2746

10. Program Official Contact Information
Anais Fern Stenson

NATIONAL INSTITUTE OF MENTAL HEALTH
anais.stenson@nih.gov
(240) 926-7572

Federal Award Information

11. Award Number
1R01MH140688-01

12. Unique Federal Award Identification Number (FAIN)
R01MH140688

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Basic Income Guarantee Chicago: A Trial of Basic Income

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/06/2025 – **End Date** 05/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$819,998
20 a. Direct Cost Amount	$499,999
20 b. Indirect Cost Amount	$319,999
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$819,998
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$819,998
26. Project Period Start Date 08/06/2025 – **End Date** 05/31/2030	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$819,998

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Maggie Campbell Paolini

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R01MH140688-01

Principal Investigator(s):
Darnell N Motley, PHD
Jade Pagkas-Bather (contact), MD

Award e-mailed to: io-ura@uchicago.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $819,998 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CHICAGO in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R01MH140688. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Maggie Campbell Paolini
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$161,445
Fringe Benefits	$33,743
Personnel Costs (Subtotal)	$195,188
Other	$304,811
Federal Direct Costs	$499,999
Federal F&A Costs	$319,999
Approved Budget	$819,998
Total Amount of Federal Funds Authorized (Federal Share)	$819,998
TOTAL FEDERAL AWARD AMOUNT	$819,998
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$819,998

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$819,998	$819,998
2	$738,000	$738,000
3	$778,998	$778,998
4	$819,998	$819,998
5	$819,998	$819,998

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1362177139A1
Document Number: RMH140688A
PMS Account Type: P (Subaccount)
Fiscal Year: 2025

IC	CAN	2025	2026	2027	2028	2029
MH	8472592	$819,998	$738,000	$778,998	$819,998	$819,998

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 9A-ASPC / **OC**: 41021 / **Released**: 08/05/2025
Award Processed: 08/06/2025 12:53:04 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MH140688-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MH140688-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MH140688. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with

disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R01MH140688-01

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:
This award has been made in response to the application submitted under the Notice of Funding Opportunity Announcement PA-20-183 which can be referenced at: https://grants.nih.gov/grants/guide/pa-files/PA-20-183.html

ADMINISTRATIVE REDUCTION:
In order to meet Institute program objectives within Fiscal Year 2025 budget constraints, years 2 and 3 have been reduced by 10% and 5%, respectively. https://www.nimh.nih.gov/funding/funding-strategy-for-research-grants.

NOTICE:
NIH funds may not be used to support activities that are outside the approved scope of the award, including Diversity, Equity and Inclusion (DEI) research or related research training activities or programs. Any funds used to support activities outside the approved scope of award will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes Diversity, Equity and Inclusion (DEI), or has questions regarding other activities that could be considered outside the approved

scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

BUDGET/PROJECT PERIOD ADJUSTMENT:
This grant has been selected under the NIMH plan to redistribute grant workloads more evenly throughout the year. Consequently, the initial budget period reflects a 5/31/2025 end date. Subsequent budget periods will begin on June 1 and will be for a 12-month duration. Although this grant will have a slightly shorter budget period this year, it is awarded the full 12-month level of funds for the budget period. If needed, additional time may be requested at the end of the project period for a first no-cost extension through eRA Commons.

DATA SHARING PLAN:
This award is subject to the data sharing guidance outlined in NOT-MH-23-100 and can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-100.html. The recipient will adhere to the resource and data sharing plan submitted by eJIT in eRA on 6/04/2025. Dissemination of study data will be in accordance with the accepted data sharing plan. **Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5 â€œOther Products and Resource Sharing.â€** Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIH/IC may result in Enforcement Actions as described in the NIH Grants Policy Statement.

Complete NIMH data sharing terms and conditions can be found at https://nda.nih.gov/nda/sharing-regimen. Instructions are available at http://grants.nih.gov/grants/rppr/index.htm. Complete guidelines on data sharing are available at https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/research-covered-under-the-data-management-sharing-policy#after.

HUMAN SUBJECTS RESEARCH:
This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 7/22/2025. It is expected that 61 of the 304 total projected participants will be recruited by 4/01/2026. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

GCP TRAINING:

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:
The clinical trial(s) supported by this award is subject to the plan within the competing application dated 9/06/2024 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Itâ€™s required that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:
This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipientâ€™s plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

DATA AND SAFETY MONITORING:
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

This grant requires a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards (cited in NOT-MH-19-027) for details regarding roles, independence, responsibilities, and review reports. Each RPPR submitted must include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, copies of all DSMB review determinations for all meetings/reviews conducted during the reporting period since the last annual award. The RPPR is expected to also include the following information: (1) the dates that the DSMB convened and name(s) of the DSMB members; (2) a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and (3) a summary of any recommendations from the DSMB and any actions taken based on the recommendations.

OTHER SUPPORT TIME COMMITMENT:

Commitment overlap is not permitted and occurs when an individualâ€™s time commitment exceeds 100 percent (I.e., 12 person months), whether or not salary is requested. Therefore, no individualâ€™s time commitment may exceed 100 percent. Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$6,000	$5,400	$5,700	$6,000	$6,000

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01MH140688-01

INSTITUTION: UNIVERSITY OF CHICAGO

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$161,445	$145,301	$153,373	$161,445	$161,445
Fringe Benefits	$33,743	$30,369	$32,056	$33,743	$33,743
Personnel Costs (Subtotal)	$195,188	$175,670	$185,429	$195,188	$195,188
Other	$304,811	$274,330	$289,570	$304,811	$304,811
TOTAL FEDERAL DC	$499,999	$450,000	$474,999	$499,999	$499,999
TOTAL FEDERAL F&A	$319,999	$288,000	$303,999	$319,999	$319,999
TOTAL COST	$819,998	$738,000	$778,998	$819,998	$819,998

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	64%	64%	64%	64%	64%
F&A Cost Base 1	$499,999	$450,000	$474,999	$499,999	$499,999
F&A Costs 1	$319,999	$288,000	$303,999	$319,999	$319,999

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF JONATHAN KYLE DAW

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Jonathan Kyle Daw, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. I am a Professor of Sociology and Demography at the Pennsylvania State University. Broadly speaking, my research focuses on how demographic, inequality, and biological processes combine to influence health and well-being. The main focus of my research currently is to study the causes of racial and ethnic disparities in kidney disease, kidney failure, treatments for kidney failure, and kidney failure patient mortality.

3. I offer this declaration in my individual capacity and not on behalf of my employer.

4. I earned a B.A. in Sociology and Government in 2005 at the University of Texas at Austin. I then earned my M.A. (in 2007) and Ph.D. (in 2011) in Sociology from the University of North Carolina – Chapel Hill.

5. Before working at Penn State, I was an Assistant Professor of Medical Sociology at the University of Alabama – Birmingham. Prior to that, I completed my postdoctoral fellowship at the Institute of Behavioral Science and the Institute for Behavioral Genetics at the University of Colorado – Boulder.

6. I am the author of over 40 peer-reviewed scientific publications, published in many top medical and sociology journals, including the *American Journal of Transplantation*, *Clinical Transplantation*, *Kidney Medicine*, *Transplant Immunology*, *Progress in Transplantation,* the *American Journal of Public Health*, the *American Journal of Preventive Medicine*, *Proceedings of the National Academies of Sciences,* the *American Journal of Sociology*, the *Journal of Health & Social Behavior*, and *Social Science & Medicine*.

7. My interest in the social determinants of kidney disease and transplantation research developed throughout my academic training. During that training, I realized that health research—and in particular, research around kidney transplantation—layered together my interests in things like family dynamics, genetics, and social outcomes. And what I observed throughout my time as a researcher is that there are huge disparities between racial and ethnic groups when it comes to kidney disease, kidney failure, kidney failure treatments, and kidney failure patient mortality.

8. Institutional grantees are the entities that host the research and receive award and funding from the National Institutes of Health (NIH), and are generally universities, hospitals, and sometimes non-profits and other entities. Awards also name one or more Principal Investigators, who are researchers directly responsible for proposing the projects, overseeing the design and implementation of studies, and managing the research from the application stage through the end of a grant. In 2022, the National Institute of Diabetes and Digestive and Kidney Diseases at the NIH awarded a four-year R01 grant for which I was the Principal Investigator. The grant number for that award is R01DK132953, and the project is titled, "The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality."

9. The goal of this project was to understand why there are racial and ethnic disparities in kidney failure, kidney failure treatment receipt, and kidney failure patient mortality. Our hypothesis, based on decades of theoretical and empirical research by our team and many others, was that structural racism is a key driver of racial and ethnic disparities in these critical outcomes. In our view, structural racism is best measured by examining area racial/ethnic disparities in key life outcomes, such as earning a college degree, owning a home, being incarcerated, having health insurance, and living in poverty. A key goal of the project was to construct the most comprehensive database of structural racism indicators ever constructed, with the aim to construct a structural racism index comprised of 8 different race/ethnicity-specific indicators on five different racial/ethnic groups at the county level over a 30-year time span. Assembling and cleaning this database and using it to construct our structural racism indices for each racial/ethnic comparison in each time period has constituted the bulk of our efforts on this project to date, and the final steps in this process are currently finally being completed.

10. Attached hereto as Exhibit 1 is a true and correct copy of this R01 grant's original Notice of Award ("NOA").

11. The grant application did not come together overnight. I started developing the application for this grant back in 2018, collaborating with a graduate student in my department at the time. The work included a broad review of literature, assessing the data sources available to us, and preliminary data analysis. All that, along with collaborating with other researchers to draft and

repeatedly revise the application materials in preparation for submission, cumulatively took hundreds of hours over almost three years.

12. A few months after the grant was awarded, I applied for a diversity supplement to the award. The goal of this diversity supplement was to mentor and collaborate with a researcher whose background had been in public policy, so that she could assist with the research funded through the original grant and eventually propose her own kidney disease-related projects.

13. NIH awarded that diversity supplement on August 18, 2023. Attached hereto as Exhibit 2 is a true and correct copy of the original NOA of this diversity supplement.

14. Until May 2025, we submitted annual progress reports and sought non-competitive renewal for these grants without any concerns raised by NIH officials regarding this project.

15. But on May 1, 2025, a colleague at Penn State informed me by email that NIH had terminated the diversity supplement grant. NIH had issued a revised NOA for this grant, listing an end date of April 29, 2025. Attached hereto as Exhibit 3 is a true and correct copy of the revised NOA of this diversity supplement. Later that day, that same colleague informed me by email that NIH had terminated the parent R01 grant. NIH had issued a revised NOA for this grant, listing an end date of April 30, 2025. Attached hereto as Exhibit 4 is a true and correct copy of the revised NOA of this grant.

16. The revised NOAs provided no individualized explanation for why the grants were canceled, and both fail to discuss the grant application, progress reports, or other related materials. The project was proceeding well, and the project's annual progress reports had never prompted questioning or reduction in funds from the NIH prior to this termination.

17. Instead, NIH provided the following statement for the termination:

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

Ex. 3 at 6; Ex. 4 at 6.

18. Prior to the termination, we had made significant progress in this project. In addition to the work noted above constructing the structural racism database, we had regularly held meetings of a community advisory board based in Pittsburgh, Pennsylvania and Baltimore, Maryland, when we met with a group of community members to talk about our research findings, connect that research to the lived experiences of those individuals as patients and as community advocates, and learn from those experiences to inform our own research. This work has thus far resulted in two research manuscripts, one (Corradi *et al.*, "Development and Integration of Community Advisory Boards to Inform Research on the Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease") published in *Health Expectations*, and the other (Corradi *et al.*, "On the Back Burner: Lived Experiences of Structural Racism and End-Stage Kidney Disease") presently under review at a peer-reviewed journal. We also published descriptive analyses comparing the treatment histories of young kidney failure patients by race/ethnicity in *Kidney Medicine* (Pessin *et al.* 2026, "Kidney Replacement Therapy Sequences: Racial/Ethnic Disparities in End-Stage Kidney Disease Patients' 10-Year Treatment Histories"). Finally, we have presented several conference papers developed based on preliminary versions of the structural racism index and associated health disparities, including the following: "County-Level Structural Racism Predicts Black-White End-Stage Kidney Disease Patient Mortality Disparities" at the 2023 American Society of Nephrology conference, "County-Level Structural Racism and the Black-White Gap in End-Stage Renal Disease Incidence" at the 2024 Population Association of American conference, "County-Level Structural Racism Measures Beyond Black and White" at the 2025 Population Association of America conference, and "County-Level Structural Racism and Mortality Rates Among Non-Hispanic White, Non-Hispanic Black, and Hispanic Populations" at the 2025 Population Association of America conference. This work supports our project's hypothesis that racial/ethnic disparities in kidney disease incidence and mortality are worsened in counties characterized by higher levels of structural racism (as measured by our index).

19. Unfortunately, the grant's termination substantially slowed and in some instances even stalled the project's progress. Following the termination, our research team sought replacement funding from the Pennsylvania State University Social Science Research Institute (PSU SSRI) and other potential funding sources, and applications for those alternative funding sources took dozens of hours

during that could not be used to conduct research related to this grant. Eventually, we did receive some funding from PSU SSRI, for which we were very grateful, but those funds were able to cover only a small percentage of the funds lost due to termination. In addition, leading up to the termination, we were pursuing further data collection, refinement, and analysis before submitting further publications. That takes a lot of time and labor. But because members of the research team lost funding from this grant to directly support this research, some of those members had to spend more of their time on responsibilities outside of the research itself, such as teaching more or taking on other non-research responsibilities at their institution. What's more, to gather and analyze data for our database, we needed a programmer dedicated to that task, but for one month prior to receiving the PSU SSRI funds we were unable to secure one because of a lack of funding resulting from this termination, and although we were eventually able to secure one, our work has been delayed as a result. As such, the research has continued at a much slower pace, meaning that the medical community and the broader public have been delayed in benefiting from the findings and recommendations of our research.

20. Prior to the grant termination, we had been scheduled to hold two more meetings of the Community Advisory Board, but those have not been held because of the termination. Due to this long period of disengagement, lost information sharing, and trust, it is unclear if we will be able to reconvene the same group in the future even if the funds are restored.

21. The delay in our research has slowed down our ability to demonstrate results from our research, limiting the competitiveness of future grant applications from my colleagues who are also working on this project and me. In addition, I have had to forego attending several medical conferences because of a lack of sufficient funding. Our team's inability to attend these important medical conferences limits our ability to keep up with the latest research presented at these conferences which is often not yet published, limits our ability to share our work with our peers working on similar topics, and limits our ability to network and establish new projects and collaborations with those peers, as conferences are often places where new ideas for grant applications or research collaborations germinate.

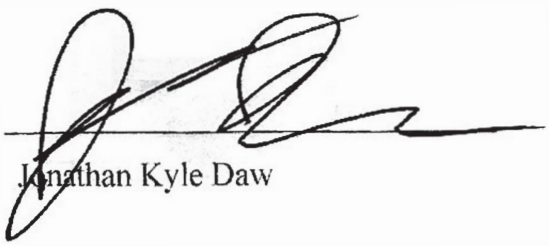
22. Given these terminations, and my understanding that research related to my grant is disfavored under NIH's current policies, I do not believe it is worthwhile to submit new grants studying

the impact of structural racism on racial/ethnic health disparities while the present administration is in power. This unfortunate situation is a loss not only for my team and myself, but also the broader medical community and for public health, as research like that supported by this grant—that is, trying to discern why different groups of people experience kidney disease and failure at different rates, with different treatments, and different mortality outcomes—is critical not only to achieving NIH's mission, but also to making sure we have a healthier society. As an expert in population health, I know that the large health disparities observed in our population by race/ethnicity, gender, socioeconomic status, and geography substantially account for the large gaps between U.S. life expectancy and disease burden and those of other wealthy and many middle-income countries, so this work could not be more essential to U.S. public health.

23. Restoring this grant would be a huge benefit to our research efforts and to the broader public health. That restoration would allow us to provide funding for our team members to spend more time on research relating to this project. That in turn would allow us to process and analyze data more quickly, as well as to produce publications at a faster rate, which would in turn allow us to distribute our findings more quickly than without this funding.

24. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at State College, Pennsylvania this 21st day of September 2026.



Jonathan Kyle Daw

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# R01DK132953
Federal Award Date
10/13/2022

Recipient Information

1. Recipient Name
PENNSYLVANIA STATE UNIVERSITY, THE
201 OLD MAIN

UNIVERSITY PARK, 16802

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1246000376A1

4. Employer Identification Number (EIN)
246000376

5. Data Universal Numbering System (DUNS)
003403953

6. Recipient's Unique Entity Identifier
NPM2J7MSCF61

7. Project Director or Principal Investigator
Jonathan Kyle Daw, PHD
Associate Professor
jud36@psu.edu
814-863-0096

8. Authorized Official
Ms. Barbara E Rigg

Federal Agency Information

9. Awarding Agency Contact Information
Norma G DeGuzman
Senior Grants Management Specialist
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
norma.deguzman@nih.gov
301-480-1810

10. Program Official Contact Information
JENNIFER MICHELLE Norton

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
jenna.norton@nih.gov
301-451-7314

Federal Award Information

11. Award Number
1R01DK132953-01

12. Unique Federal Award Identification Number (FAIN)
R01DK132953

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases Extramural Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 08/01/2022 **– End Date** 05/31/2023	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$756,925
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$756,925
26. Project Period Start Date 08/01/2022 **– End Date** 05/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$756,925

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Diana T Ly

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 1R01DK132953-01 REVISED

Principal Investigator(s):
Jonathan Kyle Daw, PHD

Award e-mailed to: osp@psu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PENNSYLVANIA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number R01DK132953. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Diana T Ly
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$234,614
Fringe Benefits	$77,337
Personnel Costs (Subtotal)	$311,951
Consultant Services	$21,000
Travel	$16,692
Other	$47,730
Subawards/Consortium/Contractual Costs	$90,377
Federal Direct Costs	$487,750
Federal F&A Costs	$269,175
Approved Budget	$756,925
Total Amount of Federal Funds Authorized (Federal Share)	$756,925
TOTAL FEDERAL AWARD AMOUNT	$756,925
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$756,925	$756,925
2	$658,335	$658,335
3	$651,574	$651,574
4	$580,038	$580,038

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1246000376A1
Document Number:	RDK132953A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025
DK	8472279	$756,925	$658,335	$651,574	$580,038

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: KJN KHE / **OC**: 41021 / **Released**: Ly, Diana 10/13/2022
Award Processed: 10/14/2022 12:03:44 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01DK132953-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01DK132953-01 REVISED

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This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01DK132953. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in

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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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 1R01DK132953-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION #1:
Revised to add subaward to Georgia Southern University (GSU) and revised the budget to Florida State University (FSU) per request dated 09/15/2022.

Georgian Southern University in the amount of $ 42,730 ($ 30,092 direct costs + $12,638 facilities and administrative costs).

Florida State University in the amount of $25,909 ($16,824 direct costs + $9,085 facilities and administrative costs). Budget revision applied.

Consortiums are to be established and administered as described in the NIH Grants Policy Statement.

The following terms from the previous notice of award also apply to this award:

Budget Period Adjustment
Although the initial budget period for this award is 08/01/2022 – 05/31/2023, the award includes funds for 12 months of support. Future year budget periods will cycle each year on 06/01.

The recycling of this award may have changed the receipt date for the next competing continuation (Type 2) application. Please consult the NIH Grants and Funding Application Cycle for the established deadline date.

Award Budget
The award is based on the IRG recommendations as noted on the Summary Statement and no further administrative reductions have been taken.

See the budget information below for additional information.

Period of Support
To achieve an average competitive segment of 4 years for all NIDDK awards, the duration of the recommended competitive segment for this grant has been administratively reduced.

Salary Cap
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap (Executive Level II). Therefore, this award and/or future

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years are adjusted accordingly, if applicable. See the Salary Cap Summary for the current and historical record of the salary cap, including effective dates.

Consortium Involvement
This award includes funds awarded for consortium activity with the following:

Temple University in the amount of $20,343 ($12,835 direct costs + $7,508 facilities and administrative costs).

Johns Hopkins University in the amount of $50,171 ($30,639 direct costs + $ 19,532 facilities and administrative costs).

Consortiums are to be established and administered as described in the NIH Grants Policy Statement.

Graduate Student Compensation
In accordance with the NIH Grants Policy Statement (NIH GPS) Section 2.3.7.9 Graduate Student Compensation, total direct costs (salary, fringe benefits and tuition remission) for graduate students must not exceed the Ruth L. Kirschstein National Research Service Award (NRSA) zero-level stipend in effect at the time of the competing award. Support recommended for future years has been adjusted accordingly, if applicable. See the NIH GPS for full details and a link to the schedule for NRSA stipends.

Human Subjects Enrollment Reporting
The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Investigators must report sex/gender, race, and ethnicity information using the Human Subjects System (HSS) module in the eRA Commons.

For more information see the NIH Guide Notice NOT-OD-18-179

Milestones
Future year support is contingent on satisfactory achievement of approved performance milestones. If approved milestones are not achieved fully, NIDDK may request development of a remedial plan and more frequent monitoring of progress or take other remedial actions.

Grantees can determine which progress reports are due through the website located at https://public.era.nih.gov/chl/public/search/index.jsp and should periodically check the site, which is updated on or around the 30th of each month. Progress report due dates are also available in the eRA Commons Status system. In addition, automatic e-mail notifications are sent to the PD/PI prior to due date.

As of October 17, 2014, the National Institutes of Health (NIH) requires grantees to submit all type 5 progress reports using the eRA Research Performance Progress Report (RPPR) module. 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 module in accordance with NIH Guide Notice NOT-OD-15-014 released October 16, 2014.

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SPREADSHEET SUMMARY
AWARD NUMBER: 1R01DK132953-01 REVISED

INSTITUTION: PENNSYLVANIA STATE UNIVERSITY

Budget	Year 1	Year 2	Year 3	Year 4
Salaries and Wages	$234,614	$232,097	$238,259	$204,860
Fringe Benefits	$77,337	$76,295	$78,472	$66,678
Personnel Costs (Subtotal)	$311,951	$308,392	$316,731	$271,538
Consultant Services	$21,000	$17,250	$13,500	$13,500
Travel	$16,692	$17,302	$17,302	$17,302
Other	$47,730	$2,080	$2,080	$1,500
Subawards/Consortium/Contractual Costs	$90,377	$90,377	$82,928	$82,928
Publication Costs		$2,500	$2,500	$2,500
TOTAL FEDERAL DC	$487,750	$437,901	$435,041	$389,268
TOTAL FEDERAL F&A	$269,175	$220,434	$216,533	$190,770
TOTAL COST	$756,925	$658,335	$651,574	$580,038

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4
F&A Cost Rate 1	58.19%	58.19%	58.19%	58.19%
F&A Cost Base 1	$462,579	$378,818	$372,113	$327,840
F&A Costs 1	$269,175	$220,434	$216,533	$190,770

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Exhibit 2

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# R01DK132953
Federal Award Date
08/18/2023

Recipient Information

1. Recipient Name
THE PENNSYLVANIA STATE UNIVERSITY
201 OLD MAIN
UNIVERSITY PARK, PA 16802

2. Congressional District of Recipient
15

3. Payment System Identifier (ID)
1246000376A1

4. Employer Identification Number (EIN)
246000376

5. Data Universal Numbering System (DUNS)
003403953

6. Recipient's Unique Entity Identifier
NPM2J7MSCF61

7. Project Director or Principal Investigator
Jonathan Kyle Daw, PHD
Associate Professor
jud36@psu.edu
814-863-0096

8. Authorized Official
Ms. Barbara E Rigg

Federal Agency Information

9. Awarding Agency Contact Information
Norma G DeGuzman
Senior Grants Management Specialist
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
norma.deguzman@nih.gov
301-480-1810

10. Program Official Contact Information
JENNIFER MICHELLE Norton

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
jenna.norton@nih.gov
301-451-7314

Federal Award Information

11. Award Number
3R01DK132953-02S1

12. Unique Federal Award Identification Number (FAIN)
R01DK132953

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases Extramural Research

17. Award Action Type
Supplement

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 08/01/2023 **– End Date** 05/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$119,808
20 a. Direct Cost Amount	$74,740
20 b. Indirect Cost Amount	$45,068
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$119,808
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$119,808
26. Project Period Start Date 08/01/2022 **– End Date** 05/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,535,068

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Tommy Gunter

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 3R01DK132953-02S1

Principal Investigator(s):
Jonathan Kyle Daw, PHD

Award e-mailed to: osp@psu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $119,808 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PENNSYLVANIA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number R01DK132953. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Tommy Gunter
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$48,865
Fringe Benefits	$17,542
Personnel Costs (Subtotal)	$66,407
Travel	$8,333
Federal Direct Costs	$74,740
Federal F&A Costs	$45,068
Approved Budget	$119,808
Total Amount of Federal Funds Authorized (Federal Share)	$119,808
TOTAL FEDERAL AWARD AMOUNT	$119,808
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$119,808

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (2) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3R01DK132953-02S1	$119,808
5R01DK132953-02	$658,335
TOTAL	**$778,143**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$119,808	$778,143
3	$144,270	$795,844
4	$24,462	$604,500

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1246000376A1
Document Number: RDK132953A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023	2024	2025
DK	8472280	$119,808	$144,270	$24,462

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: KJN KHE / **OC**: 41023 / **Released**: Gunter, Tommy 08/17/2023
Award Processed: 08/18/2023 12:38:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01DK132953-02S1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

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SECTION III – STANDARD TERMS AND CONDITIONS – 3R01DK132953-02S1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01DK132953. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 3R01DK132953-02S1

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Supplement Funding

This award provides support for Research Supplements to Promote Diversity in Health-Related Research for Niki Von Lockette beginning August 1, 2023. These funds are restricted for the above purpose only and may not be transferred to any other individual. Funds awarded are available for carryover for awards given carryover authority as reflected

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in Section III of this award notice. However, the funds remain restricted for the individual and the purpose for which the supplement is awarded.

In future years, a separate progress report for this supplement is required as part of the Research Performance Progress Report (RPPR) of the parent grant. In addition, unless this award is included under the Streamlined Non-Competing Award Process (SNAP), a detailed budget page must be submitted.

Should the Diversity Investigator not initiate or complete this experience, please inform the awarding office immediately.

SPREADSHEET SUMMARY
AWARD NUMBER: 3R01DK132953-02S1

INSTITUTION: PENNSYLVANIA STATE UNIVERSITY

Budget	Year 2	Year 3	Year 4
Salaries and Wages	$48,865	$58,868	$10,002
Fringe Benefits	$17,542	$21,132	$3,591
Personnel Costs (Subtotal)	$66,407	$80,000	$13,593
Travel	$8,333	$10,000	$1,667
TOTAL FEDERAL DC	$74,740	$90,000	$15,260
TOTAL FEDERAL F&A	$45,068	$54,270	$9,202
TOTAL COST	$119,808	$144,270	$24,462

Facilities and Administrative Costs	Year 2	Year 3	Year 4
F&A Cost Rate 1	60.3%	60.3%	60.3%
F&A Cost Base 1	$74,740	$90,000	$15,260
F&A Costs 1	$45,068	$54,270	$9,202

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Exhibit 3

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# R01DK132953
Federal Award Date
04/29/2025

Recipient Information

1. Recipient Name
THE PENNSYLVANIA STATE UNIVERSITY
201 OLD MAIN
UNIVERSITY PARK, PA 16802

2. Congressional District of Recipient
15

3. Payment System Identifier (ID)
1246000376A1

4. Employer Identification Number (EIN)
246000376

5. Data Universal Numbering System (DUNS)
003403953

6. Recipient's Unique Entity Identifier
NPM2J7MSCF61

7. Project Director or Principal Investigator
Jonathan Kyle Daw
Associate Professor
jud36@psu.edu
814-863-0096

8. Authorized Official
Ms. Barbara E Rigg

Federal Agency Information

9. Awarding Agency Contact Information
Lesley Whipp
Grants Specialist
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
whipplc2@niddk.nih.gov
301-443-9360

10. Program Official Contact Information
JENNIFER MICHELLE Norton

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
jenna.norton@nih.gov
301-451-7314

Federal Award Information

11. Award Number
3R01DK132953-03S1

12. Unique Federal Award Identification Number (FAIN)
R01DK132953

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases Extramural Research

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 04/29/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$144,270
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$144,270
26. Project Period Start Date 08/01/2022 **– End Date** 04/29/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,304,849

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Dee Doherty

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 3R01DK132953-03S1 REVISED

Principal Investigator(s):
Jonathan Kyle Daw

Award e-mailed to: osp@psu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PENNSYLVANIA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number R01DK132953. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Dee Doherty
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$58,868
Fringe Benefits	$21,132
Personnel Costs (Subtotal)	$80,000
Travel	$10,000
Federal Direct Costs	$90,000
Federal F&A Costs	$54,270
Approved Budget	$144,270
Total Amount of Federal Funds Authorized (Federal Share)	$144,270
TOTAL FEDERAL AWARD AMOUNT	$144,270
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3R01DK132953-03S1	$144,270
5R01DK132953-03	$625,511
TOTAL	**$769,781**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$144,270	$769,781
4	$0	$580,038

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1246000376A1
Document Number:	RDK132953A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
DK	8472280	$144,270

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: KJN KEPT / **OC**: 41023 / **Released**: 04/29/2025
Award Processed: 04/30/2025 12:04:36 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01DK132953-03S1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 3R01DK132953-03S1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01DK132953. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in

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the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 3R01DK132953-03S1 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION 1: TERMINATE AWARD

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It is the policy of NIH not to prioritize research programs related to DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Therefore, no additional funding will be awarded for this project, and all future years have been removed PENNSYLVANIA STATE UNIVERSITY, THE may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

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

Supplement Funding

This award provides support for Research Supplements to Promote Diversity in Health-Related Research for Niki Von Lockette beginning August 1, 2023. These funds are restricted for the above purpose only and may not be transferred to any other individual. Funds awarded are available for carryover for awards given carryover authority as reflected in Section III of this award notice. However, the funds remain restricted for the individual and the purpose for which the supplement is awarded.

In future years, a separate progress report for this supplement is required as part of the Research Performance Progress Report (RPPR) of the parent grant. In addition, unless this award is included under the Streamlined Non-Competing Award Process (SNAP), a detailed budget page must be submitted.

Should the Diversity Investigator not initiate or complete this experience, please inform the awarding office immediately.

SPREADSHEET SUMMARY
AWARD NUMBER: 3R01DK132953-03S1 REVISED

INSTITUTION: PENNSYLVANIA STATE UNIVERSITY

Budget	Year 3	Year 4
Salaries and Wages	$58,868	
Fringe Benefits	$21,132	
Personnel Costs (Subtotal)	$80,000	
Travel	$10,000	
TOTAL FEDERAL DC	$90,000	
TOTAL FEDERAL F&A	$54,270	
TOTAL COST	$144,270	$0

Facilities and Administrative Costs	Year 3	Year 4
F&A Cost Rate 1	60.3%	
F&A Cost Base 1	$90,000	
F&A Costs 1	$54,270	

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Exhibit 4

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# R01DK132953
Federal Award Date
05/01/2025

Recipient Information

1. Recipient Name
THE PENNSYLVANIA STATE UNIVERSITY
201 OLD MAIN
UNIVERSITY PARK, PA 16802

2. Congressional District of Recipient
15

3. Payment System Identifier (ID)
1246000376A1

4. Employer Identification Number (EIN)
246000376

5. Data Universal Numbering System (DUNS)
003403953

6. Recipient's Unique Entity Identifier
NPM2J7MSCF61

7. Project Director or Principal Investigator
Jonathan Kyle Daw, PHD
Associate Professor
jud36@psu.edu
814-863-0096

8. Authorized Official
Ms. Barbara E Rigg

Federal Agency Information

9. Awarding Agency Contact Information
Lesley Whipp
Grants Specialist
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
whipplc2@niddk.nih.gov
301-443-9360

10. Program Official Contact Information
JENNIFER MICHELLE Norton

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
jenna.norton@nih.gov
301-451-7314

Federal Award Information

11. Award Number
5R01DK132953-03

12. Unique Federal Award Identification Number (FAIN)
R01DK132953

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 04/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$625,511
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$625,511
26. Project Period Start Date 08/01/2022 **– End Date** 04/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,304,849

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Dee Doherty

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 5R01DK132953-03 REVISED

Principal Investigator(s):
Jonathan Kyle Daw, PHD

Award e-mailed to: osp@psu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PENNSYLVANIA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number R01DK132953. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Dee Doherty
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:04 AM

Salaries and Wages	$228,729
Fringe Benefits	$75,333
Personnel Costs (Subtotal)	$304,062
Consultant Services	$12,960
Travel	$16,610
Other	$1,997
Subawards/Consortium/Contractual Costs	$79,611
Publication Costs	$2,400
Federal Direct Costs	$417,640
Federal F&A Costs	$207,871
Approved Budget	$625,511
Total Amount of Federal Funds Authorized (Federal Share)	$625,511
TOTAL FEDERAL AWARD AMOUNT	$625,511
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5R01DK132953-03	$625,511
3R01DK132953-03S1	$144,270
TOTAL	**$769,781**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$625,511	$769,781

Fiscal Information:
Payment System Identifier: 1246000376A1
Document Number: RDK132953A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
DK	8472279	$625,511

NIH Administrative Data:
PCC: KJN KEPT / **OC**: 41025 / **Released**: 04/30/2025
Award Processed: 05/01/2025 12:04:53 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01DK132953-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01DK132953-03 REVISED

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c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:04 AM

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- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 5R01DK132953-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Award Termination:

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It is the policy of NIH not to prioritize research programs related to DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.. Therefore, no additional funding will be awarded for this project, and all future years have been removed. The Pennsylvania State University may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

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

In accordance with NOT-OD-24-109, and the availability of FY2024 appropriated funds, this award provides funding at the 96% committed level.

Other Support
NIDDK has received the updated other support information provided for all key personnel as identified by the applicant. Only other support information for the PD/PI(s) and any individual(s) named as key personnel on the Notice of Grant Award have been reviewed for overlap. It is the responsibility of the recipient to make sure no overlap of budget, effort, or aims exist for all personnel devoted to this grant.

Salary Cap
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap (Executive Level II). Therefore, this award and/or future years are adjusted accordingly, if applicable. See the Salary Cap Summary for the current and historical record of the salary cap, including effective dates.

Consortium Involvement
This award includes funds awarded for consortium activity with Temple University, Johns Hopkins University, Georgian Southern University, Florida State University and CRESTENSAE/GENES of France. Consortiums are to be established and administered as described in the NIH Grants Policy Statement.

Human Subjects Enrollment Reporting
The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Investigators must report sex/gender, race, and ethnicity information using the Human Subjects System (HSS) module in the eRA Commons.

For more information see the NIH Guide Notice NOT-OD-18-179

Milestones

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Future year support is contingent on satisfactory achievement of approved performance milestones. If approved milestones are not achieved fully, NIDDK may request development of a remedial plan and more frequent monitoring of progress or take other remedial actions.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01DK132953-03 REVISED

INSTITUTION: PENNSYLVANIA STATE UNIVERSITY

Budget	Year 3
Salaries and Wages	$228,729
Fringe Benefits	$75,333
Personnel Costs (Subtotal)	$304,062
Consultant Services	$12,960
Travel	$16,610
Other	$1,997
Subawards/Consortium/Contractual Costs	$79,611
Publication Costs	$2,400
TOTAL FEDERAL DC	$417,640
TOTAL FEDERAL F&A	$207,871
TOTAL COST	$625,511

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	58.19%
F&A Cost Base 1	$357,228
F&A Costs 1	$207,871

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AMERICAN CIVIL LIBERTIES UNION FOUNDATION
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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF KATIE EDWARDS

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Katie Edwards, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. I am a Professor of Social Work at the University of Michigan. My research focuses on preventing sexual and related forms of violence among minority communities by using evidence-based, affirming, and culturally-grounded approaches. My current work is focused on program development and evaluation with Indigenous youth and communities, as well as LGBTQ+ youth. In 2025, I was named by Stanford University as one of the top two percent researchers in the world, and ranked 25th out of 13,543 researchers in the field of criminology. In my lab, we have some of the first studies ever to show we have reduced violence and alcohol use among LGBTQ+ youth as well as sexual violence among Indigenous youth.

3. I offer this declaration in my individual capacity and not on behalf of my employer.

4. My interest in this area of work began during my undergraduate studies. Through my studies and volunteer work, I saw the damaging effects of sexual violence and other forms of violence, and I wanted to learn how to prevent violence from happening in the first place. While most of my work in graduate school focused on college students, early on in my career as an assistant professor, I realized that most of the scientific literature at the time did not address the particular needs of LGBTQ+ youth, a glaring gap especially given that this demographic experiences disproportionately higher rates of sexual and other forms of violence. My passion grew from wanting to work to help all youth who were experiencing these harms and especially youth experiencing high rates of violence about whom we as a field had done relatively less research.

5. Before working at the University of Michigan, I was a Professor of Educational Psychology at the University of Nebraska-Lincoln. Before that, I was an Assistant and Associate Professor of Psychology at the University of New Hampshire.

6. I received my B.S. in Psychology in 2005 from the University of Georgia. I completed my Ph.D. in Clinical Psychology at Ohio University in 2011, and I received a graduate certificate in Women and Gender Studies from Ohio University that same year.

7. To date, I have published more than 240 peer-reviewed journal articles, which were made possible, in part, through obtaining more than $25 million in research funding over the course of my career.

8. I have applied for and received 13 grants from the National Institutes of Health (NIH) over the course of my career. The application process for each grant was a lengthy and involved one, but that process—at least until recently—helped ensure that the most rigorous and impactful research is conducted. In my experience, preparing an application requires months, if not years, of work—from pilot studies, literature review or other background research, to input from community partners and fellow researchers, to honing methodological design—and often new studies will build off of the work and findings from previous studies.

9. I am a plaintiff in the lawsuit *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787 (D. Mass.). Several of my grants and research applications were the subject of the lawsuit. The grant applications discussed in this declaration are separate from the grants and applications that are at issue in that lawsuit.

10. I have had at least one grant application—an application for an R21 grant—for which I have been told by NIH to remove certain words or concepts from the scope of my intended work. Our goal with this study is to evaluate the impact of a sexual violence prevention program for youth living on or near the Pine Ridge Indian Reservation.

11. Through previous work, we developed a program that served K-12 Indigenous youth, with the goal of developing skills to reduce and prevent instances of sexual violence. The program was tailored to the developmental needs of different age groups. For example, students in third through fifth grade were grouped into the same program, where they learned skills like how to seek help from adults if someone is hurting them. As another example, high school students were also grouped in one of two classes, with high school girls getting lessons on empowerment self-defense, including verbal and physical resistance strategies, and high school boys received lessons on bystander intervention, sexual consent, and gender equity. There were six classes for each age bracket, and each class met once a week for two hours. In total, around 650 students in schools on or near the Pine Ridge Indian Reservation participated in this program, and we collected data in the form of surveys to measure the efficacy of this

program. However, we have not yet been able to thoroughly analyze the data we have collected due to limited funding; new funding would permit staff to spend dedicated time processing and analyzing the data, as well as allow us to hire a biostatistician to spend time dedicated to this project.

12. The goal of the R21 grant application is to evaluate the impact of this program using the data that has been collected. Funding from this grant would go towards the time and labor to clean and analyze the data and disseminate the findings. That would allow us to better understand the efficacy of the program, which demographic subgroups benefitted from this program, and whether and how the program could be implemented more broadly to benefit other Indigenous youth and communities. In addition, conducting these analyses would benefit the members on the team who would be able to disseminate the findings of this research in peer-reviewed journals, helping not only spread this information to the broader scientific community but also supporting their career trajectory and supporting more meaningful engagement with Tribal community members.

13. We submitted the R21 application in June 2025. Putting together this application took a significant amount of time, totaling hundreds of hours over months across members of our team.

14. In February 2026, we received our summary statement for this application. In July 2026, I emailed the program officer assigned to the application to meet to discuss it, and around that time, the status of my application on eRA Commons changed from "Council Review Completed" to "Pending."

15. On August 6, 2026, I met with my program officer to discuss this application. During that meeting, she told me that I could not use the term "gender" in the application, and that instead I should change the word "gender" to "biological sex." Following that meeting, later that day, I received an official request from NIH to submit Just-in-Time information for the application.

16. On August 10, 2026, the program officer assigned to my grant emailed me about the status of the grant application. Attached hereto as Exhibit 1 is a true and correct copy of that email. According to the program officer, "[t]he purpose of [that] email is to resolve any administrative issues that may delay the release of a Notice of Award should we be able to fund your application pending final NICHD leadership and budgetary review." Ex. 1 at 1. In that email, the program officer also stated: "To ensure alignment with Administration priorities, please adjust the term gender in the abstract and specific aims when referring to biological sex. Use the attached word document template for the edits,

and have your [Authorized Organization Representative] submit the edits via email, back to me." Attached hereto as Exhibit 2 is a true and correct copy of the Word document template attached to that email.

17. Following this conversation and email with my program officer, I revised the application materials for this R21 grant application, changing the word "gender equitable attitudes" to "healthy attitudes." I did not and do not believe that the term "biological sex attitudes," instead of "gender equitable attitudes," meaningfully or accurately describes the scope of our work. In addition, I revised the application materials to change standalone uses of the word "gender" to "biological sex." On September 18, 2026, NIH issued a notice of award (NOA) for this grant (R21HD122186). Attached hereto as Exhibit 3 is a true and correct copy of that NOA.

18. In light of these interactions with the program officer assigned to this grant application, as well as the priority statements issued by NIH since 2025, including in August 2025 and December 2025, I am concerned that the revisions to my application will limit the scope and scientific accuracy of our analyses, publications, and findings. Some of the youth in our study identify as Two Spirit, transgender, or nonbinary, and restrictions on the use of the term "gender" may prevent us from fully examining and reporting their experiences, meaning that we will not as fully be able to analyze the impact of the program on these populations. More broadly, gender is central to the study and prevention of sexual violence. Gender socialization, gender norms, and attitudes about gender and gender equity are among the factors that can shape sexual violence and are directly relevant to understanding how and why prevention programs work. Replacing a concept such as "gender equitable attitudes" with "healthy attitudes" changes its meaning and makes it more difficult to accurately describe and evaluate the mechanisms our intervention is designed to address. These restrictions could therefore cause our analyses to miss important differences and nuances in how youth experience and respond to the intervention and limit our ability to understand for whom and how the program works, which in turn limits the scope of the recommendations that can be used to better public health. I am concerned that this will both exclude or obscure the experiences of populations who may particularly benefit from this research and reduce the scientific quality and usefulness of the findings. And I am worried about being

able to describe any work funded by this grant in publications or presentations in a manner that is inconsistent with the language that NIH forced me to adopt in my application materials.

19. In addition, I have at least one R01 grant application that I have not resubmitted because of the actions NIH has taken against disfavored viewpoints. The research that would be funded by this grant application builds off the findings and research coming out of a successful R34 grant, titled Development and Pilot Evaluation of an Online Intervention to Prevent Dating Violence and Problem Drinking in Sexual Minority Youth. Through that R34 grant, my team developed and evaluated a new intervention program (called the Promoting Resilient Youth and Strong Hearts and Minds program), which provided online support and skill building to LGBTQ+ youth. The program consisted of one-hour weekly sessions for nine weeks, where 2 LGBTQ+ adults would lead group sessions with 10-15 LGBTQ+ youth. Topics covered during these sessions included positive identity development, debunking myths and dispelling stigma around being LGBTQ+, and building skills such as regulating emotions and handling conflict. Our results showed that this type of program was an efficacious intervention to reduce teen dating violence, alcohol use, and alcohol consequences in LGBTQ+ youth, and findings from this work were published in the *Journal of Studies on Alcohol and Drugs*, a leading peer-reviewed journal.

20. As is the standard scientific progression following a successful R34 grant, we submitted an R01 application in early February 2025 to build on our prior work. Our goal with an R01 was to evaluate the efficacy of the program in a larger sample, examine whether effects from the program differed across demographic subgroups, and better understand how and why the program was producing reductions in dating violence, alcohol use, and related harms in youth. Our goal was also to follow participants for a substantially longer period, extending follow-up from 3 months in the R34 study to 18 months in the R01, which would allow us to determine whether the program's effects were sustained over time.

21. In July 2025, NIH informed us that our application had been denied. The peer reviewers recognized the significance and public health importance of the project, the strength of the pilot findings, the expertise of the investigative team, and additional strengths of the proposed study. The reviewers consistently recognized the need for an evidence-based intervention addressing teen dating

violence and alcohol use among LGBTQ+ youth and viewed the pilot findings from the R34 research as promising. The principal critiques focused on methodological issues—including statistical modeling, implementation details, and aspects of the analytic plan—that are readily addressable in an R01 resubmission, rather than fundamental concerns about the intervention itself or its scientific merit.

22. Under ordinary circumstances, I would have revised the R01 application and submitted a revised R01 proposal. However, following the initial submission of this application, the federal funding environment for research involving LGBTQ+ populations has changed substantially, appearing to target and forbid studies explicitly including transgender and gender-diverse youth. Based on my experience as an NIH-funded investigator and the changes I observed in NIH funding priorities and decision, along with the public guidance issued by NIH in August 2025 and December 2025, I believe that the likelihood of successfully obtaining funding for this R01 application in its intended form is extremely low. My hesitation to resubmit this application is also informed by my experience of being told that I must remove certain concepts from the other grant application discussed above. Especially in light of the experiences discussed in this declaration, I am concerned that I would have to remove certain demographic populations from the R01 application before resubmitting, such as transgender individuals, nonbinary individuals, and racial and ethnic minorities. Doing so would not only exclude populations who experience disproportionately high rates of dating violence and alcohol-related harms from research intended to benefit them, but would also weaken the scientific value of the study by preventing us from examining important differences and nuances in how the intervention works for youth with different identities and experiences.

23. At this time, I am not sure whether I will resubmit this R01 application. Even if I do, the application will not be as strong, and will not benefit as broad of a population, as it would be if I could resubmit with the populations and terms targeted by the NIH.

24. I have never been so scared in my life about the future of our field and my work. Many of our major grants are nearing an end, and in light of the current censorship by the NIH, I am concerned about the ability to obtain enough funding to support my staff of approximately 50 individuals. I am also concerned about the erasure of populations in public health—such as transgender, Two-Spirit, and nonbinary individuals—who experience substance abuse, sexual assault, and dating violence at higher

rates than the general population, and who would therefore stand to benefit significantly from research aimed at understanding and addressing those disparities. And at a personal level, I am concerned that, even if I do receive funding with revised and more limited grant proposal, the restrictions required to obtain that funding will compromise the scientific quality of our research. The restrictions required to obtain that funding may prevent us from asking important research questions, examining meaningful differences across populations, accurately studying factors such as gender that are central to understanding and preventing violence, and fully reporting what our data show. These limitations would ultimately reduce the usefulness and impact of the research and the publications that result from it, hinder the development of effective prevention strategies, and reduce the positive impact of this research on the health of LGBTQ+ youth and/or Indigenous youth.

25. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Ann Arbor, Michigan this 22nd day of September 2026.

Katie Edwards

Exhibit 1

UNIVERSITY OF MICHIGAN

Katie Edwards <edkatie@umich.edu>

1R21HD122186-01

Gilbert, Leah (NIH/NICHD) [E] <leah.gilbert@nih.gov> Mon, Aug 10, 2026 at 11:36 AM
To: "edkatie@umich.edu" <edkatie@umich.edu>
Cc: "orsp-triage@umich.edu" <orsp-triage@umich.edu>, "NICHD HD eRA Notifications (NIH/NICHD)" <hderanotifications@mail.nih.gov>, "Fritz, Kelly (NIH/NICHD) [E]" <kelly.fritz@nih.gov>

Dear Dr. Dr. Edwards,

I am the Program Official assigned to your grant R21HD122186-01, and I am completing a review of your application. The purpose of this email is to resolve any administrative issues that may delay the release of a Notice of Award should we be able fund your application pending final NICHD leadership and budgetary review. Please review and address the following items at your earliest convenience.

1. There are some issues in your Data Management and Sharing Plan (DMSP) that need to be addressed to be in compliance with NIH Policy…Please revise your DMSP and then have the Authorized Organization Representative submit it through the “Data Management and Sharing Plan (DMSP) Revision” section of the Just in Time (JIT) Screen in eRA Commons.
    1. While we understand data sharing is determined by the Tribe from which the data originated, for a secondary analysis project however, we do encourage the PI to describe when, where, and how the documentation and/or code for processing and analyzing the data will be shared (e.g., a generalist repository, GitHub).
2. Please submit all Just in Time materials including investigator statements of support ensuring no scientific or budgetary overlap
3. To ensure alignment with Administration priorities, please adjust the term gender in the abstract and specific aims when referring to biological sex. Use the attached word document template for the edits, and have your AOR submit the edits via email, back to me.

Leah Gilbert, MD, MSPH, FACEP

Medical Officer, Pediatric Trauma and Critical Illness Branch

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

Office Phone: 301-594-3154

Email: leah.gilbert@nih.gov

RAA_Template (3).docx
13K

Exhibit 2

Modified Project Summary/Abstract Section

Enter the text here that is the new abstract information for your application.

Modified Specific Aims Section

Enter the text here that is the new specific aims information for your application.

Modified Public Health Relevance Section

Enter the text here that is the new public health relevance information for your application. Using no more than two or three sentences, describe the relevance of this research to public health.

Exhibit 3

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R21HD122186
Federal Award Date
09/18/2026

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF MICHIGAN
1109 GEDDES AVE STE 3300
ANN ARBOR, MI 48109

2. Congressional District of Recipient
06

3. Payment System Identifier (ID)
1386006309A1

4. Employer Identification Number (EIN)
386006309

5. Data Universal Numbering System (DUNS)
073133571

6. Recipient's Unique Entity Identifier
GNJ7BBP73WE9

7. Project Director or Principal Investigator
Katie M Edwards, PHD
Professor
edkatie@umich.edu
734-763-2345

8. Authorized Official
Shandra White

Federal Agency Information

9. Awarding Agency Contact Information
Kelly Fritz

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
kelly.fritz@nih.gov
301-827-5429

10. Program Official Contact Information
LEAH KAYE Gilbert
Program Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
leah.gilbert@nih.gov
(301) 594-3154

Federal Award Information

11. Award Number
1R21HD122186-01

12. Unique Federal Award Identification Number (FAIN)
R21HD122186

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Evaluation of a Sexual Violence Program for Youth Living on or Near a Rural Indian Reservation in the Northern Great Plains

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/03/2026 **– End Date** 08/31/2028	
20. Total Amount of Federal Funds Obligated by this Action	$429,000
20 a. Direct Cost Amount	$275,000
20 b. Indirect Cost Amount	$154,000
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$429,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$429,000
26. Project Period Start Date 09/03/2026 **– End Date** 08/31/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$429,000

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Kelly Fritz

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R21HD122186-01

Principal Investigator(s):
Katie M Edwards, PHD

Award e-mailed to: swhite-gov@umich.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $429,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the University of Michigan in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R21HD122186. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Kelly Fritz
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Federal Direct Costs	$275,000
Federal F&A Costs	$154,000
Approved Budget	$429,000
Total Amount of Federal Funds Authorized (Federal Share)	$429,000
TOTAL FEDERAL AWARD AMOUNT	$429,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$429,000

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$429,000	$429,000

Fiscal Information:
Payment System Identifier: 1386006309A1
Document Number: RHD122186A
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026
HD	8014702	$429,000

NIH Administrative Data:
PCC: PTCIB-LG / **OC**: 41021 / **Released**: 09/18/2026
Award Processed: 09/20/2026 12:06:30 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R21HD122186-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R21HD122186-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R21HD122186. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit

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discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

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Treatment of Program Income:
Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R21HD122186-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Special Term and Condition
The recipient has revised the **Abstract, Public Health Relevance Statement, and Specific Aims** to ensure alignment with current agency priorities in **Training future biomedical scientists** and/or **Promoting research focused on scientifically valid, measurable health outcomes**. The project must be carried out in accordance with the revised **plan/section** submitted on **9/14**, which reflects the agreed upon updates. In accordance with this renegotiation, NIH funds may only be used to support activities within the revised scope of the award as described in the documents dated **DATE**. NIH funds may not be used to support activities that are not consistent with the revised scope of the award.

*****
Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the **application** dated **6/13/2025**.

***

This is a Modular Grant Award without direct categorical cost breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement (rev. 3/26). Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

****
This award is being issued as a multi-year funded (MYF) project, which provides all funding in a single budget period instead of annual, incremental awards. Due to the use of the MYF funding model, this award will be affected by the Federal funds expiration policy. Per Section 5.3 of the NIH Grants Policy Statement (rev. 3/26), "All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability." Based on this restriction, all funds issued for this award must be obligated by **June 30,2031**.

NOTE: No Cost Extension (NCE) requests at the end of the original project period require written NIH prior approval. Such requests must be submitted prior to the project period end date.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1

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DMS Costs	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R21HD122186-01

INSTITUTION: The Regents of the University of Michigan

Budget	Year 1
TOTAL FEDERAL DC	$275,000
TOTAL FEDERAL F&A	$154,000
TOTAL COST	$429,000

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	56%
F&A Cost Base 1	$275,000
F&A Costs 1	$154,000

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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF KELTON MINOR

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Kelton Minor, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I am an Associate Professor of Planetary Behavioral Data Science at the University of Copenhagen. My research combines advances from the computational and behavioral sciences with spatial data science, causal inference and AI to examine how individuals and populations adapt their health behaviors to extreme weather, climate hazards and rapid global environmental changes.

4. I earned my PhD in Planetary Social and Behavioral Data Science at the University of Copenhagen and completed my postdoctoral training at Columbia University's Data Science Institute. I was also previously a visiting researcher at U.C. Berkeley's Global Policy Lab and completed my Master's of Science at Cornell University.

5. I have published widely in my field, including in The Lancet, JAMA Psychiatry, Proceedings of the National Academy of Sciences, Nature Mental Health, The Journal of the American Academy of Child & Adolescent Psychiatry, Nature Climate Change, Psychological Science, Sleep, Sleep Medicine Reviews, and many other top general science and health journals. My work has been cited over eight thousand and seven hundred times according to Google Scholar. I am a former Fulbright Research Grantee and Cornell Merrill Presidential Scholar.

6. In 2024 I was awarded the prestigious NIH Director's Early Independence Award, a five-year, approximately $2 million dollar grant award described by NIH as "supporting exceptional junior scientists in establishing accelerated career paths leading to outstanding and sustained contributions to biomedical and behavioral research." This extremely competitive award provides five years of funding for the recipient to open and run their own research lab, and supports the transition directly to an independent faculty or research position.

7. Putting together the proposal for this award was an enormous undertaking that spanned about two years from idea development through final award. The NIH Director's Early Independence Award is one of the most competitive and transformative early career scientific research awards in the

United States. For the 2024 award competition, each university in the United States could nominate two candidates who recently earned their PhDs through a highly competitive internal selection process. From Fall 2022 - Spring 2023 I spent part of the first five months of my postdoc at Columbia developing the research idea for the project and then an additional concerted month drafting my internal Columbia application submitted in late Spring 2023. After winning one of Columbia University's two nominations in summer 2023, I spent approximately 6 weeks intensively writing and submitting my invited full ~60 page proposal to the national competition. Only the top subset of applications were selected by the NIH to undergo full committee review in early 2024. Following multiple rounds of rigorous review by an NIH-invited panel of top US scientific experts, my application was scored and selected among the very top batch of proposals for final consideration by the NIH Director's Office. I was notified in September 2024 that the NIH had formally awarded my project a 2024 NIH Director's Early Independence Award (DP5), representing the top academic achievement of my scientific career and culmination of years of training and rigorous research. Attached hereto as **Exhibit 1** is a true and correct copy of this NIH-mailed Award Certificate.

8. My award project is titled "The Behavioral Cost of Carbon." The goal of the project is to generate the first empirical estimate of the human health-related behavioral impacts (the net sum of costs and benefits) imposed by incremental increases in greenhouse gas emissions through (a) estimating the first US domestic substance use cost of carbon by linking alcohol consumption observations and substance use panel data with high resolution meteorological data (i.e. weather and climate observations) across the U.S.; (b) evaluating the US and global sleep cost of carbon by applying multi-stage multivariate time-series fixed effects models to estimate associations between local meteorological conditions and both self-reported and actigraphy-recorded sleep outcomes; and (c) assessing the preliminary physical activity cost of carbon and estimating local climate-behavioral impact projections – statistically accounting for acclimatization – for every county in the U.S. and every region worldwide. Attached hereto as **Exhibit 2** is a true and correct copy of this Notice of Award (i.e., NOA).

9. Hot and cold weather hazards continue to pose substantial health risks for Americans. Recent empirical estimates suggest that ~5% of all-cause mortality deaths in the U.S. are attributable to suboptimal cold and hot temperatures. Yet very little is known about the burden of cold and hot

temperatures on human health behaviors and related healthcare utilization in the US and globally. Studying health behavioral impacts from and adaptation to these hazards can inform prevention, preparedness and practical health protection by revealing health adaptation targets. This research can further help people and health systems prepare for and prevent future climate impacts by accounting for the downstream health behavioral costs and benefits of greenhouse gas emissions.

10. My award was to be hosted by Columbia University, where I completed my postdoc. During my faculty onboarding when I was to begin receiving NIH funding, Columbia was targeted by the Trump Administration for alleged antisemitism, and as a result I was notified by Columbia on March 13th that my award was on the list of NIH terminated awards. The ~$400M in grant terminations had been first announced by the US Government a week earlier on March 7th after I had just given my first lecture to medical students on March 6th. NIH formally announced the termination via a notice posted on March 14th, 2025. Attached hereto as **Exhibit 3** is a true and correct copy of the termination notice.

11. Two weeks later I was notified by Columbia that due to the award termination they had to halt my faculty onboarding.

12. I spent several months assessing my options and looking for another job and applied for and later accepted a June 25th, 2025 offer from the University of Copenhagen. I started my new position as a tenured associate professor in Copenhagen in September of 2025.

13. In late July of 2025, Columbia University came to an agreement with the Trump Administration and my award was formally reinstated by the NIH on July 25th.

14. On August 11, 2025, I received a revised NOA allowing the work to move forward and administratively extending the budget year. Attached hereto as **Exhibit 4** is a true and correct copy of this revised NOA.

15. Columbia agreed to transfer the grant to a different US institution willing to administer the grant so that I would be able to begin my research and make progress on the primary scientific aims.

16. After fielding offers from multiple institutions interested in my work, I selected the Laureate Institute for Brain Research ("LIBR") in Tulsa, Oklahoma to administer the award. I worked with LIBR to prepare an NIH transfer application over several weeks. On November 13, 2025, LIBR

submitted the transfer application to NIH. Such transfer requests are common when faculty move research institutions and are generally granted within several weeks.

17. I checked in every few weeks with my NIH Program Officer ("PO") about the status of the transfer application, and on December 8, 2025, my PO responded that their review of the application was complete but the Grants Officer's review was still pending. Over the next few weeks I repeatedly reached out for updates and each time I was told the transfer application was awaiting Grants Officer review. Finally, on January 21, 2025, I learned that the Grants' Officer had signed off on the transfer and that I should expect to receive the updated NOA in the next day or two. I was thrilled. My University of Copenhagen Center Director and LIBR Director prepared and signed an agreement for my imminent reduction in hours at the University of Copenhagen in order for me to focus on completing my NIH Director's Award project at LIBR.

18. But this did not occur. After additional unexplained delay I heard from my NIH PO that the transfer application was awaiting signature by the Grants Management Officer at the NIH Director's Office. This is a different individual than the Grants Officer. I reached out for updates regularly through February and March, without success.

19. On March 13, 2026 (the one-year anniversary of the first termination) I received an email stating:

> The NIH Office of Extramural Research reviewed your grant 7DP5OD037400-02 and determined it was "out of alignment with the NIH's priorities" due to its focus on overall effects of carbon emissions and climate change on human behavior. I was asked last week to reevaluate the grant for consistency with NIH priorities. Could you please schedule a time to speak with me about this issue? I apologize for the paucity of speaking slots, but I'm in the heart of program meetings and reviews.

20. Attached hereto as **Exhibit 5** is a true and correct copy of this email.

21. I learned that the Office of Extramural Research ("OER") is using an AI tool to screen funding decisions for alignment with administration priorities and that my transfer application had been flagged as "red" or "non-aligned."

22. On March 19, 2026, I received an email from NIH restating the OER finding and suggesting that my grant could be brought into alignment with NIH priorities by "reframing" the description of my research "to make it clear that [I am] assessing the effects of temperature fluctuations on human behaviors, not climate change directly." Attached hereto as **Exhibit 6** is a true and correct copy of this email.

23. Over the next week I worked around the clock to remove all mentions of "climate" "carbon" and "climate change" from my award to align with NIH priorities, including censoring out references to many of my previously published scientific articles. I updated the analysis methodology to only estimate health behavioral adaptation to temperatures, removing all components involving climate models and behavioral cost benefit analyses of carbon emissions. LIBR emailed my revised research description to NIH on March 25, 2026.

24. On May 11, 2026, I received an email from my NIH Grants Officer stating that NIH is unable to approve the requested transfer. The email stated:

> NIH initially requested clarification on how the application project aligns with NIH mission priorities. In response to the request, revised research aims were submitted that included additional experimental activities that were not part of the originally reviewed and awarded application. These changes materially alter the scope and scientific direction of the funded project and are not consistent with the originally approved award. Because a change of recipient organization through a Type 7 transfer must maintain continuity with the originally peer-reviewed and approved project, NIH cannot approve a transfer application that substantially changes the project's scope, aims, or scientific framework beyond what was originally awarded.

25. Attached hereto as **Exhibit 7** is a true and correct copy of this email.

26. I can only assume that the reference to "experimental activities" is an AI hallucination, as my award quite clearly does not include any experiments or interventions.

27. Nor is the second explanation for the denial accurate. The core science in my revised research description remained fundamentally consistent with those in the original application, with climate change components removed per NIH's request. On May 13, 2026, I sent NIH an email making these two points and reiterating my interest in continuing my project as previously awarded. I further

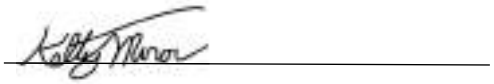
attached both the original version of my awarded project description, and the NIH-requested revised version that integrated NIH's direct guidance to remove the climate change-related terms and climate model components while otherwise maintaining the original core science and rigorous statistical approach.

28. Now months later, I still have not heard back from NIH. The last entry on ERA Commons indicates "Application entered into system." I assume the grant will be re-terminated at any moment.

29. As of today, I have not been able to begin work on the project. Every additional day of delay that goes by is another day of lost scientific progress and forgone knowledge that could help identify practical opportunities to protect Americans and their health behaviors during periods of extreme temperature before they translate into downstream burdens on the US healthcare system. The need for this research is particularly acute at a time when one of the strongest-ever recorded El Niño events is now underway and forecast to affect US weather and the population as it intensifies in late 2026 and early 2027, and when extreme temperature hazards continue to pose substantial health risks for Americans in the current warming climate as evidenced by recent events and as documented by rigorous science. I remain thoroughly committed to the project and am fully prepared to maintain continuity with the core science that merited an NIH Director's Award after rigorous peer review and competitive assessment by top US health scientists and the NIH. I am ready to resume this work immediately as soon as the transfer is approved.

30. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed in Copenhagen, Denmark this 9th day of September 2026.



Kelton Minor

Exhibit 1

THE NATIONAL INSTITUTES OF HEALTH

OFFICE OF THE DIRECTOR

IS PLEASED TO PRESENT TO

Kelton Minor, Ph.D.

THE 2024

NIH DIRECTOR'S EARLY INDEPENDENCE AWARD

FROM THE COMMON FUND'S HIGH-RISK, HIGH-REWARD RESEARCH PROGRAM

Supporting exceptional junior scientists in establishing accelerated career paths leading to outstanding and sustained contributions to biomedical and behavioral research.

NIH DIRECTOR'S EARLY INDEPENDENCE AWARD

Monica M. Bertagnolli, M.D.
Director, NIH

Exhibit 2

Department of Health and Human Services
National Institutes of Health
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Notice of Award
FAIN# DP5OD037400
Federal Award Date
09/18/2024

Recipient Information

1. Recipient Name
THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
630 W 168TH ST FL 4
NEW YORK, NY 10032

2. Congressional District of Recipient
13

3. Payment System Identifier (ID)
1135598093A7

4. Employer Identification Number (EIN)
135598093

5. Data Universal Numbering System (DUNS)
621889815

6. Recipient's Unique Entity Identifier
QHF5ZZ114M72

7. Project Director or Principal Investigator
Kelton Minor

km3876@columbia.edu
650-709-6234

8. Authorized Official
William Berger

Federal Agency Information

9. Awarding Agency Contact Information
Gabriel Hidalgo

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH
hidalgoge@nidcr.nih.gov
301-827-4630

10. Program Official Contact Information
Becky Miller

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH
becky.miller2@nih.gov
301-594-9979

Federal Award Information

11. Award Number
1DP5OD037400-01

12. Unique Federal Award Identification Number (FAIN)
DP5OD037400

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Behavioral Cost of Carbon

15. Assistance Listing Number
93.310

16. Assistance Listing Program Title
Trans-NIH Research Support

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/18/2024 **– End Date** 07/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$411,250
20 a. Direct Cost Amount	$250,000
20 b. Indirect Cost Amount	$161,250
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$411,250
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$411,250
26. Project Period Start Date 09/18/2024 **– End Date** 07/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$411,250

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
April Harrison

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Early Independence Award
Department of Health and Human Services
National Institutes of Health

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

SECTION I – AWARD DATA – 1DP5OD037400-01

Principal Investigator(s):
Kelton Minor

Award e-mailed to: grants-office@columbia.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $411,250 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COLUMBIA UNIVERSITY HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Office Of The Director, National Institutes Of Health of the National Institutes of Health under Award Number DP5OD037400. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

April Harrison
Grants Management Officer
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/18/2024 12:19 AM

Federal Direct Costs	$250,000
Federal F&A Costs	$161,250
Approved Budget	$411,250
Total Amount of Federal Funds Authorized (Federal Share)	$411,250
TOTAL FEDERAL AWARD AMOUNT	$411,250
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$411,250

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$411,250	$411,250
2	$411,250	$411,250
3	$411,250	$411,250
4	$411,250	$411,250
5	$411,250	$411,250

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1135598093A7
Document Number: DOD037400A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027	2028
OD	8018959	$411,249	$411,249	$411,249	$411,249	$411,249
DE	8472268	$1	$1	$1	$1	$1

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2HR401 / **OC**: 41021 / **Released**: 09/17/2024
Award Processed: 09/18/2024 12:19:40 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1DP5OD037400-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1DP5OD037400-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

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some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) DP5OD037400. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

National Institute Of Dental & Craniofacial Research (NIDCR) Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious

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nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – OD SPECIFIC AWARD CONDITIONS – 1DP5OD037400-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This is a Modular Grant Award without direct cost categorical breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement, April 2024, see http://grants.nih.gov/grants/policy/policy.htm. Inflationary increases for future year commitments are discontinued for all competing and non-competing research awards issued in FY 24. Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle on August 1. The NIH is taking this action to redistribute start dates more evenly throughout the year. Allowable pre-award costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, April 2024, http://grants.nih.gov/grants/policy/policy.htm, and with institutional requirements for prior approval.

This award is funded by the NIH Common Fund, Office of the Director, NIH, and administered by the National Institute of Dental and Craniofacial Research.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found in the following Notice: NOT-OD-24-057.

The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is zero-level Kirschstein-NRSA Stipend in effect when NIH issues the grant award. Current levels are posted at: http://grants.nih.gov/training/nrsa.htm. Support recommended for future years has been adjusted accordingly, if applicable.

When issuing statements, press releases, and other documents describing projects or programs funded through the NIH Common Fund, please use the following acknowledgement: This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this

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research should acknowledge support by the NIH Common Fund with reference to the specific grant number.

Information on the Early Independence Award Program, which is part of the NIH Common Fund can be found at http://commonfund.nih.gov/earlyindependence/.

It is understood that at no time must the PI's total research effort exceed 12 calendar months.

This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this research should acknowledge support by the NIH Common Fund with reference to the specific grant number.

This award is subject to the SPECIAL REQUIREMENTS section of the NOFO RM-23-007, NIH Director's Early Independence Awards (DP5), which is hereby incorporated by reference as special terms and conditions of this award. Copies of this announcement may be accessed at the following internet address: https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-23-007.html

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$0	$0	$0	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1DP5OD037400-01

INSTITUTION: COLUMBIA UNIVERSITY HEALTH SCIENCES

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
TOTAL FEDERAL DC	$250,000	$250,000	$250,000	$250,000	$250,000
TOTAL FEDERAL F&A	$161,250	$161,250	$161,250	$161,250	$161,250
TOTAL COST	$411,250	$411,250	$411,250	$411,250	$411,250

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	64.5%	64.5%	64.5%	64.5%	64.5%
F&A Cost Base 1	$250,000	$250,000	$250,000	$250,000	$250,000
F&A Costs 1	$161,250	$161,250	$161,250	$161,250	$161,250

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Exhibit 3

Department of Health and Human Services
National Institutes of Health
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Notice of Award
FAIN# DP5OD037400
Federal Award Date
03/14/2025

Recipient Information

1. Recipient Name
THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
630 W 168TH ST FL 4
NEW YORK, NY 10032

2. Congressional District of Recipient
13

3. Payment System Identifier (ID)
1135598093A7

4. Employer Identification Number (EIN)
135598093

5. Data Universal Numbering System (DUNS)
621889815

6. Recipient's Unique Entity Identifier
QHF5ZZ114M72

7. Project Director or Principal Investigator
Kelton Minor

km3876@columbia.edu
650-709-6234

8. Authorized Official
William Berger

Federal Agency Information

9. Awarding Agency Contact Information
Gabriel Hidalgo

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH
hidalgoge@nidcr.nih.gov
301-827-4630

10. Program Official Contact Information
Becky Miller

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH
becky.miller2@nih.gov
301-594-9979

Federal Award Information

11. Award Number
1DP5OD037400-01

12. Unique Federal Award Identification Number (FAIN)
DP5OD037400

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Behavioral Cost of Carbon

15. Assistance Listing Number
93.310

16. Assistance Listing Program Title
Trans-NIH Research Support

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/18/2024 **– End Date** 03/14/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$411,250
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$411,250
26. Project Period Start Date 09/18/2024 **– End Date** 03/14/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$411,250

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Gabriel Hidalgo

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Early Independence Award
Department of Health and Human Services
National Institutes of Health

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

SECTION I – AWARD DATA – 1DP5OD037400-01 REVISED

Principal Investigator(s):
Kelton Minor

Award e-mailed to: grants-office@columbia.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COLUMBIA UNIVERSITY HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Office Of The Director, National Institutes Of Health of the National Institutes of Health under Award Number DP5OD037400. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Gabriel Hidalgo
Grants Management Officer
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/15/2025 12:08 AM

Federal Direct Costs	$250,000
Federal F&A Costs	$161,250
Approved Budget	$411,250
Total Amount of Federal Funds Authorized (Federal Share)	$411,250
TOTAL FEDERAL AWARD AMOUNT	$411,250

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$411,250	$411,250

Fiscal Information:
Payment System Identifier: 1135598093A7
Document Number: DOD037400A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8018959	$411,249
DE	8472268	$1

NIH Administrative Data:
PCC: 2HR401 / **OC**: 41021 / **Released**: 03/14/2025
Award Processed: 03/15/2025 12:08:47 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1DP5OD037400-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1DP5OD037400-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) DP5OD037400. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

National Institute Of Dental & Craniofacial Research (NIDCR) Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – OD SPECIFIC AWARD CONDITIONS – 1DP5OD037400-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This project has been terminated due to unsafe antisemitic actions that suggest the institution lacks concern for the safety and wellbeing of Jewish students. Columbia University may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable** within 120 days of the end of this grant.

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

PREVIOUS TERMS AND CONDITIONS ISSUED 01/22/2025

This revised award reflects the following restriction:

RESTRICTION I: All funds and collaboration associated with research at Technical University of Denmark, Denmark, are restricted, and no activity related to the foreign site(s) can be conducted until the NIH has notified the Columbia University in writing.

RESTRICTION II: All funds for this project are restricted, pending the submission and approval of an updated timeline, updated foreign justification, updated project budget, and additional materials discussed with Dr. Kelton Minor and Mr. William Berger, Columbia University, on January 21, 2025.

PREVIOUS TERMS AND CONDITIONS ISSUED 09/18/2024

This is a Modular Grant Award without direct cost categorical breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement, April 2024, see http://grants.nih.gov/grants/policy/policy.htm. Inflationary increases for future year commitments are discontinued for all competing and non-competing research awards issued in FY 24. Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle on August 1. The NIH is taking this action to redistribute start dates more evenly throughout the year. Allowable pre-award costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, April 2024, http://grants.nih.gov/grants/policy/policy.htm, and with institutional requirements for prior approval.

This award is funded by the NIH Common Fund, Office of the Director, NIH, and administered by the National Institute of Dental and Craniofacial Research.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found in the following Notice: NOT-OD-24-057.

The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is zero-level Kirschstein-NRSA Stipend in effect when NIH issues the grant award. Current levels are posted at: http://grants.nih.gov/training/nrsa.htm. Support recommended for future years has been adjusted accordingly, if applicable.

When issuing statements, press releases, and other documents describing projects or programs funded through the NIH Common Fund, please use the following acknowledgement: This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this research should acknowledge support by the NIH Common Fund with reference to the specific grant number.

Information on the Early Independence Award Program, which is part of the NIH Common Fund can be found at http://commonfund.nih.gov/earlyindependence/.

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It is understood that at no time must the PI's total research effort exceed 12 calendar months.

This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this research should acknowledge support by the NIH Common Fund with reference to the specific grant number.

This award is subject to the SPECIAL REQUIREMENTS section of the NOFO RM-23-007, NIH Director's Early Independence Awards (DP5), which is hereby incorporated by reference as special terms and conditions of this award. Copies of this announcement may be accessed at the following internet address: https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-23-007.html

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1
DMS Costs	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1DP5OD037400-01 REVISED

INSTITUTION: COLUMBIA UNIVERSITY HEALTH SCIENCES

Budget	Year 1
TOTAL FEDERAL DC	$250,000
TOTAL FEDERAL F&A	$161,250
TOTAL COST	$411,250

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	64.5%
F&A Cost Base 1	$250,000
F&A Costs 1	$161,250

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Exhibit 4

Department of Health and Human Services
National Institutes of Health
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Notice of Award
FAIN# DP5OD037400
Federal Award Date
08/11/2025

Recipient Information

1. Recipient Name
THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
630 W 168TH ST FL 4
NEW YORK, NY 10032

2. Congressional District of Recipient
13

3. Payment System Identifier (ID)
1135598093A7

4. Employer Identification Number (EIN)
135598093

5. Data Universal Numbering System (DUNS)
621889815

6. Recipient's Unique Entity Identifier
QHF5ZZ114M72

7. Project Director or Principal Investigator
Kelton Minor

km3876@columbia.edu
650-709-6234

8. Authorized Official
William Berger

Federal Agency Information

9. Awarding Agency Contact Information
Gabriel Hidalgo

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH
hidalgoge@nidcr.nih.gov
301-827-4630

10. Program Official Contact Information
Becky Miller

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH
becky.miller2@nih.gov
301-594-9979

Federal Award Information

11. Award Number
1DP5OD037400-01

12. Unique Federal Award Identification Number (FAIN)
DP5OD037400

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Behavioral Cost of Carbon

15. Assistance Listing Number
93.310

16. Assistance Listing Program Title
Trans-NIH Research Support

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/18/2024 **– End Date** 07/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$411,250
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$411,250
26. Project Period Start Date 09/18/2024 **– End Date** 07/31/2030	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$411,250

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
April Harrison

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Early Independence Award
Department of Health and Human Services
National Institutes of Health

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

SECTION I – AWARD DATA – 1DP5OD037400-01 REVISED

Principal Investigator(s):
Kelton Minor

Award e-mailed to: grants-office@columbia.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COLUMBIA UNIVERSITY HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Office Of The Director, National Institutes Of Health of the National Institutes of Health under Award Number DP5OD037400. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

April Harrison
Grants Management Officer
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Federal Direct Costs	$250,000
Federal F&A Costs	$161,250
Approved Budget	$411,250
Total Amount of Federal Funds Authorized (Federal Share)	$411,250
TOTAL FEDERAL AWARD AMOUNT	$411,250

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$411,250	$411,250
2	$411,250	$411,250
3	$411,250	$411,250
4	$411,250	$411,250
5	$411,250	$411,250

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1135598093A7
Document Number: DOD037400A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2026	2027	2028	2029
OD	8018959	$411,249	$411,249	$411,249	$411,249	$411,249
DE	8472268	$1	$1	$1	$1	$1

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2HR401 / **OC**: 41021 / **Released**: 08/11/2025
Award Processed: 08/12/2025 11:55:15 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1DP5OD037400-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1DP5OD037400-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

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some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) DP5OD037400. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

National Institute Of Dental & Craniofacial Research (NIDCR) Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious

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nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – OD SPECIFIC AWARD CONDITIONS – 1DP5OD037400-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This revised award extends the -01 budget period for an additional 12 months, as an administrative action. The new budget period end date will be 07/31/2026. Recipients are reminded that all terms and conditions of the award apply during the extended period.

Additionally, this revised award lifts RESTRICTION I and RESTRICTION II, thus collaboration with Technical University of Denmark, Denmark can commence.

PREVIOUS TERMS AND CONDITIONS ISSUED 07/29/2025

Award Reinstatement

Effective with the date of this revised Notice of Award, funding for Project Number DP5OD037400 is hereby fully reinstated; therefore, the Notice of Award and language included therein, dated 03/15/2025 that terminated the project is rescinded without conditions. Funds made available to Columbia University used to support the project titled "The Behavioral Cost of Carbon," under the direction of Dr. Kelton Minor, are no longer restricted and are available for use in accordance with the terms and conditions of the award.

All previous terms and conditions issued prior 03/15/2025 remain in effect.

PREVIOUS TERMS AND CONDITIONS ISSUED 03/15/2025

This project has been terminated due to unsafe antisemitic actions that suggest the institution lacks concern for the safety and wellbeing of Jewish students. Columbia University may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable** within 120 days of the end of this grant.

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

PREVIOUS TERMS AND CONDITIONS ISSUED 01/22/2025

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This revised award reflects the following restriction:

RESTRICTION I: All funds and collaboration associated with research at Technical University of Denmark, Denmark, are restricted, and no activity related to the foreign site(s) can be conducted until the NIH has notified the Columbia University in writing.

RESTRICTION II: All funds for this project are restricted, pending the submission and approval of an updated timeline, updated foreign justification, updated project budget, and additional materials discussed with Dr. Kelton Minor and Mr. William Berger, Columbia University, on January 21, 2025.

PREVIOUS TERMS AND CONDITIONS ISSUED 09/18/2024

This is a Modular Grant Award without direct cost categorical breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement, April 2024, see http://grants.nih.gov/grants/policy/policy.htm. Inflationary increases for future year commitments are discontinued for all competing and non-competing research awards issued in FY 24. Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle on August 1. The NIH is taking this action to redistribute start dates more evenly throughout the year. Allowable pre-award costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, April 2024, http://grants.nih.gov/grants/policy/policy.htm, and with institutional requirements for prior approval.

This award is funded by the NIH Common Fund, Office of the Director, NIH, and administered by the National Institute of Dental and Craniofacial Research.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found in the following Notice: NOT-OD-24-057.

The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is zero-level Kirschstein-NRSA Stipend in effect when NIH issues the grant award. Current levels are posted at: http://grants.nih.gov/training/nrsa.htm. Support recommended for future years has been adjusted accordingly, if applicable.

When issuing statements, press releases, and other documents describing projects or programs funded through the NIH Common Fund, please use the following acknowledgement: This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this research should acknowledge support by the NIH Common Fund with reference to the specific grant number.

Information on the Early Independence Award Program, which is part of the NIH Common Fund can be found at http://commonfund.nih.gov/earlyindependence/.

It is understood that at no time must the PI's total research effort exceed 12 calendar months.

This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this research should acknowledge support by the NIH Common Fund with reference to the specific grant number.

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This award is subject to the SPECIAL REQUIREMENTS section of the NOFO RM-23-007, NIH Director's Early Independence Awards (DP5), which is hereby incorporated by reference as special terms and conditions of this award. Copies of this announcement may be accessed at the following internet address: https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-23-007.html

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$0	$0	$0	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1DP5OD037400-01 REVISED

INSTITUTION: COLUMBIA UNIVERSITY HEALTH SCIENCES

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
TOTAL FEDERAL DC	$250,000	$250,000	$250,000	$250,000	$250,000
TOTAL FEDERAL F&A	$161,250	$161,250	$161,250	$161,250	$161,250
TOTAL COST	$411,250	$411,250	$411,250	$411,250	$411,250

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	64.5%	64.5%	64.5%	64.5%	64.5%
F&A Cost Base 1	$250,000	$250,000	$250,000	$250,000	$250,000
F&A Costs 1	$161,250	$161,250	$161,250	$161,250	$161,250

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2025 11:55 AM

Exhibit 5

Gmail Kelton Minor <kelton.minor@gmail.com>

7DP5OD037400-02 concerns

Miller, Becky (NIH/OD) [E] <becky.miller2@nih.gov> Fri, Mar 13, 2026 at 9:31 PM
To: Kelton Minor <kelton.minor@gmail.com>
Cc: "Hidalgo Castro, Gabriel (NIH/NIDCR) [E]" <gabriel.hidalgo@nih.gov>, "Harrison, April (NIH/NIDCR) [E]" <harrisona@mail.nih.gov>

Dear Dr. Minor,

The NIH Office of Extramural Research reviewed your grant 7DP5OD037400-02 and determined it was “out of alignment with the NIH’s priorities” due to its focus on overall effects of carbon emissions and climate change on human behavior. I was asked last week to reevaluate the grant for consistency with NIH priorities. Could you please schedule a time to speak with me about this issue? I apologize for the paucity of speaking slots, but I’m in the heart of program meetings and reviews.

We also need to discuss the new NIH policy regarding monetary foreign components. NIH has not yet come up with a process for non-competing applications without human subjects and with monetary foreign components, but I’m afraid this is another hurdle we will face.

I wish I had better news. Talk to you soon.

Best regards,

Becky

Becky Miller, Ph.D.
Program Leader

Office of Strategic Coordination The Common Fund
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director, NIH

6001 Executive Blvd, Ste 8190, Rockville, MD 20852

(p): 301-594-9979 | **(e):** becky.miller2@nih.gov

NIH National Institutes of Health
Office of Strategic Coordination - The Common Fund

Exhibit 6

Gmail

Kelton Minor <kelton.minor@gmail.com>

7DP5OD037400-02 concerns

Miller, Becky (NIH/OD) [E] <becky.miller2@nih.gov> Thu, Mar 19, 2026 at 4:30 PM
To: Kelton Minor <kelton.minor@gmail.com>
Cc: "cmccallum@laureateinstitute.org" <cmccallum@laureateinstitute.org>, "Hidalgo Castro, Gabriel (NIH/NIDCR) [E]" <gabriel.hidalgo@nih.gov>, "Harrison, April (NIH/NIDCR) [E]" <harrisona@mail.nih.gov>

Dear Dr. Minor,

The NIH Office of Extramural Research reviewed your grant 7DP5OD037400-02 and determined it was “out of alignment with the NIH’s priorities” due to its focus on overall effects of carbon emissions and climate change on human behavior. I was asked to reevaluate the grant for consistency with NIH priorities. I believe the description of your research can be reframed to make it clear that you are assessing the effects of temperature fluctuations on human behaviors, not climate change directly. You should update sections of your application to make this distinction clear. Your Office of Sponsored Research should email NIH your finalized updated sections to Gabe Hidalgo and April Harrison (on this email) with me copied.

Please let me know if you have any questions.

Best regards,

Becky

Becky Miller, Ph.D.
Program Leader

Office of Strategic Coordination The Common Fund
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director, NIH

6001 Executive Blvd, Ste 8190, Rockville, MD 20852

(p): 301-594-9979 | **(e):** becky.miller2@nih.gov

NIH National Institutes of Health
Office of Strategic Coordination - The Common Fund

Exhibit 7

Gmail

Kelton Minor <kelton.minor@gmail.com>

Transfer Application for Grant Number: 7DP5OD037400 - 02 PI Name: Minor, Kelton

Hidalgo Castro, Gabriel (NIH/NIDCR) [E] <gabriel.hidalgo@nih.gov> Mon, May 11, 2026 at 5:05 PM
To: "cmccallum@laureateinstitute.org" <cmccallum@laureateinstitute.org>, Kelton Minor <kelton.minor@gmail.com>
Cc: "Miller, Becky (NIH/OD) [E]" <becky.miller2@nih.gov>, "Harrison, April (NIH/NIDCR) [E]" <harrisona@mail.nih.gov>

Dear AOR and PI,

Thank you for the transfer application submitted on November 13, 2025, requesting the transfer of grant DP5-OD037400-02, “The Behavioral Cost of Carbon,” from Columbia University to Laureate Institute for Brain Research.

NIH has completed its review of the submitted transfer application and the additional materials provided in March 2026. Based on that review, NIH is unable to approve the requested transfer.

NIH initially requested clarification on how the application project aligns with NIH mission priorities. In response to the request, revised research aims were submitted that included additional experimental activities that were not part of the originally reviewed and awarded application. These changes materially alter the scope and scientific direction of the funded project and are not consistent with the originally approved award.

Because a change of recipient organization through a Type 7 transfer must maintain continuity with the originally peer-reviewed and approved project, NIH cannot approve a transfer application that substantially changes the project’s scope, aims, or scientific framework beyond what was originally awarded.

Accordingly, NIH will not approve the transfer of DP5OD037400 to Laureate Institute for Brain Research.

Please let us know if you have any administrative closeout questions related to this matter.

Sincerely,

Gabriel Hidalgo

Gabriel E. Hidalgo, MBA

Chief, Grants Management Branch

ational Institute of Dental and Craniofacial Research

ational Institutes of Health

B31B/5B49B

301 827 4630

Gabriel Hidalgo@nih gov

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
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oakselrod@aclu.org
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125 Broad Street, 18th Floor
New York, NY 10004
Telephone: (212) 549-2659

Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF MICHAEL D. GREEN

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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Telephone: (301) 823-1148

* Application for *Pro Hac Vice* Admission Forthcoming

I, Michael D. Green, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. I am a postdoctoral fellow in the Department of Health, Behavior and Society at Johns Hopkins University's Bloomberg School of Public Health. My research is in the field of population health sciences, focusing on understanding and eliminating inequities.

3. I offer this declaration in my individual capacity and not on behalf of my employer.

4. My interest in this area of work developed because of the needs of my family members. Many did not feel listened to in medical settings and, because of their lack of trust in traditional allopathic medicine, they forewent care. I saw firsthand how even when there were great medicines available to people in my family, social factors and whether or not they were treated with respect and dignity were major determining factors in management of their chronic illnesses. Because of those experiences, I sought out to become a researcher who studies health at the population level.

5. Prior to my postdoctoral fellowship, I earned my Ph.D. in population health sciences from Duke University. Before that, I earned my undergraduate degree from Dartmouth College.

6. Although early in my career, I have published in a number of peer-reviewed academic journals as lead author or co-author, in the *BMJ*, *Circulation: Population Health and Outcomes, Journal of Participatory Research Methods*, and *American Heart Journal.* In November 2025, I received the Person-In-Training Award from the Health Sciences Section of the Gerontological Society of America for the best student paper presented at the Gerontological Society's Annual Scientific Meeting. I am a member of the American Heart Association's Quality of Care and Outcomes Research Council Early Career Committee. I am also a member of several professional organizations including the Alzheimer's Association, and Interdisciplinary Association for Population Health Science.

7. Institutional grantees are the entities that host the research and receive the award and funding from the National Institutes of Health (NIH), and are generally universities, hospitals, and sometimes non-profits and other entities. Awards also name one or more Principal Investigators, who are researchers directly responsible for proposing the projects, overseeing the design and

implementation of studies, and managing the research from the application stage through the end of a grant. Institutional grantees can change.

8. In September 2023, I applied for an F99/K00 award, a type of award that supports early career researchers as they complete their Ph.D. dissertation research training (the F99 phase) and transition to mentored postdoctoral career development research positions like postdoctoral fellowships (the K00 phase). Preparing this grant was time consuming and demanding. The process required hundreds of hours of work, from reviewing literature to analyzing preliminary data to working with my mentors and colleagues to constantly revising drafts—all to put together my application materials. As other young researchers do for F99/K00 grants, I applied to this grant to help launch the start of my academic career as a postdoctoral fellow. The main benefit that I perceived for this kind of NIH grant was the dedicated time this grant would provide me to focus on research and career stability at a such a pivotal point of my career.

9. The application received a historically fundable score in February 2024, and in August 2024, NIH issued the award, which had a beginning date in September 2024. The grant was titled Assessing the Impact of Discrimination in Healthcare on the Cardiovascular and Cognitive Health of Aging Adults, and the first research goal of the project was to understand how discrimination reported in healthcare settings is associated with the incidence of adverse cardiovascular events, as well as to support my predoctoral training. The second research goal of this project was also to understand how reported discrimination in healthcare may contribute to cognitive impairment and decline, including with conditions like Alzheimer's disease and related dementias. That training and research would help shed light on discrimination specifically reported in health care's role in shaping health outcomes, and it would help contribute to my development as an independent researcher in aging.

10. The award had a grant number of F99AG088695, and is currently issued as K00AG088695. Attached hereto as Exhibit 1 is a true and correct copy of the notice of award (NOA) for this grant issued in August 2024.

11. The first annual progress report for this grant was due in May 2025. I timely submitted that progress report. At the time of initial submission, based on research tied to this grant, I had submitted 2 lead-author conference abstracts, and also had a working draft of the lead author manuscript

which was the primary research output I proposed for my grant application. Also, I had begun scheduling my dissertation defense and meeting with my prospective postdoctoral advisor about transitioning from being a Ph.D. student to a postdoctoral fellow.

12. On July 22, 2025, I received an email from an NIH program officer regarding my grant. Attached hereto as Exhibit 2 is a true and correct copy of that email. That email states that, "to proceed with funding consideration, the scope of the award must be renegotiated to make it consistent with NIH's ongoing internal review of HHS/NIH's priorities and the alignment of awards with those priorities." Ex. 2. The email went on to state that, "Specifically, NIH funds may not be used to support any Diversity Equity and Inclusion (DEI) related activities that were proposed in the application, or for any other DEI-related research or training activities, or programs." *Id.* The email went on to state that, "You will need to revise the current abstract, specific aims, grant, and annual progress report to remove any DEI language accordingly so that no NIH funds will be used to support these types of activities." *Id.* However, the program officer did not provide any examples of what constituted "DEI-related research or training activities, or programs."

13. Like many other young researchers, I had been following the news about NIH's change in policies targeting certain viewpoints. I was also aware of other researchers whose health disparities research had been either terminated earlier that year, or whose health disparities research had to go through a similar renegotiation process and who had to remove specific terms from their grant applications to receive funding. In line with my impression of what NIH was targeting, and because without this funding I would be unable to continue my transition to my postdoctoral fellowship, I went back to my grant application and removed specific population groups to be studied (such as "Black adults") and removed words such as "racism" and "discrimination in healthcare."

14. I submitted a revised application for this grant and received a revised NOA in August 2025. Attached hereto as Exhibit 3 is a true and correct copy of the revised NOA.

15. In September 2025, with my Ph.D. graduation to occur in December 2025 and my postdoctoral fellowship set to begin in January 2026, an institutional official from Duke submitted a K00 transition plan for my grant, so that the funding could transition to Johns Hopkins to support my postdoctoral fellowship. Without this transition processed by NIH, I would not be able to start that

postdoctoral fellowship. For months, however, NIH did not process this funding transition, despite my repeated requests to NIH for an update on the status of my award.

16. As a result of this delay, I was unable to start my postdoctoral fellowship in January 2026. And instead of receiving confirmation that the transition had been approved, on January 7, 2026—two days *after* I was supposed to start my postdoctoral fellowship—I received another request from NIH to renegotiate the terms of my grant. Attached hereto as Exhibit 4 is a true and correct copy of that email. In that email, the program officer stated, "to proceed with funding consideration, the scope of the award must be renegotiated to make it consistent with NIH's ongoing internal review of HHS/NIH's priorities and the alignment of awards with those priorities." Ex. 4. The program officer went on to state, "Specifically, NIH funds may not be used to support any Diversity Equity and Inclusion (DEI) related activities that were proposed in the application, or for any other DEI-related research or training activities, or programs." *Id.* The program officer also stated, "You will need to remove any DEI language from the application that gives the perception that NIH funds can be used to support these types of activities." *Id.* I was given one week to resubmit my grant materials, with no information as to the timeline for review or approval of my application.

17. To better understand what NIH was asking me to change in the grant, I reached out to the program officer, who indicated that another government official indicated that, for this application to be approved, that "DEI" items would need to be removed. The program officer stated that things like "structural racism" were to be removed from grant applications, but did not offer any other specific examples. As noted above, I had been following the news about NIH's change in policies (including its policy statements in August 2025 and December 2025), and I was aware about research by other health disparities researchers that had either been terminated or was required to be renegotiated to remove certain terms and viewpoints. I thus believed that NIH was targeting certain viewpoints. In line with my impression of what NIH was targeting, I revised my grant application materials to remove words such as "discrimination," "health equity," "health disparities," "race," and "unequal," and I resubmitted my materials in February 2026.

18. On March 19, 2026, I was informed that NIH issued a revised NOA for my grant. Attached hereto as Exhibit 5 is a true and correct copy of that revised NOA. On September 10, 2026,

NIH issued a revised NOA for the grant, stating the revision was "an administrative action to reflect the appropriate Common Accounting Number (CAN) for internal NIA purposes." Attached hereto as Exhibit 6 is a true and correct copy of that revised NOA.

19. Because of these delays by NIH, I was essentially in limbo between my graduate program and my postdoctoral fellowship, as I was unable to use the funding in its F99 form because I had already completed my Ph.D., but without the transition of funds to its K00 form, I was unable to start my postdoctoral fellowship at Johns Hopkins until April 2026—nearly four months after I was originally supposed to start that fellowship. During that time, I was not paid as a researcher and sought outside part-time employment in the hospitality industry. I no longer had employer-sponsored health insurance or dental insurance. Further, I lacked access to institutional resources like scientific journals or services that would have supported my data analysis. I was thus severely limited in my ability to meaningfully work on any research, delaying my career progression and risking my career trajectory because of the lost time and research opportunity at this critical period of my academic career. This early in my career, it is especially important to make meaningful progress on academic research, and I am very concerned that this lost time will detrimentally impact my ability to compete for tenure-track positions in the near future. I am also concerned that, given my research interests generally, I will not be competitive for future grant funding in light of NIH's stated priorities, and as a result, I am deeply concerned about my prospects in the academic job market.

20. Further, I am concerned about the quality and scope of the research that is a part of this grant as a result of NIH's targeting of viewpoints and terms in my research. Our goal is to understand how discrimination plays out in healthcare settings, and if I am limited in what demographic groups I can study or write about, then that will limit the impact of the findings and publications that result from this research. I also believe that, as a result of that limitation, there is potentially less benefit to the public health, as there will be less granular of an understanding of how different outcomes (such as Alzheimer's disease, dementia, and/or stroke) occur among different demographic subgroups. That, in turn, means we have less meaningful research to provide to, for example, medical professionals and hospitals who care for these individuals. In addition, I am concerned about being able to describe any

work funded by this grant in publications, presentations, or other avenues in a manner that is inconsistent with the language that NIH forced me to adopt in my grant materials.

21. I worry most about how this censorship undermines the process of science itself, and especially the professional development of early career researchers like myself. So much of my time spent on writing and assembling my grant application I viewed as worthwhile because of the stability of funding provided through the NIH if the application was awarded. Instead of stability, I had a career gap, health insurance coverage gap, and loss in income. Currently, I am very concerned about my future as an academic given how NIH has recently approached evaluating research in my field, including by targeting certain essential research through its censorship efforts.

22. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Baltimore, Maryland this 22 day of September 2026.



Michael D. Green

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# F99AG088695
Federal Award Date
08/26/2024

Recipient Information

1. Recipient Name
DUKE UNIVERSITY
2200 W MAIN ST
DURHAM, NC 27705

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1560532129A1

4. Employer Identification Number (EIN)
560532129

5. Data Universal Numbering System (DUNS)
044387793

6. Recipient's Unique Entity Identifier
TP7EK8DZV6N5

7. Project Director or Principal Investigator
Michael D. Green, BA

michael.d.green@duke.edu
443-764-5706

8. Authorized Official
Jennifer L. McCallister
gcmail@mc.duke.edu
919-684-5175

Federal Agency Information

9. Awarding Agency Contact Information
Anna Catherine Wysocki

NATIONAL INSTITUTE ON AGING
anna.wysocki@nih.gov

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
1F99AG088695-01

12. Unique Federal Award Identification Number (FAIN)
F99AG088695

13. Statutory Authority
284(b)(1)(C) 42 CFR Part 63a

14. Federal Award Project Title
Assessing the Impact of Discrimination in Healthcare on the Cardiovascular and Cognitive Health of Aging Black Adults

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/26/2025 **– End Date**	
20. Total Amount of Federal Funds Obligated by this Action	$50,474
20 a. Direct Cost Amount	$50,474
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$50,474
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$50,474
26. Project Period Start Date 02/26/2025 **– End Date** 06/30/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$50,474

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jessica Perez

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Pre-doc to Post-doc Transition Award
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1F99AG088695-01

Principal Investigator(s):
Michael D. Green, BA

Award e-mailed to: gcmail@mc.duke.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $50,474 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to DUKE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 284(b)(1)(C) 42 CFR Part 63a and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number F99AG088695. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jessica Perez
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Institutional Allowance	$4,750

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Travel	$1,500
Other	$16,000
Stipends	$28,224
Federal Direct Costs	$50,474
Total Award	$50,474
Total Amount of Federal Funds Authorized (Federal Share)	$50,474
TOTAL FEDERAL AWARD AMOUNT	$50,474
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$50,474

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$50,474	$50,474
2	$41,846	$41,846

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1560532129A1
Document Number: FAG088695A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025
AG	8470711	$50,474	$41,846

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2CEPIFB / **OC**: 41010 / **Released**: 08/22/2024
Award Processed: 08/26/2024 12:15:49 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1F99AG088695-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1F99AG088695-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-

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research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) F99AG088695. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

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Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1F99AG088695-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Stipends and the Institutional Allowance, if applicable, have been awarded in accordance with the NIH Guide for Grants and Contracts, Notice: NOT-OD-24-104, April 23, 2024.

The sponsor for this fellowship award is Dr. Matthew E. Dupre.

This award is subject to the conditions set forth in RFA-AG-23-016 "Transition to Aging Research Award for Predoctoral Students (F99/K00)," NIH Guide to Grants and Contracts, June 28, 2019, which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this funding opportunity announcement may be accessed at: http://www.nih.gov/grants/guide/index.html

Activation:
In the initial year of this fellowship, an activation notice bearing original signatures must be submitted to the awarding component before funds are expended.

An Activation Notice is not required in subsequent years unless the fellowship is at a foreign or Federal site.

To activate this fellowship, complete NRSA Individual Fellowship Activation Notice (form PHS 416-5) https://grants.nih.gov/grants/funding/416/phs416-5.pdf prior to the activation date.
Please submit the completed Activation Notice to the address below or via email as a.pdf to perezj@nih.gov.

Grants & Contracts Management Branch
National Institute on Aging, NIH, DHHS
7201 Wisconsin Avenue
Gateway Building, Suite 2W100
Bethesda, MD 20892

No funds may be expended until an Activation Notice has been submitted to National Institute on Aging (NIA).
The latest activation date is reflected on the first page of the Notice of Research Fellowship Award. Activation dates between October 1 - November 30 are not permitted.

Termination:
At any point during the period of support provided under this Fellowship Award the recipient may terminate the project. Documents are not to be submitted via xTrain. A completed Termination Notice (form PHS 416-7) is to be submitted within 30 days of termination via signed .pdf to the assigned Grants Management Specialist. In addition to listing the stipend amounts on the form, the remaining amounts of institutional allowance and tuition/fees/insurance, if awarded, should be listed.

Travel:
This award includes support to defray travel costs to an institution to meet the proposed mentor and to discuss and prepare a postdoctoral research and career development strategy. These funds in the amount of $1,500 are restricted for the

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above purpose only and may not be transferred or rebudgeted for any other purpose.

Carryover and No-Cost Extensions:
Carryover of unspent funds is not permitted between the first and second years of the F99 phase or from a partially completed year in the F99 phase into the K00 phase. Provisions for No-Cost Extensions do not apply to the F99 phase.

Transition to the Postdoctoral Career Development K00 Phase:
The F99/K00 award is intended to facilitate the successful transition to an aging-focused postdoctoral career. Consequently, a requirement for the K00 phase award is successful completion of the doctoral research degree and subsequent transition to an aging-related, mentored, traditional postdoctoral research position. Applicants are encouraged to expand their skill set and apply for postdoctoral positions at departments and institutions other than where they conducted their doctoral research. It is important for all applicants to provide a detailed plan by which they will separate their work from their Ph.D. sponsor. Those applicants who intend to stay at the predoctoral phase institution for the postdoctoral phase should also provide a strong justification for staying.

The transition from the predoctoral phase to the postdoctoral phase is intended to be continuous in time; therefore, except in unusual circumstances, NIA will not extend the F99 phase. To begin the K00 award phase of the grant, individuals must a) have been offered a postdoctoral appointment to carry out aging-focused research and b) have received approval from NIA for the K00 transition (see below). Upon starting the K00 phase of the award, the F99 phase of the award is terminated.

Prospective applicants are strongly encouraged to contact the NIA Training Officer as soon as a plan to assume a postdoctoral position develops, not later than 6 months prior to the end of the F99 phase of the award.
A proposed K00 institution and mentor must have appropriate infrastructure to support the proposed research program and a history of external research funding. Applicants may apply for NIH-sponsored postdoctoral positions within the NIH Intramural Research Program (IRP). However, should the individual accept such a position in the IRP, the postdoctoral phase will be supported directly by NIH intramural funds.

The K00 postdoctoral phase institution must submit the materials on behalf of the candidate for the K00 award no later than 12 weeks prior to the proposed start of the K00 award. The institution's Authorized Organizational Representative will email the application in PDF format using the PHS 398 form to the NIA Scientific Contact listed in Section VII. The K00 application will be evaluated by NIA Program staff for completeness and responsiveness to the program.

Candidates who are not approved to transition will receive written notification from the awarding component communicating the rationale for the disapproval. This notification will typically be sent within 60 days of receipt of the K00 application.

Although the financial plans of NIA provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Instructions for the K00 Transition Award:

F99 awardees wishing to submit a K00 transition application must follow the Career Development (K) Instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions, except where instructed in the FOA to do otherwise, as described here.

The K00 Transition Application will include the following components:

- A new cover page signed by the K00 phase institutional representative
- A Final Progress Report for the F99 phase
- A final evaluation statement by the F99 primary sponsor
- Updated Project Summary, Abstract, Project Narrative, Bibliography and References Cited, Facilities and Other Resources, and Equipment sections
- Biographical sketches
- Detailed budget pages for a non-modular budget
- K00 budgets consist of salary and fringe benefits; the combined cost of tuition and fees in an amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year; other program-related expenses; and indirect costs, as described in Part II, Section II of the FOA
- Other costs are not allowed
- Updated sections of the PHS Career Development Award Supplemental Form, which should include the following:
- A new Candidate section
- An updated Research Plan section
- The Specific Aims should be updated to reflect current plans for the K00 phase
- The updated Research Strategy should be described in less than 3 pages
- A new Mentor, Co-Mentor, Consultant, and Collaborators section that includes a plan for transitioning the candidate to the next stage of his/her career by the end of the project award period.
- The mentor should describe his/her mentoring history, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes
- If the primary mentor has limited training experience, a co-mentor with a strong, successful track record as a mentor should be included
- An updated Description of Institutional Environment
- An Institutional Commitment to Candidate's Research Career Development
- If the candidate is not a U.S. Citizen or Permanent Resident, the sponsoring institution must include information about the candidate's visa status and an assurance that the candidate's visa provides sufficient time to complete the K00 phase of the award at a U.S. institution
- Updated Protections for Human Subjects and Inclusion of Women, Minorities, and Individuals Across the Lifespan (as appropriate)
- Updated Other Research Plan Sections (as appropriate), including:

o Vertebrate Animals
o Select Agent Research
o Resource Sharing Plans
o Authentication of Key Biological and/or Chemical Resources

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Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1F99AG088695-01

INSTITUTION: DUKE UNIVERSITY

Budget	Year 1	Year 2
Institutional Allowance	$4,750	$4,750
Travel	$1,500	
Other	$16,000	$8,872
Stipends	$28,224	$28,224
TOTAL FEDERAL DC	$50,474	$41,846
TOTAL FEDERAL F&A	$0	$0
TOTAL COST	$50,474	$41,846

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Exhibit 2

Wednesday, July 29, 2026 at 1:04:33 PM Eastern Daylight Time

Subject: FW: Grant No. 5F99AG088695-02
Date: Tuesday, July 22, 2025 at 4:02:53 PM Eastern Daylight Time
From: Bandiera, Frank (NIH/NIA/ERP) [E]
To: Michael Green
CC: Morris, Jillian (NIH/NIA/ERP) [E], Kaufman, Jessica (NIH/NIA/ERP) [E]

Dear Dr. Green,

This communication is in regard to grant [5F99AG088695-02]; to proceed with funding consideration, the scope of the award must be renegotiated to make it consistent with NIH's ongoing internal review of HHS/NIH's priorities and the alignment of awards with those priorities. Please note that scientifically justified recruitment plans to include populations at highest risk may be included.

Specifically, NIH funds may not be used to support any Diversity Equity and Inclusion (DEI) related activities that were proposed in the application, or for any other DEI-related research or training activities, or programs. A term and condition to this effect will be included in any Notice of Grant Award.

You will need to revise the current abstract, specific aims, grant, and annual progress report to remove any DEI language accordingly so that no NIH funds will be used to support these types of activities.

In order to continue with award consideration, a reply from the AOR to this communication is needed by COB [7/25/2025] affirming that the recipient organization acknowledges the funding restriction to renegotiate the scope of the award. The PI should then submit a revised annual progress report that includes tracked changes addressing these issues by [7/29/2025] at the latest.

Frank Bandiera, Ph.D., M.P.H.
Program Offiical, Macrosocial Processes, Division of Behavioral and Social Research
National Institute on Aging |National Institutes of Health
Department of Health and Human Services
5601 Fishers Lane
301-496-3136
Frank.Bandiera@nih.gov

Exhibit 3

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# F99AG088695
Federal Award Date
08/27/2025

Recipient Information

1. Recipient Name
DUKE UNIVERSITY
2200 W MAIN ST
DURHAM, NC 27705

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1560532129A1

4. Employer Identification Number (EIN)
560532129

5. Data Universal Numbering System (DUNS)
044387793

6. Recipient's Unique Entity Identifier
TP7EK8DZV6N5

7. Project Director or Principal Investigator
Michael D. Green, BA

michael.d.green@duke.edu
443-764-5706

8. Authorized Official
Jennifer L. McCallister
gcmail@mc.duke.edu
919-684-5175

Federal Agency Information

9. Awarding Agency Contact Information
Jessica Perez

NATIONAL INSTITUTE ON AGING
perezj@nia.nih.gov
301 496-1472

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
5F99AG088695-02

12. Unique Federal Award Identification Number (FAIN)
F99AG088695

13. Statutory Authority
284(b)(1)(C) 42 CFR Part 63a

14. Federal Award Project Title
Assessing the Impact of Patient-Provider Interactions on the Cardiovascular and Cognitive Health of Aging Adults

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2025 **– End Date** 08/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$42,410
20 a. Direct Cost Amount	$42,410
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$42,410
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$42,410
26. Project Period Start Date 09/01/2024 **– End Date** 08/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$92,884

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jillian Morris

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Pre-doc to Post-doc Transition Award
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5F99AG088695-02

Principal Investigator(s):
Michael D. Green, BA

Award e-mailed to: gcmail@mc.duke.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $42,410 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to DUKE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 284(b)(1)(C) 42 CFR Part 63a and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number F99AG088695. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jillian Morris
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Institutional Allowance	$4,750

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Other	$8,872
Stipends	$28,788
Federal Direct Costs	$42,410
Total Award	$42,410
Total Amount of Federal Funds Authorized (Federal Share)	$42,410
TOTAL FEDERAL AWARD AMOUNT	$42,410
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$42,410

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$42,410	$42,410

Fiscal Information:
Payment System Identifier: 1560532129A1
Document Number: FAG088695A
PMS Account Type: P (Subaccount)
Fiscal Year: 2025

IC	CAN	2025
AG	8470711	$42,410

NIH Administrative Data:
PCC: 2CMSFFB / **OC**: 41013 / **Released**: 08/26/2025
Award Processed: 08/27/2025 11:37:45 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5F99AG088695-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5F99AG088695-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) F99AG088695. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html

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and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Childcare Costs
If this award includes childcare costs of $3,000, the funds are restricted and may not be used for any other purpose without prior approval.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5F99AG088695-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

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

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes diversity, equity and inclusion (DEI) research programs, or has questions regarding other activities that could be considered outside the scope of

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the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

****

Stipends and the Institutional Allowance, if applicable, have been awarded in accordance with the NIH Guide for Grants and Contracts, Notice: NOT-OD-25-105, May 16, 2025.

The sponsor for this fellowship award is Dr. Matthew Dupre.

This award is subject to the conditions set forth in RFA-AG-23-016 "Transition to Aging Research Award for Predoctoral Students (F99/K00)," NIH Guide to Grants and Contracts, June 28, 2019, which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this funding opportunity announcement may be accessed at: http://www.nih.gov/grants/guide/index.html

Termination
At any point during the period of support provided under this Fellowship Award the recipient may terminate the project. **Documents are not to be submitted via xTrain**. A completed Termination Notice (form PHS 416-7) is to be submitted within 30 days of termination via signed .pdf to the assigned Grants Management Specialist. In addition to listing the stipend amounts on the form, the remaining amounts of institutional allowance and tuition/fees/insurance, if awarded, should be listed.

Carryover and No-Cost Extensions
Carryover of unspent funds is not permitted between the first and second years of the F99 phase or from a partially completed year in the F99 phase into the K00 phase. Provisions for No-Cost Extensions do not apply to the F99 phase.

Transition to the Postdoctoral Career Development K00 Phase
The F99/K00 award is intended to facilitate the successful transition to an aging-focused postdoctoral career. Consequently, a requirement for the K00 phase award is successful completion of the doctoral research degree and subsequent transition to an aging-related, mentored, traditional postdoctoral research position. Applicants are encouraged to expand their skill set and apply for postdoctoral positions at departments and institutions other than where they conducted their doctoral research. It is important for all applicants to provide a detailed plan by which they will separate their work from their Ph.D. sponsor. Those applicants who intend to stay at the predoctoral phase institution for the postdoctoral phase should also provide a strong justification for staying.

The transition from the predoctoral phase to the postdoctoral phase is intended to be continuous in time; therefore, except in unusual circumstances, NIA will not extend the F99 phase. To begin the K00 award phase of the grant, individuals must a) have been offered a postdoctoral appointment to carry out aging-focused research and b) have received approval from NIA for the K00 transition (see below). Upon starting the K00 phase of the award, the F99 phase of the award is terminated.

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Prospective applicants are strongly encouraged to contact the NIA Training Officer as soon as a plan to assume a postdoctoral position develops, not later than 6 months prior to the end of the F99 phase of the award.
A proposed K00 institution and mentor must have appropriate infrastructure to support the proposed research program and a history of external research funding.Applicants may apply for NIH-sponsored postdoctoral positions within the NIH Intramural Research Program (IRP). However, should the individual accept such a position in the IRP, the postdoctoral phase will be supported directly by NIH intramural funds.

The K00 postdoctoral phase institution must submit the materials on behalf of the candidate for the K00 award no later than 12 weeks prior to the proposed start of the K00 award. The institution's Authorized Organizational Representative will email the application in PDF format using the PHS 398 form to the NIA Scientific Contact listed in Section VII. The K00 application will be evaluated by NIA Program staff for completeness and responsiveness to the program.
Candidates who are not approved to transition will receive written notification from the awarding component communicating the rationale for the disapproval. This notification will typically be sent within 60 days of receipt of the K00 application.

Although the financial plans of NIA provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Instructions for the K00 Transition Award

F99 awardees wishing to submit a K00 transition application must follow the Career Development (K) Instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions, except where instructed in the FOA to do otherwise, as described here.

The K00 Transition Application will include the following components:

A new cover page signed by the K00 phase institutional representative
A Final Progress Report for the F99 phase
A final evaluation statement by the F99 primary sponsor
Updated Project Summary, Abstract, Project Narrative, Bibliography and References Cited, Facilities and Other Resources, and Equipment sections
Biographical sketches
Detailed budget pages for a non-modular budget
K00 budgets consist of salary and fringe benefits; the combined cost of tuition and fees in an amount equal to 60% of the level requested by the applicant institution, up to $4,500 per year; other program-related expenses; and indirect costs, as described in Part II, Section II of the FOA
Other costs are not allowed
Updated sections of the PHS Career Development Award Supplemental Form, which should include the following:
A new Candidate section
An updated Research Plan section
The Specific Aims should be updated to reflect current plans for the K00 phase
The updated Research Strategy should be described in less than 3 pages

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A new Mentor, Co-Mentor, Consultant, and Collaborators section that includes a plan for transitioning the candidate to the next stage of his/her career by the end of the project award period.
The mentor should describe his/her mentoring history, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes
If the primary mentor has limited training experience, a co-mentor with a strong, successful track record as a mentor should be included
An updated Description of Institutional Environment
An Institutional Commitment to Candidate's Research Career Development
If the candidate is not a U.S. Citizen or Permanent Resident, the sponsoring institution must include information about the candidate's visa status and an assurance that the candidate's visa provides sufficient time to complete the K00 phase of the award at a U.S. institution
Updated Protections for Human Subjects and Inclusion of Women, Minorities, and Individuals Across the Lifespan (as appropriate)
Updated Other Research Plan Sections (as appropriate), including:

- Vertebrate Animals
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources

Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 5F99AG088695-02

INSTITUTION: DUKE UNIVERSITY

Budget	Year 2
Institutional Allowance	$4,750
Other	$8,872
Stipends	$28,788
TOTAL FEDERAL DC	$42,410
TOTAL FEDERAL F&A	$0
TOTAL COST	$42,410

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Exhibit 4

Gmail

Michael D. Green, Ph.D. <michaeldgreenphd@gmail.com>

Grant No. 4K00AG088695-03

Bandiera, Frank (NIH/NIA/ERP) [E] <frank.bandiera@nih.gov> Wed, Jan 7 at 3:49 PM
To: michaeldgreenphd@gmail.com <michaeldgreenphd@gmail.com>
Cc: Kaufman, Jessica (NIH/NIA/ERP) [E] <jessi.perez@nih.gov>, Cruz, Amiel Mclain (NIH/NIA/ERP) [E] <amielmclain.cruz@nih.gov>, Major, Laura (NIH/NIA/ERP) [E] <laura.major@nih.gov>, Torres Salazar, Delany (NIH/NIA/ERP) [E] <delany.torressalazar@nih.gov>

Dear Dr. Green,

This communication is in regard to grant [4K00AG088695-03]; to proceed with funding consideration, the scope of the award must be renegotiated to make it consistent with NIH's ongoing internal review of HHS/NIH's priorities and the alignment of awards with those priorities. Please note that scientifically justified recruitment plans to include populations at highest risk may be included.

Specifically, NIH funds may not be used to support any Diversity Equity and Inclusion (DEI) related activities that were proposed in the application, or for any other DEI-related research or training activities, or programs. A term and condition to this effect will be included in any Notice of Grant Award.

You will need to remove any DEI language from the application that gives the perception that NIH funds can be used to support these types of activities.

In order to continue with award consideration, a reply from the AOR to this communication is needed by COB [1/9/2025] affirming that the recipient organization acknowledges the funding restriction to renegotiate the scope of the award. The PI should then submit a revised application that includes tracked changes and a cleaned final version through their AOR by [1/14/2025] at the latest.

Frank Bandiera, Ph.D., M.P.H.

Program Official, Macrosocial Processes, Division of Behavioral and Social Research
National Institute on Aging |National Institutes of Health

Department of Health and Human Services

5601 Fishers Lane

301-496-3136

Frank.Bandiera@nih.gov

Exhibit 5

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# K00AG088695
Federal Award Date
03/19/2026

Recipient Information

1. Recipient Name
THE JOHNS HOPKINS UNIVERSITY
3400 N CHARLES ST
BALTIMORE, MD 21218

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1520595110A5

4. Employer Identification Number (EIN)
520595110

5. Data Universal Numbering System (DUNS)
001910777

6. Recipient's Unique Entity Identifier
FTMTDMBR29C7

7. Project Director or Principal Investigator
Michael D. Green, BA

michaeldgreen0520@gmail.com
919-681-6801

8. Authorized Official
Brian Line
bline1@jh.edu
667-208-8796

Federal Agency Information

9. Awarding Agency Contact Information
AMIEL MCLAIN OCAMPO Cruz
Grants Management Specialist
NATIONAL INSTITUTE ON AGING
amiel.cruz@nih.gov
3014022944

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
4K00AG088695-03

12. Unique Federal Award Identification Number (FAIN)
K00AG088695

13. Statutory Authority
42 USC 241 42 CFR PART 52

14. Federal Award Project Title
Assessing the Impact of Patient-Provider Interactions on the Cardiovascular and Cognitive Health of Aging Adults

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Extension with or without funds

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/15/2026 **– End Date** 02/28/2027	
20. Total Amount of Federal Funds Obligated by this Action	$84,581
20 a. Direct Cost Amount	$78,316
20 b. Indirect Cost Amount	$6,265
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$84,581
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$84,581
26. Project Period Start Date 09/01/2024 **– End Date** 02/28/2030	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$84,581

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jessica Perez

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Post-doctoral Transition Award
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 4K00AG088695-03

Principal Investigator(s):
Michael D. Green, BA

Award e-mailed to: eawards@jhu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $84,581 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to JOHNS HOPKINS UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number K00AG088695. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jessica Perez
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$60,542

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Fringe Benefits	$12,774
Personnel Costs (Subtotal)	$73,316
Other	$5,000
Federal Direct Costs	$78,316
Federal F&A Costs	$6,265
Approved Budget	$84,581
Total Amount of Federal Funds Authorized (Federal Share)	$84,581
TOTAL FEDERAL AWARD AMOUNT	$84,581
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$84,581

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$84,581	$84,581
4	$86,743	$86,743
5	$88,978	$88,978
6	$94,043	$94,043

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1520595110A5
Document Number:	KAG088695B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2026

IC	CAN	2026	2027	2028	2029
AG	8470711	$84,581	$86,743	$88,978	$94,043

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2CMSFFB / **OC**: 41035 / **Released**: 03/10/2026
Award Processed: 03/19/2026 02:49:10 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 4K00AG088695-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 4K00AG088695-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should

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test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) K00AG088695. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value

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greater than $10,000,000 must report and maintain information 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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 4K00AG088695-03

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award approves the revised abstract and specific aims as submitted in the document dated January 14, 2026 from Brian Line, Johns Hopkins University. The revised abstract and specific aims are incorporated as terms and conditions of the award and the recipient must comply with those changes.

This award is subject to the conditions set forth in RFA-AG-23-016 "The Transition to Aging Research Award for Predoctoral Students (F99/K00 Clinical Trial Not Allowed)," released on April 11, 2022 which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this funding opportunity announcement may be accessed at: http://www.nih.gov/grants/guide/index.html

K00 awardees are required to have a full-time appointment at the applicant institution, and to commit a minimum of 9 person months (or 75% of their full-time appointment at the applicant institution) to their career development and research training. K00 awardees may engage in other duties (e.g., other research, training, clinical and teaching activities) as part of the remaining 25% effort not covered by the award, as long as such duties do not interfere with or detract from the proposed career development program.

Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY

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AWARD NUMBER: 4K00AG088695-03

INSTITUTION: JOHNS HOPKINS UNIVERSITY

Budget	Year 3	Year 4	Year 5	Year 6
Salaries and Wages	$60,542	$62,195	$63,903	$67,776
Fringe Benefits	$12,774	$13,123	$13,484	$14,301
Personnel Costs (Subtotal)	$73,316	$75,318	$77,387	$82,077
Other	$5,000	$5,000	$5,000	$5,000
TOTAL FEDERAL DC	$78,316	$80,318	$82,387	$87,077
TOTAL FEDERAL F&A	$6,265	$6,425	$6,591	$6,966
TOTAL COST	$84,581	$86,743	$88,978	$94,043

Facilities and Administrative Costs	Year 3	Year 4	Year 5	Year 6
F&A Cost Rate 1	8%	8%	8%	8%
F&A Cost Base 1	$78,316	$80,318	$82,387	$87,077
F&A Costs 1	$6,265	$6,425	$6,591	$6,966

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Exhibit 6

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# K00AG088695
Federal Award Date
09/10/2026

Recipient Information

1. Recipient Name
THE JOHNS HOPKINS UNIVERSITY
3400 N CHARLES ST
BALTIMORE, MD 21218

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1520595110A5

4. Employer Identification Number (EIN)
520595110

5. Data Universal Numbering System (DUNS)
001910777

6. Recipient's Unique Entity Identifier
FTMTDMBR29C7

7. Project Director or Principal Investigator
Michael D. Green, BA

michaeldgreen0520@gmail.com
919-681-6801

8. Authorized Official
Brian Line
bline1@jh.edu
667-208-8796

Federal Agency Information

9. Awarding Agency Contact Information
AMIEL MCLAIN OCAMPO Cruz
Grants Management Specialist
NATIONAL INSTITUTE ON AGING
amiel.cruz@nih.gov
3014022944

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
4K00AG088695-03

12. Unique Federal Award Identification Number (FAIN)
K00AG088695

13. Statutory Authority
42 USC 241 42 CFR PART 52

14. Federal Award Project Title
Assessing the Impact of Patient-Provider Interactions on the Cardiovascular and Cognitive Health of Aging Adults

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
Extension with or without funds (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/15/2026 **– End Date** 02/28/2027	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$84,581
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$84,581
26. Project Period Start Date 09/01/2024 **– End Date** 02/28/2030	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$84,581

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jeni Smits

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Post-doctoral Transition Award
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 4K00AG088695-03 REVISED

Principal Investigator(s):
Michael D. Green, BA

Award e-mailed to: eawards@jhu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to JOHNS HOPKINS UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number K00AG088695. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jeni Smits
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$60,542
Fringe Benefits	$12,774

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Personnel Costs (Subtotal)	$73,316
Other	$5,000
Federal Direct Costs	$78,316
Federal F&A Costs	$6,265
Approved Budget	$84,581
Total Amount of Federal Funds Authorized (Federal Share)	$84,581
TOTAL FEDERAL AWARD AMOUNT	$84,581
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$84,581	$84,581
4	$86,743	$86,743
5	$88,978	$88,978
6	$94,043	$94,043

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1520595110A5
Document Number:	KAG088695B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2026

IC	CAN	2026	2027	2028	2029
AG	8033191	$84,581	$86,743	$88,978	$94,043

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2CMSFFB / **OC**: 41035 / **Released**: 09/09/2026
Award Processed: 09/10/2026 12:10:07 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 4K00AG088695-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 4K00AG088695-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 2 CFR Part 200.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some

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awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) K00AG088695. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management

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(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 that is found in SAM.gov. Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities
For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See Updated Funding Guidance for Recipients on Supplies and Services.
Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmefene and/or other infectious disease prevention services.
Failure to comply with the programmatic requirements outlined in the link above,
(which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339 and 2 CFR 200.340, and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 4K00AG088695-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This revision is an administrative action to reflect the appropriate Common Accounting Number (CAN) for internal NIA purposes. No action is required on the part of the recipient.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

Supersedes Notice of Award issued 3/24/2026. Previous terms and conditions apply:

This revision is an administrative action to reflect the appropriate Common Accounting Number (CAN) for internal NIA purposes. No action is required on the part of the recipient.

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Supersedes Notice of Award issued 3/19/2026. Previous terms and conditions apply:

This award approves the revised abstract and specific aims as submitted in the document dated January 14, 2026 from Brian Line, Johns Hopkins University. The revised abstract and specific aims are incorporated as terms and conditions of the award and the recipient must comply with those changes.

This award is subject to the conditions set forth in RFA-AG-23-016 "The Transition to Aging Research Award for Predoctoral Students (F99/K00 Clinical Trial Not Allowed)," released on April 11, 2022 which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this funding opportunity announcement may be accessed at: http://www.nih.gov/grants/guide/index.html

K00 awardees are required to have a full-time appointment at the applicant institution, and to commit a minimum of 9 person months (or 75% of their full-time appointment at the applicant institution) to their career development and research training. K00 awardees may engage in other duties (e.g., other research, training, clinical and teaching activities) as part of the remaining 25% effort not covered by the award, as long as such duties do not interfere with or detract from the proposed career development program.

Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 4K00AG088695-03 REVISED

INSTITUTION: JOHNS HOPKINS UNIVERSITY

Budget	Year 3	Year 4	Year 5	Year 6
Salaries and Wages	$60,542	$62,195	$63,903	$67,776
Fringe Benefits	$12,774	$13,123	$13,484	$14,301
Personnel Costs (Subtotal)	$73,316	$75,318	$77,387	$82,077
Other	$5,000	$5,000	$5,000	$5,000
TOTAL FEDERAL DC	$78,316	$80,318	$82,387	$87,077
TOTAL FEDERAL F&A	$6,265	$6,425	$6,591	$6,966
TOTAL COST	$84,581	$86,743	$88,978	$94,043

Facilities and Administrative Costs	Year 3	Year 4	Year 5	Year 6
F&A Cost Rate 1	8%	8%	8%	8%
F&A Cost Base 1	$78,316	$80,318	$82,387	$87,077
F&A Costs 1	$6,265	$6,425	$6,591	$6,966

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AMERICAN CIVIL LIBERTIES UNION FOUNDATION
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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF SARA JACKSON

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

AMERICAN CIVIL LIBERTIES UNION FOUNDATION OF NORTHERN CALIFORNIA
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Telephone: (301) 823-1148

* Application for *Pro Hac Vice* Admission Forthcoming

I, Sara Jackson, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Sara Jackson. I previously went by my married name "Sara Bybee".

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I am a Licensed Clinical Social Worker and an Assistant Professor at the University of Utah College of Nursing. My research focuses on health equity and structural determinants of health in complex care settings. Specifically, I examine how systemic barriers shape health outcomes for historically marginalized populations, with particular emphasis on dementia, palliative care and chronic illness management.

5. I earned my PhD in Nursing from the University of Utah and did postdoctoral work through the Utah Clinical and Translational Science Institute, where I investigated screening for and addressing social needs in medical settings.

6. I am widely published in top medical journals, including The American Journal of Hospice and Palliative Medicine, The Journal of Clinical Oncology, and Psychology & Sexuality, among many others.

7. I have been funded on multiple NIH awards including as a co-investigator on the following studies:

- Enhanced Digital Access to Bridge Social Needs and Reduce Health Disparities: The e-SINCERE Study. National Institute of Nursing Research (1R01NR021501/NIH; PI: A. Wallace);
- LEADing End-of-Life Dementia Care Conversations. National Institute on Aging (1R01AG069033-01A1/NIH; PI: K. Dassel);
- Intensifying Community Referrals for Health: The SINCERE Intervention to Address Covid-19 Health Disparities. National Institute of Nursing Research (1R01NR019944; PI: A Wallace).

8. These studies have resulted in multiple publications in high impact journals such as the following:

- Bybee, S. G., Clayton, J., Aruscavage, N., Utz, R., Bigger, S. E., Iacob, E., & Dassel, K. (2025). Engaging in the Life-Planning in Early Alzheimer's and other Dementias (LEAD) Advance Care Planning (ACP) intervention is associated with perceived ACP concordance and interpersonal connectedness. The Gerontologist. https://doi.org/10.1093/geront/gnaf179
- Bybee, S., Tedford, N.J., Grigorian, E.G., Luther, B., Guo, J-W., Wong, B., Diamond, L., and Wallace, A.S. (2025). Focus groups reveal how threat vigilance hinders social needs screening and referrals in the emergency department. Frontiers in Communication, Volume 10 – 2025. https://doi.org/10.3389/fcomm.2025.1558250
- Bybee, S., Sharareh, N., Guo, J-W., Luther, B., Wang, C-Y., Wong, B., & Wallace, A. (2024). A secondary data analysis of technology access as a determinant of health and impediment in social needs screening and referral processes. AJPM Focus, 3(2), 100189. doi: 10.1016/j.focus.2024.100189

9. I was funded by the Interdisciplinary Training in Cancer, Caregiving, and End-of-Life Care training program as a pre-doctoral student (National Institute of Nursing Research (T32 NR013456; MPIs: L. Ellington & K. Mooney). And I served as a graduate research assistant on the following NIH projects:

- Sexual and Gender Minority Cancer Caregivers and Hospice Team Alignment. SGM Admin Supplement, National Institute of Nursing Research (PA-17-098; NINR/1R01NR016249; PI: L Ellington);
- Cancer Caregiver Interactions with the Hospice Team: Implications for End of Life and Bereavement Outcomes. National Institute of Nursing Research (NINR/1R01NR016249; PI: L. Ellington).

10. I am also currently the Principal Investigator on an Alzheimer's Association funded study, Fostering Equitable Dementia Care for Hispanic/Latino Communities.

11. I am the recipient of the Carroll L. Estes Rising Star Award bestowed upon me by the Social Research Policy and Practice Section of the Gerontological Society of America. In 2024, I was awarded the Excellence in Research Award by Sigma Theta Tau International Gamma Rho Chapter, and in 2025 I was honored to receive a 40 Under 40 Public Health Catalyst Award from the Boston Congress of Public Health.

12. The research I conduct is important to me because it allows me to help those who have been historically under researched or who do not have the same access to resources or assistance that those more fortunate may have. Improving quality of life for individuals, families, and communities is not only fulfilling, but I feel it is my responsibility as a scientist.

13. In 2024 I was named as a PI on a R01 grant titled Developing an Inclusive Measure of Financial Hardship for People Living with Dementia and their Care Contributors. The grant has a project term of 8/15/2024 through 6/30/2029.

14. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals often exceed 200 pages and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. To ensure this proposal was a success, I devoted nearly all my working time as well as some personal time towards developing a rigorous proposal. This meant that I took time away from my young children to devote myself to this proposal. Securing a grant is not just about money—it's an indication of a project's scientific importance, methodological rigor, and real-world potential to improve public health.

15. The award focuses on the financial burdens borne by people living with dementia (PLWD) and their care contributors, with a special emphasis on the increasing diversity of older adults in the US, who may have support networks involving families of choice. My goal is to develop and psychometrically validate an inclusive measure of financial hardship for PLWD which attends to the specific disease trajectory of Alzheimer's Disease and other forms of dementia and expands the concept of family to include non-kin care contributors, thus laying the groundwork for future intervention studies

designed to reduce financial and health inequities among this population. Attached hereto as **Exhibit 1** is a true and correct copy of this R01 grant's Notice of Award (i.e., NOA).

16. During the first two years of the grant, my research team and I successfully recruited dementia professionals and experts in sexual and gender minority health to participate in a focus group. We also developed an eligibility survey to screen LGBTQ+ and non-LGBTQ+ persons living with dementia and care partners for potential participation in our other two focus groups. All three focus groups were completed as of 2026. During focus groups, we asked participants for their opinions on several dementia-related expenses to better understand which items had the greatest impact on their financial hardship and quality of life (for example, adult day care, insurance co-payments, medications). We asked participants about their experiences affording care, how that affects their psychological wellbeing, and what types of strategies they have used to navigate any financial difficulties. We have also completed interviews with participants of these focus groups to further refine our measure of financial hardship. During interviews, we asked participants for their opinions on the wording of the measure's instructions, and to identify any areas that were confusing or where the instructions were unclear. We also asked participants for suggestions on how to ensure the measure was applicable to both persons living with dementia and to care partners, as well as how to make the measure inclusive enough to capture the lived experiences of LGBTQ+ persons living with dementia and their care partners.

17. Our next steps include refining our measure based on feedback received from our interviews and testing the refined measure with a sample of thirty care partners to persons living with dementia. We will then ensure the measure is reliable by testing it with a new sample of 435 care partners to persons living with dementia, half of which will be care partners to LGBTQ+ persons living with dementia so we can ensure the measure is inclusive enough to capture the unique caregiving experiences of these individuals.

18. In 2025, I heard through my university that I should reach out to my program officer (PO) at NIH and ask to edit my public-facing grant details, including the abstract and public health relevance statement, to remove disfavored terms, to avoid the termination of my grant. While I had some misgivings about doing this, I made the changes in an effort to protect my research. Since my project is open to any person living with dementia and their care partner and not solely focused on LGBTQ+

persons, I re-wrote the public-facing abstract to reflect this fact and removed the terms LGBTQ+, sexual and gender minority, etc. The scientific aims of the study did not change at this time.

19. After making these changes, and submitting my annual progress report as required, I received a second year of funding.

20. I submitted my second annual progress report in a timely manner.

21. On May 27, 2026, I received an email from my program officer stating that "to proceed with funding consideration" I would need to renegotiate the scope of my award "to make it consistent with NIH's ongoing internal review of HHS/NIH's priorities and the alignment of awards with those priorities." Specifically, I would "need to review the current annual progress report to remove any DEI language and, if needed" adjust my budget to avoid supporting any "DEI activities [] or programs." The email indicated that I had three days to rewrite my project materials, including my project aims, which included conducting focus groups with LGBTQ+ and non-LGBTQ+ individuals.

22. I have never heard of a request to renegotiate an already-awarded grant. It is common for NIH to request changes to a research plan prior to awarding funding, but with the exception of budgetary changes, I have not heard of NIH requesting changes in agreed-upon research.

23. As I had already completed these research aims, I did not feel that I could re-write them without being dishonest about the work, so my authorized organization representative in the Office of Sponsored Projects at the University of Utah emailed my PO to state that I would not be renegotiating the scope of my work.

24. An NIH supervisory grants management specialist responded by asking "[i]f the PI is not willing to renegotiate the scope of work, will you be submitting a request for early termination?"

25. I responded that I would not; that I wanted to "continue on with the award as originally agreed upon in the notice of award I received in 2024." Upon NIH's request, my university indicated their concurrence with that decision. Attached hereto as **Exhibit 2** is a true and correct copy of this email correspondence.

26. I have not heard from NIH since. I have not received a termination notice, but I have also not received any confirmation of my third year of funding. My second-year budget ended June 30, 2026. Given my refusal to renegotiate my research aims to remove all mention of LGBTQ+ people and other

"DEI language," I expect that my project will be terminated, either through a notice of termination, a denial of my noncompetitive renewal (NCR), or through what has come to be called a "ghost termination"—when NIH does not award or deny continuation funds, but simply lets the award languish without funding.

27. I have begun planning for what I will do without the final three years of anticipated funding. I am looking for bridge funding, and trying to come up with creative ways to continue the work, but unless my NCR arrives soon, I expect to have to lay off two employees, and discontinue work on this research study. One of my employees has already accepted another job because of our lapse in funding.

28. My work relies on NIH funding, so unless this situation resolves soon, I will likely have to pivot to other areas of research, like palliative care, that are not currently disfavored by the NIH. Once I make that change it is unlikely that I will be able to restart my current work.

29. Ending work on this project means that the individuals who participated in the focus groups and cognitive interviews (those who have shared some of their most personal and painful stories related to dementia) will have to be told that their contributions will not make a difference in the lives of others in the future, as they originally were told.

30. In addition to the loss of three staff members, I have four additional co-investigators on this project, who are all losing time devoted to this project. For some, this means that a lower percentage of their time is covered by NIH funding, which could affect their requirements for receiving tenure. The loss of this funding means I will no longer manage a research lab in which I can supervise trainees, including pre-doctoral and postdoctoral scholars. Our ability to disseminate any findings from the focus groups and cognitive interviews is also affected, as funding was allocated to publishing fees as well as conference registration and travel that would have allowed us to present our findings at national and international conferences.

31. Furthermore, as an early-career scholar, the termination of this funding may put me at jeopardy of not receiving tenure or promotion to associate professor in the future. My income comes from a base salary plus incentive pay for NIH funding above and beyond what is required. Without the NIH funding, my income will be substantially reduced.

32. The decision to not remove "DEI language" from my research aims was not an easy one and has caused me a great deal of stress. Changing the language would reduce the integrity of the scientific rigor of this project, as the theoretical and conceptual underpinnings integrate minority stress, allostatic load, and intersectionality of multiple social identities. Moreover, NIH pressure to "renegotiate the scope of my award" has put me in a very difficult position: To turn my back on my morals, the research I have conducted, the participants who have trusted me with their stories, and the LGBTQ+ community with whom I have worked to build trust, or to turn my back on my co-investigators and my staff members who will lose their jobs if I refuse to renegotiate. This was not an easy decision to make, but ultimately, I cannot in good conscience erase the stories and identities of my research participants just to "align with the new NIH/HHS priorities" that were not in effect when the grant was awarded.

33. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Millcreek, Utah this 8th day of September 2026.

Sara Jackson

Sara Jackson

Exhibit 1

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG088560
Federal Award Date
08/07/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF UTAH
201 PRESIDENTS CIR
SALT LAKE CITY, UT 84112

2. Congressional District of Recipient
01

3. Payment System Identifier (ID)
1876000525A1

4. Employer Identification Number (EIN)
876000525

5. Data Universal Numbering System (DUNS)
009095365

6. Recipient's Unique Entity Identifier
LL8GLEVH6MG3

7. Project Director or Principal Investigator
Sara Bybee, PHD

sara.bybee@nurs.utah.edu
801-646-7569

8. Authorized Official
ROHMEE TAMANG
rohmee.tamang@osp.utah.edu
801-581-4913

Federal Agency Information

9. Awarding Agency Contact Information
FOLASADE TEMITOPE Onireti

NATIONAL INSTITUTE ON AGING
sade.onireti@nih.gov
13015551212

10. Program Official Contact Information
PRISCILLA JOY Novak

NATIONAL INSTITUTE ON AGING
priscilla.novak@nih.gov
301-496-3136

Federal Award Information

11. Award Number
1R01AG088560-01

12. Unique Federal Award Identification Number (FAIN)
R01AG088560

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Developing an Inclusive Measure of Financial Hardship for People Living with Dementia and their Care Contributors

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/15/2024 **– End Date** 06/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$605,072
20 a. Direct Cost Amount	$392,904
20 b. Indirect Cost Amount	$212,168
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$605,072
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$605,072
26. Project Period Start Date 08/15/2024 **– End Date** 06/30/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$605,072

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jorge E. Machuca

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG088560-01

Principal Investigator(s):
Sara Bybee, PHD

Award e-mailed to: ospawards@osp.utah.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $605,072 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF UTAH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG088560. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jorge E. Machuca
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$235,822

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Fringe Benefits	$119,924
Personnel Costs (Subtotal)	$355,746
Consultant Services	$6,000
Materials & Supplies	$3,300
Travel	$4,832
Other	$23,026
Federal Direct Costs	$392,904
Federal F&A Costs	$212,168
Approved Budget	$605,072
Total Amount of Federal Funds Authorized (Federal Share)	$605,072
TOTAL FEDERAL AWARD AMOUNT	$605,072
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$605,072

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$605,072	$605,072
2	$595,721	$595,721
3	$576,524	$576,524
4	$607,016	$607,016
5	$599,691	$599,691

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1876000525A1
Document Number: RAG088560A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027	2028
AG	8033157	$605,072	$595,721	$576,524	$607,016	$599,691

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2CHSRPN / **OC**: 41021 / **Released**: 07/29/2024
Award Processed: 08/07/2024 12:18:15 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG088560-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AG088560-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG088560. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1R01AG088560-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.
==========

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on **7/1.** The Research Performance Progress Report (RPPR) is due 45 days prior to this date for SNAP awards or 60 days prior for non-SNAP awards.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$0	$0	$0	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG088560-01

INSTITUTION: UNIVERSITY OF UTAH

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$235,822	$235,822	$235,822	$235,822	$235,822
Fringe Benefits	$119,924	$119,924	$119,924	$119,924	$119,924
Personnel Costs (Subtotal)	$355,746	$355,746	$355,746	$355,746	$355,746
Consultant Services	$6,000	$6,000	$6,000	$6,000	$6,000
Materials & Supplies	$3,300			$3,000	
Travel	$4,832	$4,832	$4,832	$4,832	$9,664
Other	$23,026	$17,254	$4,788	$21,588	$9,000
Publication Costs		$3,000	$3,000	$3,000	$9,000
TOTAL FEDERAL DC	$392,904	$386,832	$374,366	$394,166	$389,410
TOTAL FEDERAL F&A	$212,168	$208,889	$202,158	$212,850	$210,281

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TOTAL COST	$605,072	$595,721	$576,524	$607,016	$599,691

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	54%	54%	54%	54%	54%
F&A Cost Base 1	$392,904	$386,832	$374,366	$394,166	$389,410
F&A Costs 1	$212,168	$208,889	$202,158	$212,850	$210,281

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Exhibit 2

Wednesday, September 2, 2026 at 4:05:23 PM Mountain Daylight Time

Subject:	RE: [Ext]RE: [ospawards:[list->sequence]] 5R01AG088560-03
Date:	Friday, June 5, 2026 at 10:00:12 AM Mountain Daylight Time
From:	Rohmee Tamang
To:	Blakeney, Ryan (NIH/NIA/ERP) [E], Sara Jackson, Novak, Priscilla (NIH/NIA/ERP) [E]
CC:	NIA AG eRA Notifications, Lafferty, Traci (NIH/NIA/ERP) [C], Hollie Fuhrmann
Attachments:	image002.png

Hi Ryan,

I concur with Sara's email.

Thank you,

Rohmee Tamang, MPA CRA
Sponsored Projects Officer | AOR
University of Utah | Office of Sponsored Projects



From: Blakeney, Ryan (NIH/NIA/ERP) [E] <blakeneyr@mail.nih.gov>
Sent: Friday, June 5, 2026 9:26 AM
To: Sara Jackson <sara.jackson@nurs.utah.edu>; Rohmee Tamang <rohmee.tamang@osp.utah.edu>; Novak, Priscilla (NIH/NIA/ERP) [E] <priscilla.novak@nih.gov>
Cc: NIA AG eRA Notifications <niaageranotification@mail.nih.gov>; Lafferty, Traci (NIH/NIA/ERP) [C] <traci.lafferty@nih.gov>; Hollie Fuhrmann <Hollie.Fuhrmann@nurs.utah.edu>
Subject: RE: [Ext]RE: [ospawards:[list->sequence]] 5R01AG088560-03

You don't often get email from blakeneyr@mail.nih.gov. Learn why this is important
Hi Sara,

Please provide institutional concurrence of your email below.

Thank you.

Ryan Blakeney
Supervisory Grants Management Specialist
National Institute on Aging
National Institutes of Health
5601 Fishers Ln. Room 8A50
301-451-9802
blakeneyr@mail.nih.gov

From: Sara Jackson <sara.jackson@nurs.utah.edu>
Sent: Friday, June 5, 2026 11:23 AM
To: Blakeney, Ryan (NIH/NIA/ERP) [E] <blakeneyr@mail.nih.gov>; Rohmee Tamang

<rohmee.tamang@osp.utah.edu>; Novak, Priscilla (NIH/NIA/ERP) [E] <priscilla.novak@nih.gov>
Cc: NIA AG eRA Notifications <niaageranotification@mail.nih.gov>; Lafferty, Traci (NIH/NIA/ERP) [C] <traci.lafferty@nih.gov>; Hollie Fuhrmann <Hollie.Fuhrmann@nurs.utah.edu>
Subject: [EXTERNAL] Re: [Ext]RE: [ospawards:[list->sequence]] 5R01AG088560-03

Good morning, Dr. Blakeney,
Thank you for your email. I am the PI on the award, and while I will not be renegotiating the scope of the award, I am also not requesting early termination. I would like to continue on with the award as originally agreed upon in the notice of award I received in 2024.
Best,
Sara

Get Outlook for iOS

From: Blakeney, Ryan (NIH/NIA/ERP) [E] <blakeneyr@mail.nih.gov>
Sent: Friday, June 5, 2026 7:55:30 AM
To: Rohmee Tamang <rohmee.tamang@osp.utah.edu>; Novak, Priscilla (NIH/NIA/ERP) [E] <priscilla.novak@nih.gov>; Sara Jackson <sara.jackson@nurs.utah.edu>
Cc: NIA AG eRA Notifications <niaageranotification@mail.nih.gov>; Lafferty, Traci (NIH/NIA/ERP) [C] <traci.lafferty@nih.gov>; Hollie Fuhrmann <Hollie.Fuhrmann@nurs.utah.edu>
Subject: [Ext]RE: [ospawards:[list->sequence]] 5R01AG088560-03

Some people who received this message don't often get email from blakeneyr@mail.nih.gov. Learn why this is important

WARNING: Stop. Think. Read. This is an external email.

Good morning, Tamang,

If the PI is not willing to renegotiate the scope of work, will you be submitting a request for early termination? If so, you can address the request letter directly to me and cc Dr. Novak.

Thank you.

Ryan Blakeney
Supervisory Grants Management Specialist
National Institute on Aging
National Institutes of Health
5601 Fishers Ln. Room 8A50
301-451-9802
blakeneyr@mail.nih.gov

From: Rohmee Tamang <rohmee.tamang@osp.utah.edu>
Sent: Friday, May 29, 2026 4:51 PM
To: Novak, Priscilla (NIH/NIA/ERP) [E] <priscilla.novak@nih.gov>; Sara Jackson <sara.jackson@nurs.utah.edu>

Cc: NIA AG eRA Notifications <niaageranotification@mail.nih.gov>; Lafferty, Traci (NIH/NIA/ERP) [C] <traci.lafferty@nih.gov>; Hollie Fuhrmann <Hollie.Fuhrmann@nurs.utah.edu>
Subject: [EXTERNAL] Re: [ospawards:[list->sequence]] 5R01AG088560-03

Dear Priscilla,

Thank you for reaching out. Dr. Jackson will not be renegotiating her scope of work.

Thank you,

Rohmee Tamang, MPA CRA
Sponsored Projects Officer | AOR
University of Utah | Office of Sponsored Projects

From: ospawards-request@lists.utah.edu <ospawards-request@lists.utah.edu> on behalf of Novak, Priscilla (NIH/NIA/ERP) [E] <priscilla.novak@nih.gov>
Sent: Wednesday, May 27, 2026 1:22:28 PM
To: Sara Jackson <sara.jackson@nurs.utah.edu>
Cc: OSP Awards <ospawards@lists.utah.edu>; NIA AG eRA Notifications <niaageranotification@mail.nih.gov>; Lafferty, Traci (NIH/NIA/ERP) [C] <traci.lafferty@nih.gov>
Subject: Re:[ospawards:[list->sequence]] 5R01AG088560-03

Some people who received this message don't often get email from priscilla.novak@nih.gov. Learn why this is important

Dear Dr Bybee (Jackson),

This communication is in regard to grant R01AG088560; to proceed with funding consideration, the scope of the award must be renegotiated to make it consistent with NIH's ongoing internal review of HHS/NIH's priorities and the alignment of awards with those priorities.

Specifically, NIH funds may not be used to support any DEI activities, or programs. A term and condition to this effect will be included in any Notice of Grant Award.

You will need to revise the current annual progress report to remove any DEI language and, if needed, adjust your budget accordingly so that no NIH funds will be used to support these types of activities.

In order to continue with award consideration, a **reply from the AOR to this communication is needed by COB 5/29/2026** affirming that the recipient organization acknowledges the funding restriction to renegotiate the scope of the award.

The PI should then **submit, as separate Word Documents with changes tracked**

- Title
- RPPR
- Specific aims

- Abstract
- Public Health Impact statement

By 6/1/2026. Once the documents are sufficiently revised to demonstrate alignment with current priorities, I will respond to the PI's email, requesting the AOR upload 'clean' no tracked changes of the documents via the prior approval module in eRA.

Please let us know if you have any questions or need further clarification as you work on these updates.

Best regards,

Priscilla Novak

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
OLGA AKSELROD (NY Bar No. 4132825) (Appearance *Pro Hac Vice*)
oakselrod@aclu.org
VERA EIDELMAN (CA Bar No. 308535)**
veidelman@aclu.org
RACHEL MEEROPOL (NY Bar No. 4100954) (Appearance *Pro Hac Vice*)
rmeeropol@aclu.org
ALEXIS AGATHOCLEOUS (NY Bar No. 4227062)*
aagathocleous@aclu.org
125 Broad Street, 18th Floor
New York, NY 10004
Telephone: (212) 549-2659

Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF SUZANNE BELL

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

AMERICAN CIVIL LIBERTIES UNION FOUNDATION OF NORTHERN CALIFORNIA
GRAYCE ZELPHIN (CA Bar No. 279112)
gzelphin@aclunc.org
CHESSIE THACHER (CA Bar No. 296767)
cthacher@aclunc.org
NEIL K. SAWHNEY (CA Bar No. 300130)
nsawhney@aclunc.org
39 Drumm Street
San Francisco, CA 94111
Telephone: (415) 621-2493

PROTECT DEMOCRACY PROJECT
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shalini.agarwal@protectdemocracy.org
2020 Pennsylvania Avenue, NW, Suite 163
Washington, DC 20006
KENNETH PARRENO (TX Bar No. 24130477)*
kenneth.parreno@protectdemocracy.org
15 Main Street, Suite 312
Watertown, MA 02472
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CENTER FOR SCIENCE IN THE PUBLIC INTEREST
LISA S. MANKOFSKY (DC Bar No. 411931) (Appearance *Pro Hac Vice*)
lmankofsky@cspi.org
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JACOBSON LAWYERS GROUP PLLC
DANIEL F. JACOBSON (DC Bar No. 1016621)*
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lynn@jacobsonlawyersgroup.com
STEPHEN K. WIRTH (DC Bar No. 1034038) (Appearance *Pro Hac Vice*)
stephen@jacobsonlawyersgroup.com
5100 Wisconsin Avenue, NW, Suite 301
Washington, DC 20016
Telephone: (301) 823-1148

* Application for *Pro Hac Vice* Admission Forthcoming

I, Suzanne Bell, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Suzanne Bell.

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I am an Associate Professor in the Department of Population, Family and Reproductive Health at the Johns Hopkins University. I also serve as the Associate Director of the NICHD-funded Hopkins Population Center.

5. I am a demographer committed to improving our understanding of fertility and related behaviors at the population level and to identifying factors that contribute to disparities in reproductive outcomes. Specifically, my work examines patterns of induced abortion, contraceptive use, and infertility. Within each of these domains I conduct methodological work to improve the measurement of these phenomena and generate evidence that informs policy and programmatic efforts to address unmet sexual and reproductive health needs and related inequities.

6. I earned my PhD from the Department of Population, Family and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health in 2018, focusing on demography.

7. I am widely published in top journals in my field, including *The American Journal of Public Health*, *JAMA*, *Social Science and Medicine, Human Reproduction*, *American Journal of Epidemiology,* and *Studies in Family Planning,* among many others. In 2023, 2024, and 2025, I had first- or senior-authored publications on the impact of US abortion bans that were among the Family Planning articles that received the top 10 most engagement globally (according to Altmetrics), garnering significant media attention from journalist at premier news outlets, including *The New York Times*, *The Washington Post*, CNN, and NPR, among others, along with substantial social media engagement.

8. I have been funded on multiple NIH awards. I also have one NIH grant application under review and one being prepared for resubmission. And I have other NIH grant applications in development about the impact of recent regulatory and policy changes on reproductive health service utilization and related outcomes.

9. I am the recipient of numerous awards, including an award for Outstanding Statistical Application from the American Statistical Association.

10. The research I conduct is important to me because I am deeply committed to ensuring people can decide when and whether to have children and to do so safely and conducting research that supports positive reproductive and pregnancy outcomes. As a woman and mother of two small girls, this work is also personal. Identifying barriers or factors that contribute to poor reproductive and pregnancy outcomes is essential public health work, work that is particularly important in low-resource international settings, where the need for improvement is substantial and the potential for impact is large.

11. In 2024, my institution was awarded a R01 grant for which I am a multiple principal investigator (MPI). The grant is titled *The fertility, maternal health, and infant health consequences of reproductive policy change*. National Institute of Child Health and Human Development (1R01HD114292). The grant has a project term of 9/01/2024 through 5/31/2029.

12. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals often exceed 200 pages and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to address the research question. They must also demonstrate that their team is uniquely qualified to achieve the proposed aims. Every application undergoes rigorous peer review by experts, and funding rates are low and decreasing—especially for R01 grants, where many researchers apply multiple times before ever being funded. To ensure this proposal was a success, my MPI and I solicited input from several senior faculty with experience receiving NIH funding and/or serving as an NIH study section reviewer, iteratively incorporating feedback over multiple months to strengthen the proposal's explanation of the project's scientific merit and necessity. This effort was rewarded as we earned a 5th percentile score and received funding on the first submission, a difficult feat, particularly for two early career faculty with no prior R01 submissions. This effort took me away from my family at times, a sacrifice I do not take lightly as a parent. Securing a grant is not just about money—it's an indication of a project's scientific importance, methodological rigor, and real-world potential to improve population health.

13. The award examines the impact of the *Dobbs v. Jackson Women's Health Organization* and resulting restrictions on abortion services on fertility, maternal morbidity and mortality, and birth outcomes in states that enacted abortion restrictions.

14. Attached hereto as **Exhibit 1 is** a true and correct copy of this R01 grant's Notice of Award (i.e., NOA).

15. My MPI and I have had seven publications resulting from this award so far, all of which I first- or senior-authored along with several co-authors, including "Abortion Bans and Maternal, Pregnancy-Related, and Pregnancy-Associated Mortality in 14 US States, 2016-2023: Estimated Impacts Amid Substantial Measurement Challenges," in the *American Journal of Public Health*, June 2026, and "U.S. Abortion Bans and Fertility," in *JAMA*, April 15, 2025. Additionally, we have presented our findings at academic conferences on six occasions and have been invited to give talks on this work at seven universities and research organizations, including at a large symposium in DC titled, "Finding Common Ground: How Research on Abortion Bans Can Inform Public Health Policy" that involved policymakers, clinicians, and other key stakeholders.

16. My MPI and I received funding for the first year of the grant without incident. During the first year, we made significant progress in data acquisition, analysis, interpretation, and dissemination. We met—and in several areas exceeded—the goals set forth in our original project timeline.

a. To address the time-sensitive nature of these research aims, we rapidly accessed and downloaded publicly available birth and death certificate data from the CDC Wonder platform. These data were cleaned, compiled, and structured into analytic files suitable for comparative interrupted time series models. We used these models to evaluate the impact of state-level abortion bans on fertility outcomes, including heterogeneity by maternal age, education, race/ethnicity, marital status, and insurance coverage. This work resulted in a peer-reviewed publication in *JAMA*, a high-impact medical journal.'

b. Across our two companion *JAMA* papers published in Year 1, we estimate that abortion bans in 14 states led to an additional 22,180 live births and 478 infant deaths beyond what would have been expected absent these bans. Subgroup analyses revealed that the increase in live births was concentrated among racially minoritized populations (non-

Hispanic Black, Hispanic, and "other" races/ethnicities); individuals without a college degree; Medicaid beneficiaries; unmarried and younger individuals; and those living in the South. For infant mortality, subgroup analyses (limited to race/ethnicity due to data constraints) showed an 11% increase in mortality among Black infants post-ban, with particularly large increases in Southern states. We believe these were the first national analyses to comprehensively quantify the impact of post-*Dobbs* abortion bans on fertility and infant mortality, including these subgroup-specific effects.

c. To support future analyses, we successfully obtained restricted-use data from the National Center for Health Statistics (NCHS) for birth and death certificates (through 2023) and from the Healthcare Cost and Utilization Project (HCUP) for hospitalization records (through 2022).

d. All major Year 1 objectives were achieved. There were no significant deviations from the proposed timeline.

17. In order to receive our second year of funding in the summer of 2025, my MPI and I submitted an annual progress report on the first year of the award. This report is intended to describe progress towards achieving study aims, including grant-related activities conducted in the year prior, and a summary of key findings from recent analyses; it is not intended to be an opportunity to change the substance or language of the funded proposal. Our NIH program officer later informed us that our grant had been placed on a flagged list with other grants that communicate disfavored viewpoints on abortion restrictions and other topics. They told us that in order to get the grant off of the flagged list and thus receive our second year of funding, we likely needed to remove any mention of "abortion" or the *Dobbs* case in the narrative and project summary, which are public-facing portions of the grant, as well as in the aims section of the grant. Without these changes, I understood that the grant would not be approved for noncompeting renewal and could potentially be terminated.

18. I have never heard of a request to renegotiate a grant that has already been awarded. In the initial application process for a competing grant award, it is common for the NIH to share feedback from the study section with applicants to improve aspects of their research plan before they resubmit a grant for a competing award. However, after a grant has been awarded and a researcher is seeking

renewal of a noncompeting award, with the exception of budgetary changes, in my experience the NIH historically has not requested changes to agreed-upon research.

19. While I had some misgivings about doing this, my MPI and I made the changes the program officer had requested in an effort to protect the research. We shifted the characterization of the work to omit all mentions of abortion or the *Dobbs* decision and reframed the work as being more broadly on the impact of reproductive health policy changes on fertility, maternal health, and infant health outcomes. Once we did so, our noncompeting renewal application was quickly approved, and the second year of the grant was funded.

20. The changes we made at the instruction of the NIH made the language describing my grant on NIH Reporter vaguer, such that it is harder for a reader to understand what we are actually studying without also referencing associated publications linked to the grant. Further, the time and resources we spent making our previously clear grant documents vaguer in order to satisfy the censors seemed a pointless exercise that required several people's time both at my institution and the NIH.

21. Because NIH required us to make these changes, I am fearful that the NIH may decide to terminate this grant if they come to know about how I speak or write about my work or present my findings. I am nervous that they may identify discrepancies between the language that NIH required us to adopt and how I conduct my research and communicate about it.

22. In 2022 I was awarded a K01 grant titled *Advancing Understanding and Measurement of Infertility, Related Fears and Stigma, and Associated Consequences in Low-Resource Countries*. National Institute of Child Health and Human Development (5K01HD107172). The grant has a project term of 9/01/2022 through 8/31/2027.

23. The award focuses on infertility in Uganda, where I aimed to improve population-level infertility prevalence estimation by evaluating modeling assumptions, to understand gendered experiences of infertility stigma, and to identify particular dimensions of infertility stigma among women.

24. Attached hereto as **Exhibit 2 is** a true and correct copy of this K01 grant's NOA.

25. I have had ten publications resulting from this award, all of which I first- or senior-authored along with several co-authors, including "Measuring non-events: infertility estimation using

cross-sectional, population-based data from four countries in sub-Saharan Africa" in *Human Reproduction*, September 30, 2024, and "Defining infertility: The varied criteria people in two regions of Uganda use to identify infertility in themselves and others" in *Social Science Medicine*, December 2025. Apart from these, I have another article recently accepted, three others under peer review, and more to be submitted in the final year of the award. In addition to peer-reviewed publications, my colleagues and I have presented on findings from this research at academic conferences on 12 occasions, and I have been invited to give talks on this research at two research organizations.

26. As I soon enter the fifth year of this award, I have nearly completed all Research Aims and Training Objectives, which were intended to prepare me for a career as an independent, NIH-funded researcher studying (in)fertility in the United States and internationally. This is the result of an incredibly productive four years, during which I took several courses that further my expertise in related methods and content, prepared survey instruments and interview guides and collected quantitative and qualitative data, and developed and submitted NIH proposals with training and support from my K01 mentors and new collaborators. The data collection included three different data collection components over the prior four years. First, I developed an infertility module for inclusion in existing population-based surveys in nine sites in sub-Saharan Africa; this involved data collection from several thousand reproductive-aged women. Second, I developed interview guides on perceptions, experiences, and stigma related to infertility for in-depth interviews and focus groups discussions among men (55) and women (53) in Uganda. Third, I used insights from analyses of the qualitative data to inform the development of a psychometrically valid scale to measure domains of infertility stigma at the population level, which I piloted with 442 women in Uganda. Importantly, these data and associated analyses provided valuable insights on infertility, a long-neglected and understudied aspect of reproductive health both in the US and internationally. Results included the first ever population-level estimates of clinical infertility in four low- and middle-income countries, improvement in our ability to measure the prevalence of clinical infertility using readily available cross-sectional data (as well as app data in the United States), advancements in our understanding of the experience of infertility and related stigma for men and women in Uganda, and development of a novel infertility stigma scale for use in a general reproductive-aged female population. Through this work I established new relationships with several

researchers doing related work in the United States and in low- and middle-income countries, presenting opportunities for cross-cultural learning and collaborations moving forward.

27. Before the fifth year of the project, in the summer of 2026, I became aware that colleagues in my field doing international work were being asked by the NIH to make changes to the public-facing sections of their grants to justify why the research was being conducted in a foreign country and what benefit this would provide the United States. Because of this, I inquired with my NIH program officer if I needed to take similar action.

28. On July 13, 2026, my NIH program officer confirmed that I needed to make those changes re-emphasizing the foreign justification to the project summary, narrative, and project aims that had already been included in the foreign justification documentation at the time of the initial grant submission. I then inserted additional foreign justifications in various parts of this grant, emphasizing that even though I was doing the work in sub-Saharan African given that this region has among the highest levels of infertility, it would improve infertility estimation and develop measures to inform strategies to reduce infertility-related stigma and fear in the United States. The noncompeting renewal for year 5 of this grant is still pending.

29. In my view, this insistence on inserting additional justifications that international research work benefits American public health is a waste of time, given that there are places in the grant where these justifications already exist; the focus of the proposal components I was required to edit should be on the science. Moreover, the implication that international public health research is not valuable unless Americans directly benefit reflects a blinkered view of public health, which is inherently global. The distinction between domestic health and international health is a false dichotomy; it's all health, it's all interrelated, and findings in each setting have implications for the other.

30. In addition to my existing NIH grants, I have also applied for two grants in recent months for which I received instruction from NIH officials to change the language of the applications in order to avoid being flagged as inconsistent with recent NIH priorities and not be reviewed by a study section.

31. In June 2026, a colleague and I submitted a grant application as MPIs about the impact of extreme heat on human fecundity. We were instructed by the program officer on an earlier call not to use the phrase "climate change" anywhere in the proposal, and certainly not as a cause of the rising

frequency and severity of extreme heat. Although I was uncomfortable with doing so, I made sure to only use "extreme heat" throughout the application before submitting it so that it would not be flagged. I thought the language changes made the proposal less precise. The program officer also discouraged us from using the phrase "pregnant people" and advised us to simply refer to "pregnant women," even though this ignores the many people who become pregnant who do not identify as women. We are awaiting a decision from NIH on that application.

32. Another grant application a colleague and I initially submitted as MPIs in February 2025 seeks to study experiences of infertility stigma among men in Uganda, recognizing that the gendered fertility expectations necessitate a focus on men's experiences, which had been neglected in research on infertility. After reading news coverage about particular words being flagged in NIH grants by reviewers and after discussing the review process with my program officer, we removed the word "gender" and all references to gender and instead talked about differences between men and women. We were also told by the program officer that because the grant review process now disfavors international research, that we should also include extra justifications about the benefits of this work for the United States in the specific aims page and research strategy. We made these changes in our resubmission – which required additional time and input from colleagues about the framing and cuts to other parts of the grant addressing the science – even though we had misgivings about changing the description of the work in order to satisfy censors. However, the application was denied, and we are now deciding whether to edit further and submit as a new grant proposal.

33. The NIH's priorities alignment process requiring changes in how I describe my research makes me feel like I must fit my research interests into a political agenda in order to keep my funding on projects already awarded or to receive funding for new proposals. This censorship makes the application language less precise and minimizes the value of the scientific/peer review process, that is intended to vet research to ensure the NIH is a good steward of public funds that is supporting high-quality research to address critical public health issues. Receipt of NIH funding now feels like it does not necessarily signal good science, but science that fits into increasingly narrow parameters around science that is politically palatable. Trying to secure NIH funding is already challenging and stressful, and this

Administration's required self-censorship and word policing adds another layer of stress, distracting me from the more important aspect of grant writing, which is being as precise and accurate as possible.

34. I understand that, as a class representative, I represent the interests of everyone in the class, and not just myself. I am prepared to stay informed about what is happening with my case and stay in touch with my attorneys to give them information they need. I am committed to being a class representative because I do not want other researchers to be subjected to the same unlawful policies and actions that I have experienced. I have never served as a class representative in any prior action.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Washington, DC this 18th day of September 2026.

Suzanne Bell

Suzanne Bell

Exhibit 1

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R01HD114292
Federal Award Date
08/26/2024

Recipient Information

1. Recipient Name
THE JOHNS HOPKINS UNIVERSITY
3400 N CHARLES ST
BALTIMORE, MD 21218

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1520595110A5

4. Employer Identification Number (EIN)
520595110

5. Data Universal Numbering System (DUNS)
001910777

6. Recipient's Unique Entity Identifier
FTMTDMBR29C7

7. Project Director or Principal Investigator
Alison Gemmill, PHD (Contact)
Assistant Professor
agemmill@jhu.edu
818-804-8190

8. Authorized Official
Jordan Dalrymple

Federal Agency Information

9. Awarding Agency Contact Information
Melissa R Copeland
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
mh601f@nih.gov
240-401-3847

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
1R01HD114292-01

12. Unique Federal Award Identification Number (FAIN)
R01HD114292

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The fertility, maternal health, and infant health consequences of reproductive policy change

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 05/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$363,663
20 a. Direct Cost Amount	$232,778
20 b. Indirect Cost Amount	$130,885
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$363,663
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$363,663
26. Project Period Start Date 09/01/2024 **– End Date** 05/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$363,663

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Melissa R Copeland

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R01HD114292-01

Principal Investigator(s):
Suzanne O'Dea Bell, PHD
Alison Gemmill (contact), PHD

Award e-mailed to: eawards@jhu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $363,663 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to JOHNS HOPKINS UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD114292. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Melissa R Copeland
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	$232,778
Federal F&A Costs	$130,885
Approved Budget	$363,663
Total Amount of Federal Funds Authorized (Federal Share)	$363,663
TOTAL FEDERAL AWARD AMOUNT	$363,663
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$363,663

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$363,663	$363,663
2	$349,895	$349,895
3	$349,831	$349,831
4	$349,769	$349,769
5	$349,767	$349,767

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1520595110A5
Document Number:	RHD114292A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026	2027	2028
HD	8014702	$363,663	$349,895	$349,831	$349,769	$349,767

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41021 / **Released**: 08/16/2024
Award Processed: 08/26/2024 12:13:01 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01HD114292-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01HD114292-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

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some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD114292. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts

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with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R01HD114292-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award includes funds for twelve months of support but is awarded for less than twelve months. Noncompeting Continuation awards will cycle on **JUNE 1**. NICHD is taking this action to redistribute start dates more evenly throughout the fiscal year.

In order to meet NICHD program objectives within FY2024 budget constraints, this grant is reduced **14 percent** below the level recommended by the Integrated Review Group. Future year levels of support are determined by applying the same administrative reduction.

This is a Modular Grant Award without direct cost categorical breakdowns issued in accordance with the guidelines published in the NIH Grants Policy Statement (rev. 4/24). Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

*****

Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the **application** dated **04/07/2023**.

*****

For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

*****

The recipient must follow the Multiple Principal Investigator Leadership Plan included in the **application** dated **04/07/2023** and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

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Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$0	$0	$0	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01HD114292-01

INSTITUTION: JOHNS HOPKINS UNIVERSITY

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
TOTAL FEDERAL DC	$232,778	$233,306	$233,849	$234,361	$234,394
TOTAL FEDERAL F&A	$130,885	$116,589	$115,982	$115,408	$115,373
TOTAL COST	$363,663	$349,895	$349,831	$349,769	$349,767

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	63.75%	63.75%	63.75%	63.75%	63.75%
F&A Cost Base 1	$205,310	$182,885	$181,932	$181,032	$180,977
F&A Costs 1	$130,885	$116,589	$115,982	$115,408	$115,373

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/26/2024 12:13 AM

Exhibit 2

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# K01HD107172
Federal Award Date
12/15/2022

Recipient Information

1. Recipient Name
JOHNS HOPKINS UNIVERSITY, THE
3400 N CHARLES ST

BALTIMORE, 21218

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1520595110A5

4. Employer Identification Number (EIN)
520595110

5. Data Universal Numbering System (DUNS)
001910777

6. Recipient's Unique Entity Identifier
FTMTDMBR29C7

7. Project Director or Principal Investigator
Suzanne O'Dea Bell, PHD

sbell32@jhu.edu
916-803-5249

8. Authorized Official
Nancy Kerner

Federal Agency Information

9. Awarding Agency Contact Information
Melissa R Copeland
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
mh601f@nih.gov
240-401-3847

10. Program Official Contact Information
Juanita Jeanne Chinn
Statistician
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
juanita.chinn@nih.gov
3018274901

Federal Award Information

11. Award Number
1K01HD107172-01A1

12. Unique Federal Award Identification Number (FAIN)
K01HD107172

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing Understanding and Measurement of Infertility, Related Fears and Stigma, and Associated Consequences in Low-Resource Countries

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/01/2022 – **End Date** 08/31/2023	
20. Total Amount of Federal Funds Obligated by this Action	$1,620
20 a. Direct Cost Amount	$1,500
20 b. Indirect Cost Amount	$120
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$137,160
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$137,160
26. Project Period Start Date 09/01/2022 – **End Date** 08/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$137,160

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Melissa R Copeland

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise

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Notice of Award

RESEARCH SCIENTIST DEVELOPMENT AWARD
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1K01HD107172-01A1 REVISED

Principal Investigator(s):
Suzanne O'Dea Bell, PHD

Award e-mailed to: eawards@jhu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of $1,620 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to JOHNS HOPKINS UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number K01HD107172. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Melissa R Copeland
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$75,000
Fringe Benefits	$27,000
Personnel Costs (Subtotal)	$102,000
Other	$25,000
Federal Direct Costs	$127,000
Federal F&A Costs	$10,160
Approved Budget	$137,160
Total Amount of Federal Funds Authorized (Federal Share)	$137,160
TOTAL FEDERAL AWARD AMOUNT	$137,160
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,620

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$137,160	$137,160
2	$136,982	$136,982
3	$137,160	$137,160
4	$136,982	$136,982
5	$137,160	$137,160

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1520595110A5
Document Number:	KHD107172A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025	2026
HD	8014707	$137,160	$136,982	$137,160	$136,982	$137,160

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PDB -JC / **OC**: 41033 / **Released**: Copeland, Melissa 12/14/2022
Award Processed: 12/15/2022 12:04:55 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K01HD107172-01A1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1K01HD107172-01A1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.

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b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) K01HD107172. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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

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performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1K01HD107172-01A1 REVISED

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: This revised award corrects the fringe rate from 34% to 36%, in accordance with the recipient's letter of request dated 12/5/2022.

The previous terms and conditions of award remain in effect as stated below.

_____

Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NICHD will consider providing greater flexibilities to recipients in meeting administrative, financial management and audit requirements. Please contact the Grants Management Specialist and Program Official indicated on this Notice of Award for more information.

This award is subject to the requirements indicated in **PA20-190**, which are hereby incorporated by reference. See the NIH Funding Opportunity Announcements site.

A Mentor's Report is required for all NIH Mentored Career (K) Awards as part of the annual Research Performance Progress Report. See Section G.3 of the RPPR Instruction Guide.

*****

This award includes foreign component at the following site(s): **Makarere University** in **UGANDA**

In accordance with the NICHD FY2022 fiscal policy, escalation on recurring costs has been removed.

Graduate Student total direct costs (salary, fringe benefits and tuition remission) cannot exceed the NRSA zero level stipend level in effect at the time of the competing award. See NIH Guide Notice NOT-OD-02-017.

*****

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

SPREADSHEET SUMMARY
AWARD NUMBER: 1K01HD107172-01A1 REVISED

INSTITUTION: JOHNS HOPKINS UNIVERSITY

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$75,000	$75,000	$75,000	$75,000	$75,000
Fringe Benefits	$27,000	$27,000	$27,000	$27,000	$27,000
Personnel Costs (Subtotal)	$102,000	$102,000	$102,000	$102,000	$102,000
Other	$25,000	$24,835	$25,000	$24,835	$25,000
TOTAL FEDERAL DC	$127,000	$126,835	$127,000	$126,835	$127,000
TOTAL FEDERAL F&A	$10,160	$10,147	$10,160	$10,147	$10,160
TOTAL COST	$137,160	$136,982	$137,160	$136,982	$137,160

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	8%	8%	8%	8%	8%
F&A Cost Base 1	$127,000	$126,835	$127,000	$126,835	$127,000
F&A Costs 1	$10,160	$10,147	$10,160	$10,147	$10,160

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AMERICAN CIVIL LIBERTIES UNION FOUNDATION
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Telephone: (212) 549-2659

Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF [redacted]
[JORDAN DOE 5]

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

AMERICAN CIVIL LIBERTIES UNION FOUNDATION OF NORTHERN CALIFORNIA
GRAYCE ZELPHIN (CA Bar No. 279112)
gzelphin@aclunc.org
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NEIL K. SAWHNEY (CA Bar No. 300130)
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JACOBSON LAWYERS GROUP PLLC
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5100 Wisconsin Avenue, NW, Suite 301
Washington, DC 20016
Telephone: (301) 823-1148

* Application for *Pro Hac Vice* Admission Forthcoming

I, [redacted], declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is [redacted].

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I am an Assistant Professor [redacted]. I am also the director of [redacted].

5. I earned my PhD in [redacted] from [redacted] and completed postdoctoral work at [redacted].

6. I have published widely in my field, including [redacted] peer-reviewed articles in journals including [redacted].

7. My h-index is [redacted]. An h-index is a metric of scientific productivity and impact (e.g. I have [redacted] papers that have been cited at least [redacted] times). My work has been cited over [redacted] times according to Google Scholar.

8. From 2015-2016, I was a [redacted].

9. I was selected to be a [redacted] by the [redacted]. Awardees participate in the [redacted], a prestigious program for early-career researchers across the U.S. I presented findings from my NIH funded paper, [redacted].

10. I was invited to speak at the [redacted]. The session was attended by 1,500 people.

11. I have been invited to [redacted] numerous times and spoken about health misinformation on multiple occasions. The panels were called [redacted].

[redacted] and [redacted]

[redacted]

12. My program of research examines misinformation and whether interventions are effective. This research is important because belief in health misinformation can have negative consequences, including increased risk of mortality.

13. In 2021, I was awarded a [redacted] NIH grant titled [redacted] The grant sought to (1) understand with what frequency misinformation [redacted] appears on social media, [redacted], (2) [redacted], and (3) study the [redacted] processes involved [redacted].

14. This research agenda directly responded to a [redacted] Research Priority called [redacted]. [redacted]. Given that I made excellent progress [redacted] As such, in 2023, my institution was awarded a [redacted] grant in support of my research [redacted], titled [redacted] to study [redacted] misinformation. The grant term was from [redacted] 2023 through [redacted] 2026.

15. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals are lengthy and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are validated and replicable approaches to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—it indicates a project's scientific importance, methodological rigor, and real-world potential to improve public health. In 2021, the success rate for a [redacted] award was [redacted]%.

16. Attached hereto as **Exhibit 1** is a true and correct copy of this grant's Notice of Award (i.e., NOA).

17. I have published [redacted] articles based on the research from this grant [redacted]. This includes the paper [redacted] published in [redacted] This also includes [redacted]

[redacted] published in [redacted] This paper was selected for [redacted] award, which represents science that is exceptionally important, impactful, and deserves additional visibility for the whole field.

18. On or around March 26, 2025, I became aware of a screenshot circulating on social media of an apparent internal NIH email from that 6:40 AM that morning marked "URGENT." The email instructed staff to screen for "contracts regarding censorship" and to respond by noon that day whether they had any such contracts. Specifically, the email indicated that flagged contracts would include those involving "any form of censorship at all or **directing people to believe one idea over another related to health outcomes**," "**promot[ing] COVID vaccine uptake**," "**grants to fight misinformation or disinformation in general**," and specifically instructing keyword searches for terms including "**media literacy**," "**disinformation**," "**social media**," and "**misinformation**," (bolding in original text). Attached hereto as **Exhibit 2** is a true and correct copy of the screenshot of the email that I reviewed. After reviewing this screenshot, I became concerned that my grant, which studied health misinformation, might be flagged by NIH.

19. On [redacted] 2025 [redacted], we were notified that NIH was terminating the grant. Attached hereto as **Exhibit 3** is a true and correct copy of the termination notice we received from NIH. The reason given for the termination was "because [the project] does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

20. On [redacted] 2025, my institution submitted an administrative appeal of the grant termination. The appeal was unsuccessful.

21. Due to the termination, I was unable to retain my research assistant or hire additional PhD students or postdoctoral fellows. The termination also placed my current postdoctoral fellow's position in immediate jeopardy. I was able to preserve their position by reallocating my startup funds [redacted], money typically intended to support the development of research programs beyond externally funded projects. However, these funds will be exhausted in several months, at which point I

currently do not have the resources to continue my misinformation project as planned. I must also end the contract of my postdoctoral fellow.

22. NIH's decision not to fund misinformation-related grants has significantly impacted my ability to do future research in this area. After the termination, I submitted an application for another NIH grant focusing on trust in evidence-based health information sources. However, I am unable to submit new projects regarding misinformation directly.

23. I am eager to pursue many other research projects in this area, including interventions for reducing misinformation belief, measuring harm associated with misinformation belief, and developing translational resources to help medical practitioners and patients navigate the online information environment. However, given NIH's position regarding misinformation, I do not believe I can seek NIH funding for this work. This has significantly constrained the scope of my research program and the societal benefits that may come from it.

24. The grant termination has had a major impact on my career. [redacted] However, that avenue has been cut off for me because of NIH's decision to discontinue funding of misinformation research as being unaligned with agency priorities. As a result, I have started applying for research grants abroad and am considering moving out of the United States.

25. I am seeking to proceed in this litigation under a pseudonym and file this declaration under seal because I am concerned about public hostility and harassment and possible retaliation by the administration. Numerous misinformation researchers have been targeted for harassment because of their work.[1] For example, Kate Starbird at the University of Washington's Center for an Informed Public has been the target of death threats, doxxing, multiple lawsuits, and weaponized records requests and

[1] *See, e.g.*, *US Disinformation Researcher Laments 'Incredible Witch Hunt,'* Digital Journal (Sep. 5, 2024), https://www.digitaljournal.com/article/us-disinformation-researcher-laments-incredible-witch-hunt/.

investigations.[2] This also extends to researchers who study health misinformation.[3] The federal government has also targeted misinformation researchers by conducting congressional inquiries and [redacted] I am concerned that public participation in this litigation as a misinformation researcher will make me vulnerable to online harassment, doxxing, and potentially threaten my physical safety. In addition, [redacted] I am concerned that my public involvement may make me a target for retaliation by the administration. In particular, I am concerned about the [redacted] or jeopardizing my ability to [redacted]

26. I also fear that public participation in this litigation could jeopardize my future eligibility for federal research funding, which is essential to my long-term academic and research goals.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at [redacted] this 24th day of September 2026.

[redacted]

[2] *See* Jonathan Blitzer, *Jim Jordan's Conspiratorial Quest for Power*, The New Yorker (Oct. 21, 2023), https://www.newyorker.com/magazine/2023/10/30/jim-jordans-conspiratorial-quest-for-power; Kai Kupferschmidt, *The Rumor Clinic: At the Center for an Informed Public, Kate Starbird Tracks Falsehoods and Counters Them in Real Time*, Science (Oct. 30, 2024), https://www.science.org/content/article/u-s-election-looms-rumor-researcher-tracks-falsehoods-and-counters-them-real-time; Rachel Leingang, *'Stakes Are Really High': Misinformation Researcher Changes Tack for 2024 US Election*, The Guardian (Jan. 1, 2024), https://www.theguardian.com/us-news/2024/jan/01/misinformation-trends-2024-election-right-wing.

[3] *See* Win Reynolds, *Two-Thirds of Physicians and Biomedical Scientists Report Harassment on Social Media: Alarming Rates Of Personal Attacks Since the Beginning of the COVID-19 Pandemic*, Northwestern Now (June 15, 2023), https://news.northwestern.edu/stories/2023/06/two-thirds-of-physicians-social-media-harrassment; Jeff Tollefson, *Harassed? Intimidated? Guidebook Offers Help to Scientists Under Attack*, Nature (Sep. 20, 2024), https://www.nature.com/articles/d41586-024-03104-y, a true and correct copy of which is attached hereto as **Exhibit 4**.

EXHIBIT 1

REDACTED

Department of Health and Human Services
National Institutes of Health
[redacted]

Notice of Award

FAIN# [redacted]
Federal Award Date [redacted]

Recipient Information

1. Recipient Name
[redacted]

2. Congressional District of Recipient
[redacted]

3. Payment System Identifier (ID)
[redacted]

4. Employer Identification Number (EIN)
[redacted]

5. Data Universal Numbering System (DUNS)
[redacted]

6. Recipient's Unique Entity Identifier
[redacted]

7. Project Director or Principal Investigator
[redacted]

8. Authorized Official
[redacted]

Federal Agency Information

9. Awarding Agency Contact Information
[redacted]

10. Program Official Contact Information
[redacted]

Federal Award Information

11. Award Number
[redacted]

12. Unique Federal Award Identification Number (FAIN)
[redacted]

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
[redacted]

15. Assistance Listing Number
[redacted]

16. Assistance Listing Program Title
[redacted]

17. Award Action Type
Extension with or without funds

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date [redacted] – End Date [redacted]
20. Total Amount of Federal Funds Obligated by this Action [redacted]
20 a. Direct Cost Amount [redacted]
20 b. Indirect Cost Amount
21. Authorized Carryover
22. Offset
23. Total Amount of Federal Funds Obligated this budget period [redacted]
24. Total Approved Cost Sharing or Matching, where applicable
25. Total Federal and Non-Federal Approved this Budget Period [redacted]

26. Project Period Start Date [redacted] – End Date [redacted]
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period [redacted]

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
[redacted]

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH TRANSITION AWARD
Department of Health and Human Services
National Institutes of Health

[redacted]

SECTION I – AWARD DATA – [redacted]

Principal Investigator(s):
[redacted]

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of [redacted] (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to [redacted] in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the [redacted] of the National Institutes of Health under Award Number [redacted]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

[redacted]
Grants Management Officer
[redacted]

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	[redacted]
Fringe Benefits	[redacted]
Personnel Costs (Subtotal)	[redacted]
Materials & Supplies	[redacted]
Travel	[redacted]
Other	[redacted]

Federal Direct Costs	[redacted]
Federal F&A Costs	[redacted]
Approved Budget	[redacted]
Total Amount of Federal Funds Authorized (Federal Share)	[redacted]
TOTAL FEDERAL AWARD AMOUNT	[redacted]

AMOUNT OF THIS ACTION (FEDERAL SHARE) [redacted]

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	[redacted]
Document Number:	[redacted]
PMS Account Type:	[redacted]
Fiscal Year:	[redacted]

IC	CAN	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: [redacted] / OC: [redacted] / Released: [redacted] [redacted]
Award Processed: [redacted]

SECTION II – PAYMENT/HOTLINE INFORMATION – [redacted]

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – [redacted]

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.

[redacted] [redacted]

b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) [redacted]. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights

laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information 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 the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – [redacted] SPECIFIC AWARD CONDITIONS – [redacted]

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REQUIREMENT: The recipient is required to follow the Data Sharing plan included in the competing application and may not implement any changes in the plan without the written prior approval of the [redacted].

INFORMATION: Any unobligated balance reported on the FFR for the [redacted] is not eligible for carryover to the [redacted] award. The unobligated funds will be used as a partial payment on a future year of the [redacted] award.

INFORMATION: In accordance with the [redacted] current fiscal year (FY) funding policies, this non-competing award has been issued at 100% of the level indicated for this budget period on the prior Notice of Grant Award.

INFORMATION: To help expedite [redacted]'s response to prior approval requests, please submit requests for change of PD/PI, carryover or no cost extensions electronically through the eRA Commons at Prior Approval Module. All other post award requests should be submitted to [redacted]. All electronically submitted requests will be tracked and forwarded to the appropriate Grants Management personnel.

INFORMATION: This award involves Human Subjects Research. See "Assurance Requirements and Institutional Review Boards" under Part II, Subpart A, Human Subjects, in the NIH Grants Policy Statement, for specific requirements and recipient responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award.

This award reflects the [redacted]'s acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with the NIH Grants Policy Statement, "Education in the Protection of Human Research Subjects."

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

SPREADSHEET SUMMARY
AWARD NUMBER: [redacted]

INSTITUTION: [redacted]

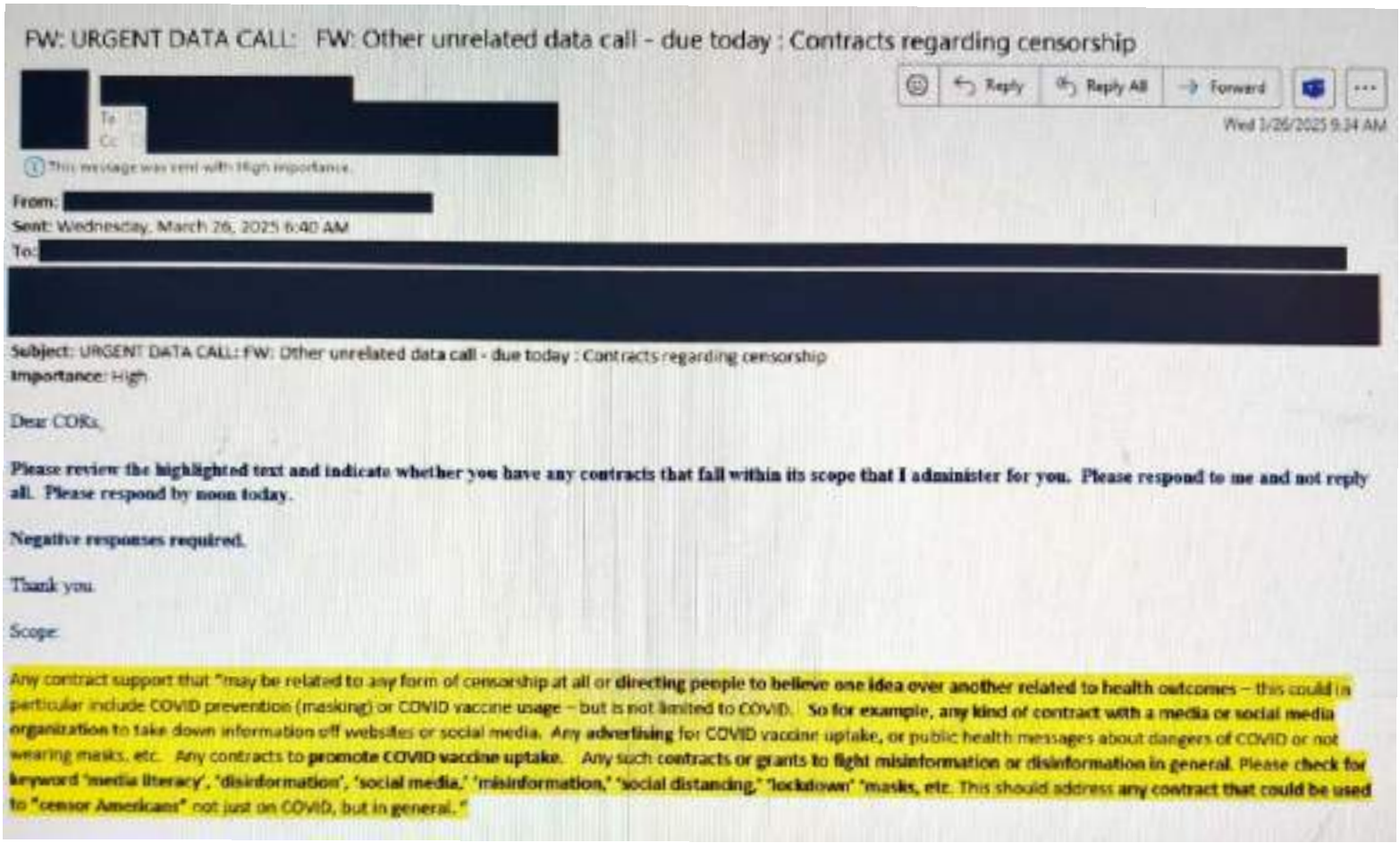
Budget	Year [redacted]	Year [redacted]	Year [redacted]
Salaries and Wages	[redacted]	[redacted]	[redacted]
Fringe Benefits	[redacted]	[redacted]	[redacted]
Personnel Costs (Subtotal)	[redacted]	[redacted]	[redacted]
Materials & Supplies	[redacted]		
Travel	[redacted]	[redacted]	[redacted]
Other	[redacted]	[redacted]	[redacted]
TOTAL FEDERAL DC	[redacted]	[redacted]	[redacted]
TOTAL FEDERAL F&A	[redacted]	[redacted]	[redacted]
TOTAL COST	[redacted]	[redacted]	[redacted]

Facilities and Administrative Costs	Year [redacted]	Year [redacted]	Year [redacted]
F&A Cost Rate 1	[redacted]	[redacted]	[redacted]
F&A Cost Base 1	[redacted]	[redacted]	[redacted]
F&A Costs 1	[redacted]	[redacted]	[redacted]
F&A Cost Rate 2	[redacted]		
F&A Cost Base 2	[redacted]		
F&A Costs 2	[redacted]		

Version: [redacted] | Generated on: [redacted]

EXHIBIT 2

[Image Contains Pre-existing Highlights and Redactions]



FW: URGENT DATA CALL: FW: Other unrelated data call - due today : Contracts regarding censorship

[redacted]

Reply | Reply All | Forward

Wed 1/29/2025 9:34 AM

To: [redacted]
Cc: [redacted]

This message was sent with High importance.

From: [redacted]
Sent: Wednesday, March 26, 2025 6:40 AM
To: [redacted]

[redacted]

Subject: URGENT DATA CALL: FW: Other unrelated data call - due today : Contracts regarding censorship
Importance: High

Dear COIKs,

Please review the highlighted text and indicate whether you have any contracts that fall within its scope that I administer for you. Please respond to me and not reply all. Please respond by noon today.

Negative responses required.

Thank you.

Scope:

Any contract support that "may be related to any form of censorship at all or **directing people to believe one idea over another related to health outcomes** – this could in particular include COVID prevention (masking) or COVID vaccine usage – but is not limited to COVID. **So for example, any kind of contract with a media or social media organization** to take down information off websites or social media. Any **advertising** for COVID vaccine uptake, or public health messages about dangers of COVID or not wearing masks, etc. Any contracts to **promote COVID vaccine uptake.** Any such **contracts or grants to fight misinformation or disinformation in general.** Please **check for keyword 'media literacy', 'disinformation', 'social media,' 'misinformation,' 'social distancing,' 'lockdown' 'masks, etc.** This should address **any contract that could be used to "censor Americans"** not just on COVID, but in general."

EXHIBIT 3

REDACTED

Tuesday, August 4, 2026 at 14:10:40 [redacted]

Subject: Grant Termination Notice_NIH_[redacted]
Date: Wednesday, April 2, 2025 at 12:49:50 PM [redacted]
From: [redacted]
To: [redacted]
CC: [redacted]
Attachments: image001.jpg, image002.png

Hello [redacted],

Attaching for your reference a termination notice [redacted] received related to your award. [redacted] will be following up with you regarding next steps.

Best,
[redacted]

[redacted]

[redacted]

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Tuesday, April 1, 2025 9:25 AM
To: [redacted]
Subject: Grant Termination Notification

You don't often get email from michelle.bulls@nih.gov. Learn why this is important

National Institutes of Health
Office of Extramural Research

4/1/2025

[redacted]

[redacted]

Dear [redacted]:

Effective with the date of this letter, funding for Project Number [redacted] is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]
The 2024 Policy Statement applies to your project because NIH approved your grant on [redacted], and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]
The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."
This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.
Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]
You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]
The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Crystal Wolfrey, Chief Grants Management Officer, NCI
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Exhibit 4

nature

NEWS | 20 September 2024

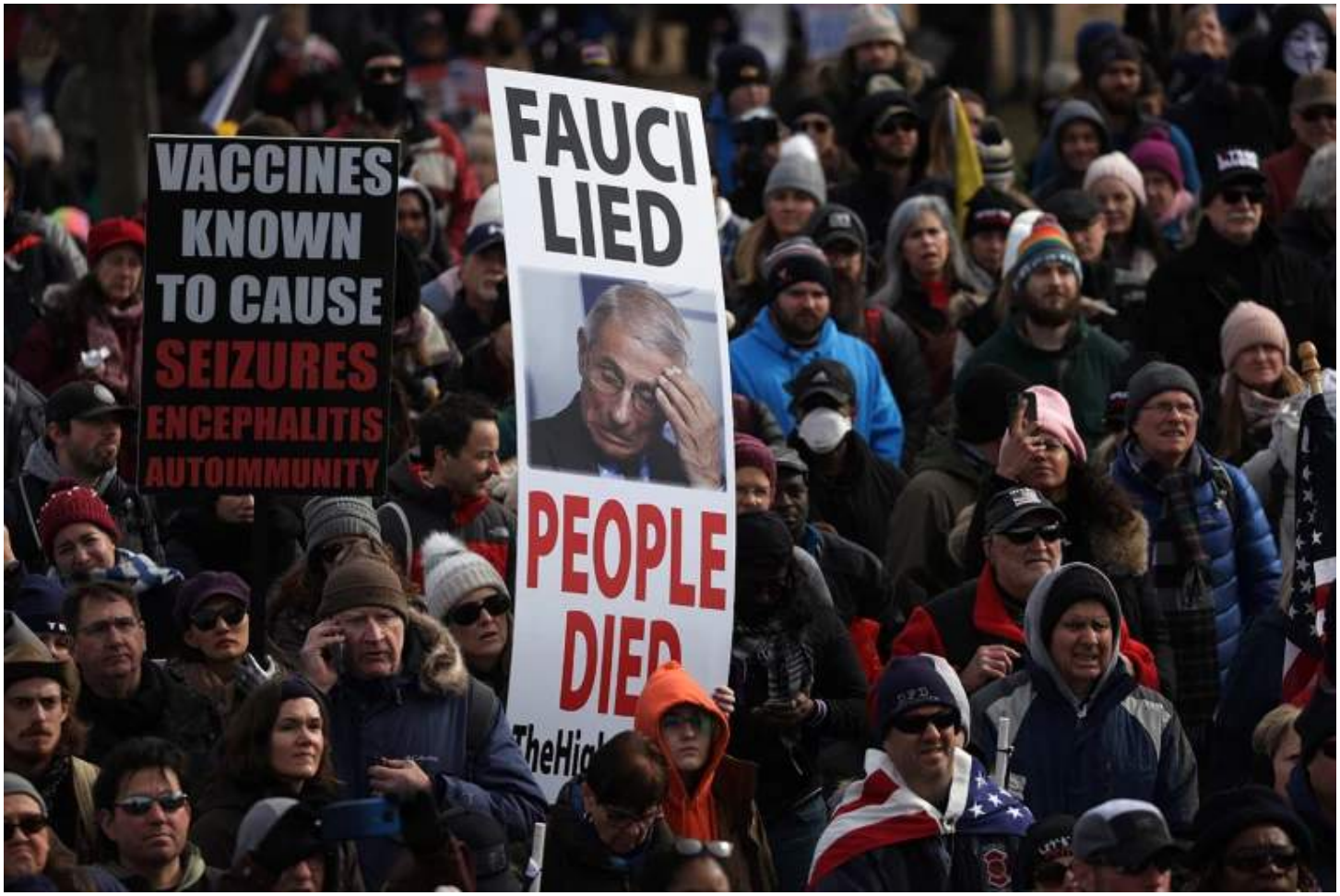
Harassed? Intimidated? Guidebook offers help to scientists under attack

Scholars provide tactics for responding to threats and abuse, but emphasize that institutions must defend their researchers.

By Jeff Tollefson

Save article

View saved research ›



Anthony Fauci, head of the US National Institute of Allergy and Infectious Diseases, was assigned personal security guards after receiving death threats during the COVID-19 pandemic. Credit: Alex Wong/Getty

Intimidation and harassment have become an occupational hazard for scholars studying phenomena linked to politics, including climate change, disinformation and virology. Now, researchers have united to create a defence playbook that offers tactics for dealing with this reality. Their message is clear: scientists can take steps to protect themselves, but their institutions also need to have a support plan in place.

"It's universities and the academic institutions that have the primary responsibility to act," says Rebekah Tromble, who leads the Institute for Data, Democracy, and Politics at George Washington University in Washington DC, and has herself experienced harassment because of her work. "They are the employers, and frankly it's the type of public-interest scholarship that they are incentivizing that puts scholars at risk."



RELATED

Harassment of scientists is surging – institutions aren't sure how to help

Tromble worked with Kathleen Searles, a political scientist at the University of South Carolina in Columbia, to develop an initiative called the Researcher Support Consortium, launched today in Washington DC. With the support of multiple non-profit organizations, they developed a series of recommendations for US researchers (although they could be used by others), funding agencies and academic institutions, including template policies for universities that lay out best practices for responding to attacks on scholars.

The consortium isn't the first to tackle the issue, but it has provided the most comprehensive guide available, says Isaac Kamola, director of the Center for the Defense of Academic Freedom at the American Association of University Professors, based in Washington DC. "It is the new industry standard."

Protection plan

Climate scientists have been grappling with harassment and threats over their work for more than a decade. In recent years, however, attacks have spread to biomedical researchers and social scientists. For instance, in 2021, a *Nature* survey of 300 scientists who had given media interviews about the COVID-19 pandemic found that more than two-thirds had had negative experiences because of their public interactions; 22% had received threats of physical or sexual violence. And in the past two years, researchers who study the spread of election and vaccine misinformation on social media have been at the centre of US congressional investigations and lawsuits.



RELATED

'I hope you die': how the COVID pandemic unleashed attacks on scientists

The consortium's advice for researchers who think they are at risk starts with simple steps such as removing personal contact information and office locations from publicly available websites. But the organization also points to more sophisticated strategies, such as applying for a 'Certificate of Confidentiality' from the US National Institutes of Health, which protects the privacy of participants in research studies. Funding agencies and grant managers, meanwhile, are urged to issue messages of support to both grant recipients and their research institutions.

But the bulk of the consortium's recommendations focus on academic institutions. The group's 43-page toolkit for institutions outlines steps universities can take to prepare for attacks on their scholars, rather than scrambling to react to harassment after it has happened. The first steps are to establish policies in advance, to set up codes of conduct for students and academic staff, and to create reporting systems. Institutions should also establish committees of administrators, department heads, members of communications staff, legal advisers and others who are ready to act.

Specialists contacted by *Nature* say these are useful guidelines and will be helpful, if they are followed. "Unfortunately, I don't think it will stop researchers from needing their own lawyers when things get dire," says Lauren Kurtz, executive director of the Climate Science Legal Defense Fund, a non-profit organization in New York City that was created in 2011 to provide free legal aid to climate scientists. The fundamental problem, Kurtz says, is that institutions often focus more on protecting themselves than on looking after their faculty members and frequently decline to provide legal counsel to their employees.



RELATED

Microbiologist who was harassed during COVID pandemic sues university

The Association of American Universities in Washington DC, whose members include more than 65 US public and private institutions, did not respond to *Nature*'s request for comment.

Tromble says the consortium is designed to operate in tandem with organizations that provide legal support to scientists. One such service is the Knight First Amendment Institute at Columbia University in New York City, which announced in November last year that it would provide legal support for researchers who study social media.

The stakes are high – for researchers, for science and for the United States, Kamola says. "Defending faculty from harassment is essential for protecting the long-term integrity of research, the integrity of the institutions in which we work and the integrity of our democracy."

doi: https://doi.org/10.1038/d41586-024-03104-y

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Attorneys for Plaintiffs

(Additional Counsel on Following Page)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated*,

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF CLAIRE ANKUDA

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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Washington, DC 20016
Telephone: (301) 823-1148

* Application for *Pro Hac Vice* Admission Forthcoming

I, Claire Ankuda, declare:

1. I have personal knowledge of the facts set forth in this declaration, and if called to testify as a witness thereto, could do so competently under oath.

2. My name is Claire Ankuda.

3. I am offering this declaration in my individual capacity and not on behalf of my employer.

4. I am an Associate Professor at Dartmouth Health as well as the Geisel School of Medicine at Dartmouth College. I am a board-certified hospice and palliative medicine physician and health services researcher. My work examines the role of Medicare Advantage plans, hospice, and home health policy in shaping the care for older adults with serious illness.

5. I earned my MD from the University of Vermont College of Medicine. I earned my MPH from the Harvard School of Public Health. I earned my MSc in health Services Research from the University of Michigan as part of the Robert Wood Johnson Clinical Scholars Program.

6. I have published widely in my field, including in the *Annals of Behavioral Medicine*, *Journal of American Geriatrics Society*, *Journal of General Internal Medicine*, *JAMA Internal Medicine*, and *Health Affairs*. I have received multiple awards recognizing my contributions, including the Terrie Fox Wetle Rising Star Award in Health Services and Aging Research from the American Federation for Aging Research and the American Academy of Hospice and Palliative Medicine Emerging Leader Award. I have just completed a 5-year NIH K76 Paul B. Beson Emerging Leaders Career Development Award in Aging. My work has been cited in Government Accountability Office reports on the Medicare Advantage program, and I served as an expert witness for the Department of Justice around Olmstead Act violations.

7. My research work is motivated through watching the difficulties of my patients navigating insurance coverage in the setting of life-threatening serious illnesses such as cancer and dementia. My goal is to conduct research that helps us to understand how the Medicare program can facilitate the best outcomes and highest quality of care for people with serious illness, including those who are at the end of life.

8. NIH grant applications are incredibly demanding. Preparing one can take months or even years. Proposals are lengthy and must make a compelling case that the health issue being studied is urgent and scientifically significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low-especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money-it indicates a project's scientific importance, methodological rigor, and real-world potential to improve public health.

9. I submitted a grant proposal to NIH in November 2024, titled *The canary in the coalmine: Medicare Advantage switches for adults with new onset dementia* (R01AG0126417). I have not yet received an R01 (a major independent research award), and am within 10 years of completing my training, thus I qualify as an early stage investigator.

10. This project proposed to investigate when and why individuals change insurance after getting diagnosed with dementia, specifically whether patients switch to a different Medicare Advantage plan or out of the Medicare Advantage program, and what the impacts of these changes are for patient care. This project aimed to understand why patients switch insurance plans to better understand the clinical impact of these decisions, including on particular populations at high risk of negative consequences from a change to Medicare Advantage plans, such as those in rural areas, those in highly concentrated Medicare Advantage markets, and those more likely to have limited financial resources.

11. My initial submission of the grant application in November 2024 scored in the 25th percentile. I made substantial edits and resubmitted this grant in July 2025. After this resubmission, my scheduled study section review was delayed due to the government shutdown, from November 2025 to January 2026. Ultimately, this resubmitted grant scored at the 5th percentile. For context, 2024 paylines for a grant such as mine (Early stage investigator, dementia focused) were at 20%.

12. Upon my request, in March 2026, I met with my NIH program officer (PO), and they did not indicate that the delays were due to my submission not aligning with current NIH priorities. Instead, they noted the backlog of highly-scored grants that meant my grant might be considered for funding later in the funding year than usual. They also noted that decisions were not as dependent on scientific

review scoring as usual. Shortly after that, my status changed on eRA Commons to note that the council review of my grant application was complete.

13. After this development, in April 2026, I again contacted my PO but received no response. After further attempts to speak with my PO, my PO told me to email my questions. I did so, asking questions about the likelihood of receiving the grant award and whether new NIH policies were impacting the award. My PO responded that my likelihood of receiving the funding was low as priorities continued to evolve and that the NIH had moved away from prioritizing research involving health policy. My PO also suggested that I submit the project as a brand new submission in the fall of 2026 and revise the title to focus on the benefits of the research to patients and doctors and remove references to Medicare Advantage. However, my existing project title, *The canary in the coalmine: Medicare Advantage switches for adults with new onset dementia*, already seems focused on patients. Colleagues receiving similar feedback from POs advised me to remove Medicare Advantage from the title, although this is challenging as this program is the centerpiece of my research.

14. Several colleagues with grants that scored worse than mine by 5-10 percentile points but that focused on different areas of policy were funded. I additionally heard about other colleagues with grants scoring as well as at the 1st percentile that similarly focused on the Medicare Advantage program either were not funded or were only awarded after heavy editing to minimize critiques of the Medicare Advantage program.

15. Based on feedback I received from my program officer, as well as the experiences of my colleagues, I believe that my grant application was flagged as influencing public policy pretextually because of hostility from the administration to research that might show the negative impacts of some Medicare Advantage plans, which is at odds with the administration's agenda.

16. I am planning to submit three additional NIH grant applications in the fall, including one on how Medicare Advantage plans influence cancer care outcomes and another one assessing how people with dementia navigate insurance plan decisions. Given my experience with my current application, I am concerned about drafting these grant applications in such a way as to accurately describe my research projects while also not running afoul of NIH's recent focus on restricting research that may influence public policy or studies the effects of a public policy.

17. If NIH were to stop using its priorities-alignment process of disqualifying research projects that shed light on the negative impacts of the administration's favored policies, I would submit these future applications without concern about triggering censors at the agency. Likewise, I would expect that my existing grant application, which scored in the top 5th percentile, would likely be funded.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Rockingham, Vermont this 8th day of September 2026.



Claire Ankuda

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ARGHAVAN SALLES; ABIGAIL HATCHER; ANDREA ROSSO; ANN D. COHEN-WILSON; DOLORES ALBARRACÍN; HEIDI MOSESON; JADE PAGKAS-BATHER; JONATHAN KYLE DAW; KATIE EDWARDS; KELTON MINOR; MICHAEL D. GREEN; SARA JACKSON; SUZANNE BELL; JORDAN DOE 1; JORDAN DOE 2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf of themselves and all others similarly situated,*

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; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES DOGE SERVICE,

Defendants.

Case No. 3:26-cv-10510-SK

DECLARATION OF OSCAR HEANUE

* Application for *Pro Hac Vice* Admission Forthcoming
** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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* Application for *Pro Hac Vice* Admission Forthcoming

I, Oscar Heanue, declare:

1. I am an attorney admitted to practice in the District of Columbia. I am employed by the Center for Science in the Public Interest, counsel for Plaintiffs in this action. I have been admitted to appear before the Court *pro hac vice*, pursuant to the Court's order at ECF No. 24.

2. I submit this declaration in support of Plaintiffs' 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, as follows:

5. Attached hereto as **Exhibit 1** is a true and correct copy of a National Institutes of Health ("NIH") webpage entitled "Mission and Goals," also available at https://perma.cc/US7D-QYTH. The copy was created on September 7, 2026.

6. Attached hereto as **Exhibit 2** are excerpts from the March 2026 NIH Grants Policy Statement, reflecting the Introduction and Sections 2.4, 8.2, 8.4, 14.9 of same.

7. Attached hereto as **Exhibit 3** is a true and correct copy of an NIH webpage entitled "New to NIH," also available at https://perma.cc/5ANL-PLSM. The copy was created on September 23, 2026.

8. Attached hereto as **Exhibit 4** is a true and correct copy of a February 21, 2025 document entitled "Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards," issued by NIH Acting Director Matthew Memoli.

9. Attached hereto as **Exhibit 5** is a true and correct copy of an email exchange between Brad Smith and Matthew Memoli dated February 22, 2025, obtained from the Administrative Record produced in *Am. Pub. Health Assoc. v. Nat'l Insts. of Health*, No. 25-cv-10787 (D. Mass. 2025) ("*APHA*"), at NIH_GRANTS_003752–53.

10. Attached hereto as **Exhibit 6** is a true and correct copy of an excerpt from the transcript of the April 4, 2025 deposition of Liza Bundesen taken in the matter of *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025), which excerpt reflects pp. 1–4 and 35–39 thereof.

11. Attached hereto as **Exhibit 7** is a true and correct copy of an email from Matthew Memoli to Liza Bundesen and accompanying attachments, dated February 28, 2025, obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_002469–87.

12. Attached hereto as **Exhibit 8** is a true and correct copy of an email from Rachel Riley to Liza Bundesen, dated February 28, 2025, and an accompanying termination letter obtained from the Administrative Record produced in *APHA*, at NIH_Grants_002296 and NIH_Grants_002303–04. For the Court's convenience, a zoomed-in and cropped version of NIH_Grants_002296 is provided as the second page of the exhibit.

13. Attached hereto as **Exhibit 9** is a true and correct copy of an email from Matthew Memoli to John Lorsch and Michelle Bulls dated March 24, 2025, obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_002562.

14. Attached hereto as **Exhibit 10** is a true and correct copy of a March 4, 2025 document entitled "Staff Guidance – Award Assessments for Alignment with Agency Priorities," obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_002136–42.

15. Attached hereto as **Exhibit 11** is a true and correct copy of a March 13, 2025 email from Michelle Bulls to Chief Grant Management Officers, with the subject line "Award Revision Guidance and List of Terminated Grants via letter on 3/12," and an attachment entitled "Termination Categories," obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_001957–58 and NIH_GRANTS_001968.

16. Attached hereto as **Exhibit 12** is a true and correct copy of a March 25, 2025 document entitled "NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities - March 2025," obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_003216–30.

17. Attached hereto as **Exhibit 13** is a true and correct copy of a May 7, 2025 document entitled "NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT," obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_003548–78.

18. Attached hereto as **Exhibit 14** is a true and correct copy of a May 15, 2025 document entitled "NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT," obtained from the Administrative Record produced in *APHA*, at NIH_GRANTS_003517–46.

19. Attached hereto as **Exhibit 15** is a true and correct copy of an August 15, 2025 document from NIH Director Jay Bhattacharya entitled "NIH Priorities and Internal Review of Intramural and Extramural Programs."

20. Attached hereto as **Exhibit 16** is a true and correct copy of an NIH Statement entitled "Advancing NIH's Mission Through a Unified Strategy," dated August 15, 2025 and updated on July 2, 2026, also available at: https://perma.cc/3WDE-NSJT. The copy was created on August 6, 2026.

21. Attached hereto as **Exhibit 17** is a true and correct copy of an NIH Notice, NOT-OD-26-007, entitled "Reminder of Compliance Requirements for NIH Extramural Recipients Related to Renegotiated Aims, Objectives, Titles, and Abstracts," also available at: https://perma.cc/3E9D-BSZ9. The copy was created on September 15, 2026.

22. Attached hereto as **Exhibit 18** is a true and correct copy of a December 12, 2025 document entitled "Staff Guidance – Reviewing Grants for Priorities Alignment."

23. Attached hereto as **Exhibit 19** is a true and correct copy of an August 11, 2026 article from Nature entitled "NIH limits funding for research on the health effects of public policy."

24. Attached hereto as **Exhibit 20** is a true and correct copy of a March 26, 2025 article from Nature entitled "Hours after NIH director confirmed, the agency tackles one of his priorities — ending 'censorship' in science." https://perma.cc/6KUNSQA8

25. Attached hereto as **Exhibit 21** is a true and correct copy of a PowerPoint slide deck published by the National Bureau of Economic Research, dated June 18, 2026, which was used during a presentation given by NIH Director Jay Bhattacharya. This exhibit is also available at: https://perma.cc/HB54-CJCE. The copy was created on September 22, 2026.

26. Attached hereto as **Exhibit 22** is a true and correct copy of a webpage published by the American Society of Health Economics, titled "NIH Signals New Era For Health Economics," available at: https://perma.cc/SW7K-X8DU. The copy was created on September 22, 2026.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed at Pittsburgh, Pennsylvania this 24 day of September 2026.

Oscar Heanue

EXHIBIT 1

National Institutes of Health
Turning Discovery Into Health

Mission and Goals

> 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.

The goals of the agency are:

- to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
- to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.



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In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

- in the causes, diagnosis, prevention, and cure of human diseases;
- in the processes of human growth and development;
- in the biological effects of environmental contaminants;
- in the understanding of mental, addictive and physical disorders; and
- in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

This page last reviewed on March 2, 2026

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

NIH...Turning Discovery Into Health®

Follow Us

EXHIBIT 2



NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NIH National Institutes of Health

MARCH 2026

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. These terms and conditions apply not only to the recipients of NIH Grant Awards, but also flow down to any subawards as well as to subrecipients unless specified otherwise in the regulation or the terms and conditions of the specific NIH award (see "Consortium Agreements" on page IIB-109).

This document also is designed to be useful to those interested in NIH grants by providing information about NIH, its organization, its staff and its grants process. The NIHGPS is available online. This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- ***Part I: NIH Grants General Information.*** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies recipient, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.
- ***Part II: Terms and Conditions of NIH Grant Awards.*** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to for-profit organizations; and research patient care activities.
- ***Part III: Points of Contact.*** Part III (chapter 20) lists pertinent offices with their contact information.

CONVENTIONS

Certain conventions are followed throughout this document. The term “grant” is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term “recipient” generally is used to refer to recipients of grants and cooperative agreements. “NIH” may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a recipient or other organization. A reference to “Part II (IIA or IIB)” or “Part III” without further elaboration means the corresponding part of the NIHGPS.

SUPERSESSION

This version of the Grants Policy Statement includes policies and requirements that have been published via Guide Notices in effect as of March 17. 2026. The updates published in this version of the GPS consolidate all such Guide Notices and supersede the April 2024 version of the NIHGPS.

ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Recipients are responsible for reviewing the *NIH Guide for Grants and Contracts* for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at https://grants.nih.gov/funding/nih-guide-for-grants-and-contracts/subscribe.

As required by 2 CFR Part 200.315, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected recipient and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover recipient costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to for-profit organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an IHE, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the Data Management & Sharing Policy Overview web page. (Also see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.)

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds have a vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate cybersecurity and other actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, tablets, mobile devices, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act.

2.4 THE PEER REVIEW PROCESS

NIH policy is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, timely, and conducted in a manner that strives to eliminate bias. Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act. The peer review system used by NIH, often referred to as the "dual review system," is based on two sequential levels of review for each application—initial review for scientific and technical merit by NIH's Center for Scientific Review (CSR), and a second level of review for mission relevance by the IC National Advisory Council / Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various scientific and professional groups. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at NIH's web site or Peer Review Policies and Practices on the NIH Grants & Funding web site.

2.4.1 Initial Review

2.4.1.1 Responsibilities

The Division of Receipt and Referral (DRR) within the CSR receives all competing grant applications submitted to NIH.

CSR centrally reviews the application for completeness and responsiveness to the NOFO, as applicable, conducts the initial technical review for scientific merit and prepares the summary statements.

CSR Referral Officers, who are senior health scientist administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to a specific study section for initial review of the scientific merit of the application. These assignments are made on the basis of the application's contents and referral guidelines.

CSR's study sections are organized into Review Branches by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc Special Emphasis Panels (SEPs) are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that their application has been received and that they can find information about the application's SRO, SRG, and IC assignments in eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO, not the PO, is the primary contact for communication with the applicant until the summary statement is released. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR, and submitted to the SRO.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application, provide initial scores, and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of the discussion, and an overall impact score. Summary statements are then provided to the IC's Advisory Councils, the PD(s)/PI(s), and applicant institution's Authorized Organization Representative.

2.4.1.2 Overall Impact

Reviewers assess overall impact in the determination of scientific and technical merit; overall impact is defined based on the different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the

project proposed). These criteria are evaluated and scored in accordance with the applicable peer review framework (standard or Simplified Review Framework (SRF.)

NIH utilizes SRF for the peer review of the majority of competing research project grants (applications under the following activity codes: R01, R03, R15, R16, R21, R33, R34, R36, R61, RC1, RC2, RC4, RF1, RL1, RL2, U01, U34, U3R, UA5, UC1, UC2, UC4, UF1, UG3, UH2, UH3, UH5, (including the following phased awards: R21/R33, UH2/UH3, UG3/UH3, R61/R33).

All other research project grant applications utilize the standard peer review criteria.

2.4.1.3 Standard Scored Review Criteria (Non SRF-applicable activity codes)

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, enhance health, and reduce illness and disability. For research grant applications, and most other types of applications, reviewers evaluate the overall impact of the proposed project based on five regulatory criteria: Significance, Investigator(s), Innovation, Approach, and Environment.

For non SRF-applicable activity codes, reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and determine a separate score for each. An application does not need to be strong in all categories to be evaluated likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The NOFO should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Standard Additional Review Criteria (Non SRF-applicable activity codes)

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

- Protections for Human Subjects
- Inclusion of Human Subjects, Policies
- Vertebrate Animals
- Biohazards
- Resubmission /Renewal / Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Standard Additional Review Considerations (Non SRF-applicable activity codes)

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.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

The NOFO should be consulted for additional information describing each of the relevant additional review considerations.

Although these review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R24 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and research related activities. However, for some activities (e.g., construction grants and research project grants subject to the Simplified Review Framework), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in NOFOs.

2.4.1.6 Simplified Review Framework (SRF)

Due to the inherent complexity of the peer review process, NIH utilizes the Simplified Review Framework (SRF) for the peer review of the majority of competing research project grants (applications under the following activity codes: R01, R03, R15, R16, R21, R33, R34, R36, R61, RC1, RC2, RC4, RF1, RL1, RL2, U01, U34, U3R, UA5, UC1, UC2, UC4, UF1, UG3, UH2, UH3, UH5, (including the following phased awards: R21/R33, UH2/UH3, UG3/UH3, R61/R33). The SRF enables peer reviewers to better focus on the central questions necessary to assess the scientific and technical merit of a proposed research project: the importance of the proposed research, whether the proposed research methods are rigorous and feasible, and whether the investigators and institution have the expertise and resources necessary to carry out the project as proposed. Additionally, the use of the SRF aids NIH in mitigating the effect of reputational bias by refocusing the evaluation of the investigator/environment to within the context of the proposed and research and also reduces burden on the reviewer by shifting policy compliance activities to NIH staff.

SRF Review Criteria

The SRF reorganizes the five regulatory criteria into three factors as listed below. Each factor is evaluated by the Reviewer in the determination of scientific merit, and in providing an overall impact score. Factors 1 and 2 will each receive a separate criterion score; Factor 3 will be evaluated for sufficiency. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Factor 1. Importance of the Research (scored 1-9):

- *Significance*
- *Innovation*

Factor 2. Rigor and Feasibility (Scored 1-9)

- *Approach (also includes Inclusion and Clinical Trial Study Timeline)*

Factor 3. Expertise and Resources (considered in overall impact: no individual score provided)

- *Investigator(s), Environment*
    - *Evaluated as 'appropriate' or 'gaps identified'*
    - *Reviewer is required to provide further explanation, if gaps are defined.*

SRF Additional Review Criteria (can affect overall impact score)

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items:

- Protections for Human Subjects
- Vertebrate Animals
- Biohazards
- Resubmission / Renewal / Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

SRF Additional Review Considerations (No effect on overall impact score)

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.

- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. As stated in the Notice of Funding Opportunity, appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of their application first should consider the comments in the summary statement, and then should contact the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than

the AOR) only or with a "cc" to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at 42 CFR Part 52h.5 "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and their concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a "cc" to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same

or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Notice of Funding Opportunity.

2.4.3 National Advisory Council or Board Review

The IC National Advisory Council or Board (hereafter "Council") provides the second level peer review of applications for grants and cooperative agreements. The Council members review the summary statement and are asked to concur with the initial peer review for scientific and technical merit, as judged by the SRG, and to consider relevance to the IC's programs and priorities. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive $2 million or more in total costs (inclusive of direct and indirect) per year of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

Consistent with 2 CFR 200.204 and 200.205, all incomplete applications, non-compliant applications, and applications determined to be nonresponsive to NOFO requirements will not be reviewed. If the NOFO remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. An application may resubmit one application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application, provided the NOFO allows resubmission applications. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

For complete, compliant and responsive applications, following the initial scientific peer review, the summary statement will be available to the PD/PI and AORs of the applicant organization with the Signing Official (SO) user role in the eRA Commons. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. If an application does not result in funding, there may be an opportunity to respond to the reviewers' comments and resubmit the application, provided the NOFO allows resubmission applications. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an

application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application (referred to as a resubmission) for review in a future cycle.

Some of the ICs publish paylines as part of their funding strategies to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in Completing the Pre-Award Process below.

For unsuccessful applicants, the NIH will send a centralized, automated correspondence to the applicant organizations to notify them of NIH's intent not to fund the indicated applications.

The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if specific award conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each NOFO will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

E-mail requests must be clearly identified as prior approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the NIH Enterprise Directory. E-mail requests must include the name of the recipient, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever recipients contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior approval authority usually is the pass-through entity. However, the pass-through entity may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the pass-through entity must obtain that approval from NIH before giving its approval to the consortium participant.

SBIR and STTR recipients are required to seek prior approval when adding a new domestic subaward to a project post-award, where the arrangement was not originally a part of the peer reviewed and approved application. A foreign risk assessment is required for the entity selected for the subaward when the prior approval request is submitted through submission of an updated SBIR STTR Foreign Disclosure Form via the "SBIR STTR Foreign Disclosure Request for Additional Materials" (RAM) feature in eRA Commons. The recipient must receive official written approval notification from the NIH Grants Management Official prior to signing a subaward agreement.

8.2 AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INTELLECTUAL PROPERTY RIGHTS, AND SHARING RESEARCH RESOURCES

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data in Part I for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as recipients abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the recipient to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources "research tools" may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

8.2.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from a grant-supported project. Specific terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 2 CFR Part 200.315) or prevents the recipient from being able to comply with NIH policies, including the 2024 NIH Public Access Policy. The disposition of royalties and other income earned from a copyrighted work is addressed in Administrative Requirements—Management Systems and Procedures—Program Income.

All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. In accordance with the Stevens Amendment,each publication, press release, or other document about research supported by an NIH grant must include both:

1) An acknowledgment of NIH grant support clearly stating the percentage and dollar amount of the total costs of the program or project funded with federal money, and the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources. For example:

   "Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under grant number [specific NIH grant number in this format: R01GM012345]." A total of $[amount], or [percentage] percent of [research/project/program] [is/was] financed with federal funds. A total of $[amount], or [percentage] percent of [research/project/program] [is/was] financed with non-governmental funds (if applicable)", and

2) A disclaimer that says:

> "The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

If the recipient plans to issue a press release about research supported by an NIH grant, it should notify the NIH funding component in advance to allow for coordination. See Media Inquiries for media contact information.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports and Administrative Requirements—Closeout—Final Reports—Final Progress Report). When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also NIH Public Access Policy below for additional requirements for publications resulting from NIH funded research.

8.2.2 NIH Public Access Policy

The 2024 NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH funded research at the NIH NLM PMC, a free digital archive of full-text biomedical and life sciences journal literature. Under the Policy NIH-funded investigators are required to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available without embargo upon the Official Date of Publication, as defined in the Policy. The Author Accepted Manuscript is defined as the author's final version that has been accepted for journal publication, and includes all revisions resulting from the peer review process, including all associated tables, graphics and supplemental material. This policy applies to any Author Accepted Manuscript accepted for publication in a journal, on or after July 1, 2025, that is the result of funding by NIH in whole or in part, through grants and cooperative agreements (including training grants), contracts, Other Transactions, NIH intramural research, and the official work of an NIH employee.

Institutions and investigators are responsible for ensuring compliance with this Policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the Policy, were authored or co-authored by the applicant and result from NIH support must include the PMCID or NIHMS ID.

More details may be found at: https://grants.nih.gov/faqs#/public-access-policy and https://grants.nih.gov/policy-and-compliance/policy-topics/public-access.

8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page.

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

NIH has published a set of principles and guidelines known as the NIH Research Tools Policy for funding recipients and the biomedical community. These serve as a reference for identifying an appropriate strategy for disseminating and sharing research tools. The NIH Research Tools Policy webpage explains these principles and guidelines in more detail and provides suggestions on implementation.

For recipients working with biological materials, NIH has a policy for allowing NIH funding recipients to retain and license biological materials for which patent protection might not be pursued. To learn more, read "NIH Procedures for Handling Non-election of Title to Patentable Biological Materials".

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding IC, the recipient also must provide a copy of documents or a sample of any material developed under an NIH grant award. The recipient may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see Administrative Requirements—Management Systems and Procedures—Program Income).

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced *NIH Research Tools Policy webpage*. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

8.2.3.1 Operational and Security Standards for Controlled-Access Repositories

The Required Security and Operational Standards for NIH Controlled-Access Data Repositories apply to grants and cooperative agreements, for the purposes of the NIH GPS, and other funding mechanisms not covered by the NIH GPS (e.g. intramural contracts and Other Transactions), regardless of the activity code, that support NIH controlled-access data repositories and access management systems (hereafter NIH CADRs) that meet all the following criteria:

- Are supported by an NIH funding mechanism (e.g. grants and cooperative agreements);
- Provide long-term storage for, or provide access to, data for research purposes (hereafter, "data");
- Control access to data by prospective review of data access requests or partner with access systems that control access via prospective review of requests; and
- Use federal employees to conduct reviews and authorize access, or partner with access systems that use federal employees for those purposes.

NIH will determine which repositories are subject to these requirements and will maintain a public list of NIH CADRs, which can be found here. NIH will periodically update this list as needed.

Repositories and access management systems that control access to data, but do not meet the criteria of an NIH CADR as described above, will not be subject to these requirements. Repositories that only facilitate direct sharing between investigator teams, cloud workspaces that only temporarily store data, data

coordinating centers, and similar activities that do not manage data sharing beyond specific programs or initiatives, will not be considered an NIH CADR.

To meet the requirements, NIH CADRs must follow the NIH Controlled-Access Data Repository Guidebook to Adhere to "Required Security and Operational Standards for NIH Controlled-Access Data Repositories" (NIH CADR Guidebook), including all relevant effective dates listed in the Guidebook.

8.2.3.2 Policy for Data Management and Sharing (DMS Policy)

The NIH Policy for Data Management and Sharing (DMS Policy) applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants or other funding agreements regardless of NIH funding level or funding mechanism. The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities. A list of NIH activity codes subject to the DMS Policy is available on the NIH website, and the applicability of the DMS Policy will be specified in each NIH NOFO.

Applicants must submit a DMS Plan in each competitive grant application, and outline DMS costs in the appropriate cost categories in the budget (see NIH Application Guide for detailed instructions). DMS Plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared. If DMS Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), DMS Plans should be updated by researchers and reviewed by the NIH ICO during regular reporting intervals or sooner. DMS Plans from NIH-funded or conducted research may be made publicly available and should not include proprietary or private information. Costs associated with data management and data sharing are subject to Federal cost principles for the reimbursement of actual costs that are allowable, allocable, reasonable, and consistently treated as described in NIHGPS Section 7.2 The Cost Principles.

Under the NIH DMS Policy, NIH expects researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may limit data sharing to some extent. Per the supplemental information "Elements of an NIH Data Management Sharing Plan," a compelling rationale for limiting scientific data sharing should be provided and will be assessed by NIH. Shared scientific data must be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.

Consistent with 2 CFR 200.403 and the NIHGPS Section 7.4, budget requests must not include infrastructure costs that are included in institutional overhead (e.g., indirect costs) or costs associated with the routine conduct of research. Costs associated with collecting or otherwise gaining access to research data (e.g., data access fees) are considered costs of doing research and should not be included in scientific data management and sharing budgets. Costs may not be double charged or inconsistently charged as both direct and indirect costs.

Applicants may request data management and sharing costs that are allowable and reasonable when associated with (1) Curating data and developing supporting documentation, including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access. (2) Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository). (3) Preserving and sharing data through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a DMS Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of

performance. If the DMS Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

Generally, DMS Plans are not considered during peer review, unless the NOFO identifies data sharing as integral to the project. DMS Plans will undergo programmatic assessment by NIH staff following peer review. ICs may request additional information at Just-in-Time in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research.

Once approved, the DMS Plan will become a Term and Condition of the NOA, and failure to comply may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions. In accordance with NIHGPS Section 8.1.1 NIH Standard Terms of Award, recipients must obtain prior approval to make changes to the previously approved DMS Plan (e.g. change in scientific direction, change in repository, or change in the timeline). All prior approval requests must be submitted in the eRA Prior Approval Module (see NIH Application Guide).

All allowable Data Management and Sharing costs in budget requests must be incurred (e.g., curation fees, data repository fees) during the performance period, even for scientific data and metadata preserved and shared beyond the award period.

Recipients are required to provide updates on the activities described in the DMS plan as part of the annual RPPR, and the IC will use this information to assess compliance with the previously approved DMS Plan.

For additional information and resources, see the grants policy website on the Data Management and Sharing Policy.

8.2.3.3 Genomic Data Sharing (GDS) Policy

The NIH Genomic Data Sharing (GDS) Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of the GDS Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data. The grants policy website on Genomic Data Sharing Policy Overview provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to describe plans for sharing genomic data in the Data Management and Sharing (DMS) Plan submitted with the application as described in 8.2.3.2 Policy for Data Management and Sharing. For guidance on developing a DMS plan that meets the requirements of the DMS and GDS policies, refer to the grants policy website on Writing a Data Management & Sharing Plan. Once approved, the DMS Plan will become a Term and Condition of the NOA and compliance and enforcement will be handled as described in 8.2.3.2 Policy for Data Management and Sharing.

PD / PIs should register all studies with human genomic data that fall within the scope of the GDS Policy in the NIH database of Genotypes and Phenotypes (dbGaP) by the time that data cleaning and quality control measures begin. After registration in dbGaP, PD / PIs, through the recipient institution, should submit large-scale human genomic data as well as relevant associated data (e.g., phenotype and exposure data) to an NIH-designated data repository in a timely manner, consistent with their NIH-

approved DMS Plan. PD / PIs should also submit any information necessary to interpret the submitted genomic data, such as study protocols, data instruments, and survey tools.

For research that falls within the scope of the GDS Policy, institutions submitting data, through their Institutional Review Boards (IRBs), privacy boards, or equivalent bodies, are to review the informed consent materials to determine whether it is appropriate for data to be shared for secondary research use. For studies proposing to use genomic data from cell lines or clinical specimens that were created or collected after the effective date of the GDS Policy, NIH expects that informed consent for future research use and sharing will have been obtained even if the cell lines or clinical specimens are de-identified. The responsible Institutional Signing Official of the submitting institution must provide an Institutional Certification to the funding IC prior to award. For guidance on completing an Institutional Certification under the GDS Policy, see the NIH Scientific Data Sharing website and section 2.3.7.10.

If there are compelling scientific reasons that necessitate the use of genomic data from cell lines or clinical specimens that were created or collected after the effective date of this Policy and that lack consent for research use and data sharing, investigators should provide a justification in the funding request for their use. The funding IC will review the justification and decide whether to make an exception to the consent expectation. In some instances, the funding IC may need to determine whether to grant an exception to the data submission expectation under the GDS Policy. Studies provided exceptions to data submission under the GDS Policy will still be expected to be registered in the NIH Database of Genotypes and Phenotypes (dbGaP) for transparency.

Investigators approved to access data and their institution are responsible for maintaining the confidentiality, integrity, and security of data accessed from a NIH-designated repository in accordance with the NIH Security Best Practices for Users of Controlled-Access Data included in Data Use Certifications (DUCs), or similar data use agreements, stipulating terms of access and the requirements of the Genomic Data User Code of Conduct. Violating these terms and requirements is considered a data management incident.

If an investigator plans to use a Cloud Service Provider (CSP) and/or a third-party IT system to store and analyze controlled-access data, NIH expects the CSP and/or third party IT system to meet the same standards as outlined in the NIH Security Best Practices for Users of Controlled-Access Data.

The institution, not the CSP and/or third-party IT system, will be held responsible for any failure in the oversight of controlled-access data.

NIH requires Lead Developers, and those they directly supervise, who seek access to controlled-access human genomic data under the GDS Policy for developer work (e.g., testing platforms, pipelines, analysis tools, and user interfaces that store, manage, and interact with human genomic data; providing infrastructure development and repository maintenance), to submit a request containing a Developer Use Statement (DUS) to the NIH Developer Data Access Committee (DeveloperAccessDAC@od.nih.gov) no later than at Just-in-Time (JIT) for grants and cooperative agreements. If a project has multiple Lead Developers, (e.g., for multicomponent awards), each Lead Developer must submit a DUS. All Lead Developers must be associated with an institution that is receiving or applying for NIH or other federal support for the developer work with a funding mechanism that has incorporated the developer terms of access. Once established, Lead Developers must follow the Developer Terms of Access.

Additional information about the GDS Policy can be found on NIH's "Genomic Data Sharing Policy" webpage.

8.2.3.4 Sharing Model Organisms

All applications, regardless of amount requested, where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible.

Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, Arabidopsis, fruit fly, zebrafish, and frog. Research resources to be shared include, but are not limited to, genetically modified organisms, mutant organisms, sperm, embryos, vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, genetic and phenotypic data for all mutant strains.

For additional information on this policy, see the NIH Scientific Data Sharing Model Organism Sharing Policy website.

8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development. Unless waived by NIH or the funding agreement is for educational purposes, e.g. fellowships, training grants or certain types of career development awards, the Bayh-Dole Act applies to all NIH research and development funding granted to for-profit organizations regardless of size and all non-profit entities. (See 2 CFR Part 200 and 37 CFR Part 401.1(b)).

To retain rights and title to Subject Inventions, the NIH funding recipient must comply with the Bayh-Dole statute and implementing regulations that ensure the Invention will be brought to practical application while protecting certain rights of the Federal government. The compliance actions required by the Bayh-Dole Act are summarized below at Exhibit 8.

Failure of the recipient to comply with any of the Bayh-Dole regulations cited at 37 CFR Part 401 or other requirements may result in the loss of patent rights or the suspension, termination or withholding of NIH funding support. See also Section 8.5.2 for additional remedies for noncompliance of the Bayh-Dole Act.

All Bayh-Dole compliance actions are required to be submitted to NIH by using the iEdison data base (See 37 CFR Part 401.16). All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to OPERA/OER at edison@nih.gov.

Exhibit 8. Extramural Invention Reporting Compliance Responsibilities

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Employee Agreement to Disclose All Subject Inventions	Recipient employees working under a federal funding award (other than clerical and nontechnical employees) must sign an agreement with the recipient organization. This agreement requires the Recipient employee to: (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions.	Before a Recipient or a consortium employee participates in NIH-funded research and development.	401.14(f)(2)
Consortium Participant Rights in Inventions	All consortium participants, regardless of tier, for experimental, developmental or research work retain all rights and obligations provided to the Consortium Participant in the NIH funding agreement.	At the time of issuance of a consortium agreement, recipient must include in all consortium agreements, regardless of tier, for experimental, development, or research work 37 CFR Part 401 *et seq* suitably modified to identify the parties and the rights and obligations awarded to the contractor.	401.14(g)(1) 401.14(g)(2) 401.14(g)(3)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Invention Disclosure	**The term "Subject Invention"** means any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement. The recipient must submit to NIH a disclosure for all Subject Inventions. There is no single format for disclosing the invention to NIH. However, the disclosure of the Subject Invention must include: a detailed technical description of the invention conveying a clear understanding of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention; the names of all inventors; title of the Subject Invention; all federal funding agreement numbers; date of disclosure of the Subject Invention from the researcher or inventor to the Recipient; and whether a manuscript describing the invention was submitted, accepted and/or published.	Within 2 months of the inventor's disclosure to the recipient organization.	401.14(a)(2) 401.14(c)(1)
Government Assignment to Recipient of Rights in Invention of Government Employee	Disclosure to NIH that a federal employee is a co-inventor on a Subject Invention.	Within 2 months of receipt of the initial invention report.	401.14(f)(2) 401.10

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Acceptance of Manuscript following Submission of Initial Invention Disclosure	The recipient needs to promptly notify NIH of the acceptance of any manuscript describing the Subject Invention.	Promptly following the acceptance of a manuscript describing a Subject Invention.	401.14(c)(1)
Election of Title to a Subject Invention	The recipient must notify NIH of its decision to retain title to a Subject Invention and any associated patent rights. Election of title is made before the filing of an **Initial Patent Application**. **Statutory Period** is defined as the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102 (b) as amended by the Leah-Smith American Inventions Act, Public Law 112-29.	Within 2 years of the disclosure of the invention to NIH. In any case where a patent, a printed publication, public use, sale or other availability to the public has initiated the one-year **Statutory Period** wherein valid patent protection can still be obtained in the United States, the period for election of title is shortened by NIH to a date that is no more than 60 days prior to the end of the statutory period.	401.14(b) 401.14(c)(2) 401.2(n)
Confirmatory License	For each Subject Invention, the recipient must provide a license to NIH confirming the rights the Government has throughout the world in the Subject Invention. When a confirmatory license is filed on the **Initial Patent Application** the license applies to all subsequent patent applications linked in the patent family.	When the **Initial Patent Application** is filed.	401.14(f)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Government Support Clause	The recipient must include, within the specification of all United States patent applications and any patent issuing thereon covering a Subject Invention, the following statement, "This invention was made with government support under (grant number, including the two-letter institute code and six-digit serial number, e.g., CA012345) awarded by the National Institutes of Health. The government has certain rights in the invention."	Must be included within the specifications of any United States patent applications and any patent(s) issuing thereon covering a Subject Invention.	401.14(f)(4)
Patent Applications and Issued Patents	The recipient must inform NIH of the filing date of its **Initial Patent Application**, the **Initial Patent Application** number and title and all subsequently filed patent applications. **Initial Patent Application** is defined as the first provisional or nonprovisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(2) and (3), respectively, the first international application filed under the Patent Cooperation Treaty as defined in 37 CFR Part 1.9(b) that designates the United States, or the first application for a Plan Variety Protection certificate, as applicable, a non-provisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(3).	Within 1 year after election of title, or, if earlier, prior to the end of any Statutory Period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use, unless there is an extension of time granted by NIH.	401.14(c)(3) 401.14.(f)(6) 401.2(n)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Notification to NIH to Not to Continue Prosecution	Notify NIH of any decision to: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a part to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office including but not limited to post-grant review, review of a business method patent, *inter partes* review, and deviation proceeding; or to request, be a part to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.	Notify NIH no less than 60 days prior to taking any action defined under "Action Required."	401.14(f)(3)
Assignment of Rights to Third Party	If the recipient is a non-profit organization, it must request NIH prior approval to assign a Subject Invention or U.S. patent rights to any third party, including the inventor(s). Recipients that are for-profit entities (including small businesses) do not need to request approval for the assignment of a Subject Invention or U.S. patent rights to any third party.	Recipient must submit a Third-Party Waiver Request or an Inventor Waiver Request and must have NIH approval before any rights of the recipient are transferred or assigned.	401.10 401.14(k)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Preference for United States Industry	Recipient cannot grant to any person, unless approved by NIH in advance, the exclusive right to use or sell any Subject Invention in the United States unless any such product embodying the Subject Invention or produced through the use of the Subject Invention is manufactured substantially in the United States.	For a waiver of this compliance requirement, a request is required to NIH providing specific details and reasons why the Subject Invention cannot be substantially manufactured in the United States.	401.14(i)
Issued Patent	Recipient must notify NIH of the date a patent is issued, patent number, and the expiration date of the issued patent.	When patent is issued.	401.5(f)(2)
Extension of Time to Disclose a Subject Invention	The recipient may request for NIH's approval for an extension of time to disclose a Subject Invention.	Not less than 30 days in advance of the 60-day disclosure reporting deadline.	401.14(c)(5)
Extension of Time to Elect Title to a Subject Invention	Recipient may request with justification, NIH's approval of a request for an extension of up to 2 years to elect title to a Subject Invention.	As needed before the expiration of the time allowed.	401.14(c)(5)
Extension of Time to File a Patent Application	The recipient may request, subject to NIH's approval, an extension time up to 1 year to file a patent application. The request must include details of why an extension is needed.	As needed before the expiration of the time allowed.	401.14(c)(5)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Extension of Time to File a Non-provisional Patent Application following the Filing of a Provisional Application as the Initial Patent Application	When a recipient requests an extension of time for filing a non-provisional application, after filing a provisional application as an **Initial Patent Application**, a 1-year extension will be granted unless NIH notifies the recipient within 60 days of receiving the request. Recipient must submit this request citing an extension of time pursuant to 401.14(c)(5). No additional details for the request are required.	As needed before the expiration of the time allowed.	401.14(c)(5)
Invention Utilization Report	The recipient must submit an annual utilization report with information about the status of commercialization of any Subject Invention for which title has been elected.	Annually, based on the fiscal year of the recipient.	401.14(h)
Annual Invention Statement	The recipient must indicate any inventions made during the previous budget period in Section C of the Research Performance Progress Report (RPPR).	Part of all competing applications and non-competing continuation progress reports.	SF424, (R&R) PHS 2590, RPPR
Final Invention Statement and Certification	The recipient must submit to the NIH awarding IC CGMO through the eRA Closeout Module a summary of all inventions made during the entire term of each grant award.	Within 120 days after the project period (competitive segment) ends.	401.14(f)(5)

8.2.5 Interim Research Products

Interim Research Products are complete, public research products that are not final. A common form is the preprint, which is a complete and public draft of a scientific document. Interim research products are effective ways for NIH funded scientists to speed dissemination, establish priority, obtain feedback, and reduce bias. They may also be cited in applications for NIH funding.

NIH intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects recipients to ensure a high level of public access to NIH supported interim products.

To facilitate text mining and other analysis of these products as data, NIH expects standardized terms of use. NIH also expects recipients will adhere to other norms of responsible scientific communication.

Specifically, to claim an interim research product as a product of an NIH award, NIH expects that the recipient will:

- Make the product publicly available. To maximize the impact of an interim research product, NIH strongly encourages recipients to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
  - Acknowledge NIH funding in accordance with NIH GPS Section 8.2.1
  - Clearly state that the work is not peer-reviewed
  - Declare any competing interests, as an author would do for any journal article

8.3 MANAGEMENT SYSTEMS AND PROCEDURES

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 2 CFR Part 200 and the NIHGPS. NIH may review the adequacy of those systems and may take appropriate action, as necessary, to protect the Federal government's interests, including, but not limited to, the use of specific terms and conditions. NIH also will oversee the recipient's systems as part of its routine post-award monitoring. The recipient's systems also are subject to audit (see Administrative Requirements—Monitoring—Audit).

NIH seeks to foster within recipient organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; performance assessment; administrative simplifications; information sharing; management controls and other internal controls.

Recipient organizations must establish and maintain effective internal controls to provide reasonable assurance that they are in compliance with Federal statutes, regulations, and terms and conditions of award (2 CFR 200.303(a) and (b)). They must evaluate and monitor their compliance with statutes, regulations, and terms and conditions (2 CFR 200.303(c)), and they must take prompt action when instances of noncompliance are identified (2 CFR 200.303(d)).

Recipient organizations' internal controls should be in compliance with guidance in "Standards for Control in the Federal Government." (2 CFR 200.303(a)). Thus, recipient organizations are expected to establish codes of conduct which define expectations of integrity and ethical values and criteria of competence of personnel involved in the work supported by NIH grant funds. Codes of conduct should articulate expectations to assure compliance with terms and conditions of award, including but not limited to, providing true, complete, and accurate information on application documents (2.3.7.6); assuring work environments are free of discriminatory harassment and are safe and conducive to high-quality work (4); and meeting applicable public policy requirements (4.1).

8.3.1 Financial Management System Standards

Recipients are required to meet the standards and requirements for financial management systems set forth or referenced in 2 CFR Part 200.302 as applicable. The standards and requirements for a financial

- The procurement is expected to exceed the "simplified acquisition threshold" (currently $250,000 per OMB memo M-18-18) (formerly the "small purchase threshold") established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the simplified acquisition threshold specifies a "brand name" product.
- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When NIH prior approval is required, the recipient must make available sufficient information to enable review. This may include, at NIH discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the applicant or recipient or may be conditioned on the receipt of additional information. Any resulting NIH approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish NIH as a party to the contract or any of its provisions.

8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, Women's Business Enterprises, and Veteran-Owned Businesses

Recipients must make positive efforts to use small businesses, minority-owned firms, women's business enterprises and veteran-owned businesses as sources of goods and services whenever possible. Recipients should take the steps outlined in the applicable administrative requirements (2 CFR Part 200.321) to implement this policy.

8.3.4.4 Domestic Preferences for Procurements

The recipient or subrecipient should, to the greatest extent practicable and consistent with law, provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products). The requirements of this section must be included in all subawards, contracts, and purchase orders under Federal awards. See 2 CFR Part 200.322.

8.4 MONITORING

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and NIH is no longer providing active grant support (see Administrative Requirements—Closeout).

8.4.1 Reporting

NIH requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Recipients also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and closeout documents (final grant progress reports and final invention statements and certifications). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to NIH (see Financial Reports below) through PMS unless otherwise indicated in the award's terms and conditions.

Recipients are allowed a specified period of time to submit required financial and final progress reports (see 2 CFR 200.328 and 2 CFR Part 200.329, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

8.4.1.1 Non-Competing Continuation Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The Research Performance Progress Report (RPPR) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information.

NIH requires the use of the RPPR for all Type 5 progress reports, including accessing the Human Subjects System link in the RPPR, if applicable, that will allow reporting of inclusion enrollment data.

Recipients may query eRA Commons Status and Research Performance Progress Report (RPPR) to view a list their organization's pending grant progress reports and respective due dates. Late submission of a grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

Recipients also have an obligation to submit a complete and accurate progress report. NIH program or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may result in a delay of continued support.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the

recipient does not submit an application for continued support, a final RPPR is required (see Final Research Performance Progress Report).

The NIH awarding IC will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, major alteration and renovation, and non-construction activities.

8.4.1.1.1 Requirement for Commons ID

For progress reports using the RPPR, the Commons ID requirement is part of the Participants Section and is required for the PD/PI(s) and those who worked on the project in a postdoctoral role. This could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

For undergraduate and graduate students supported on a particular research grant, a Commons ID is required. Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now. For graduate students, this could include project roles of graduate research assistant or graduate student.

When an individual is assigned the Undergraduate, Graduate Student, and/or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

8.4.1.1.2 Expectation for Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers

In an effort to assist graduate students and post-doctoral researchers in achieving their career goals and become contributing members of the biomedical workforce, NIH encourages recipients to develop an institutional policy requiring that an Individual Development Plan (IDP) be implemented for every graduate student and postdoctoral researcher supported by any NIH grant and reportable on the progress report, regardless of the type of NIH grant that is used for support. This is an expectation that should be broadly implemented by institutions for all graduate students and postdoctoral researchers supported by NIH. The actual reporting of the implementation of this expectation is in the RPPR; recipients must report in RPPR *Section B. Accomplishments*, Question B.4 the use of the IDP for graduate students and/or postdoctoral researchers included in RPPR *Section D*. Participants or on a Statement of Appointment Form (PHS 2271). Do not include the actual IDP; instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

8.4.1.2 Streamlined Non-Competing Award Process

SNAP includes a number of provisions that modify annual progress reports, NoAs, and financial reports.

The NoA will specify whether an award is subject to SNAP. Awards routinely included in SNAP are “K” awards and “R” awards, except R35. Awards excluded from SNAP are those that generally do not have the authority to automatically carry over unobligated balances (centers; cooperative agreements, Kirschstein-NRSA institutional research training grants, non-Fast Track Phase I SBIR and STTR

awards), clinical trials (regardless of activity code), P01, R35, and awards to individuals. However, these grants can be included in SNAP on a grant-specific basis. In addition, specific awards may be excluded from SNAP if:

- they require close project monitoring or technical assistance, e.g., high-risk recipients, certain large individual or multi-project grants, or grants with significant unobligated balances, or
- the recipient has a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

8.4.1.2.1 Modified Annual Progress Reports

While a modified, streamlined, progress report is still a feature of grants awarded under the 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.

8.4.1.2.2 Modified NoAs

Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and any negotiations, and reduces the information NIH requires to review, approve, and monitor non-competing continuation awards. SNAP NoAs are issued with only total direct and indirect costs awarded for the budget period. While direct costs categorical breakdowns are not awarded, recipients are required to allocate and account for costs by category in accordance with applicable cost principles. Future year commitments on SNAP awards reflect total cost commitments (direct plus indirect costs).

8.4.1.2.3 Modified Financial Reporting Requirements

For awards under SNAP, an FFR is required only at the end of a competitive segment rather than annually. The FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

8.4.1.2.4 Submitting SNAP Progress Reports

All SNAP progress reports are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). If the 15th falls on a weekend or Federal holiday, the due date is automatically extended to the next business day. Paper submissions are not acceptable, will not be used for consideration for funding, and will not become part of the official file. If a paper SNAP progress report is submitted, recipients will be required to resubmit the information electronically.

The RPPR module in the eRA Commons allows recipients to electronically prepare and submit progress reports and supporting documentation. The RPPR module provides the user with dedicated screens to collect the required progress report information, including appropriate uploads for text documents. Data submitted through RPPR for Performance Sites and Participants is retained in the system to assist the recipient in completion of future progress reports.

The RPPR may be routed to authorizing officials at the applicant institution for review and approval prior to submission to NIH. For SNAP awards, the RPPR module provides recipients with the option to delegate to the PD/PI the authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eRA Commons; such authority can be rescinded at any time.

Guidance on RPPR submission is documented in the RPPR Instruction Guide.

8.4.1.3 Progress Reports for Multiyear Funded Awards

A limited number of NIH grant awards are multi-year funded, i.e., not funded in budget years but funded in full at the start of the project period from a single fiscal year appropriation. The project period and the budget period are the same in a multi-year funded (MYF) award and are longer than one year. Progress reports for MYF awards are due annually on or before the anniversary of the budget/project period start date of the award. A progress report is not required if the award is in a no-cost extension period unless specifically required by the IC. The reporting period for a MYF progress report is the calendar year preceding the anniversary date of the award. For example, if an award is made on 04/01/2021, the MYF progress report is due on or before 04/01/2022, and should report on the activities performed under the award between 04/01/2021 and 03/31/2022. For the subsequent year the MYF progress report will be due 04/01/2023, and should report on the activities performed under the award between 04/01/2022 and 03/31/2023. Information on the content of a MYF progress report and instructions on how to submit the report through the eRA Commons are posted at NIH Instructions for Progress Reports for Multi-year Funded (MYF) Awards and NIH RPPR Instruction Guide. The multi-year research performance progress report (MYRPPR) link to upload the report will be available two months before the anniversary date of the award, on the eRA Commons Status search page in the folder “List of Applications/Grants” in the “Action” column. Progress reports for MYF awards must be completed by the PD/PI, and then submitted by a Signing Official (SO) or a PD/PI with delegated authority from the SO to submit a progress report. Information about SO delegation of authority to a PD/PI to submit a progress report appears in the eRA Commons User Guide under Section 10.2 Delegations..

8.4.1.4 Final Research Performance Progress Report (F-RPPR)

The F-RPPR has replaced the Final Progress Report for closeout. NIH is no longer accepting Final Progress Reports. Generally, the F-RPPR format is the same as the current annual RPPR. As part of the F-RPPR recipients will be required to report on Project Outcomes. This section will be made publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

NIH will not maintain its previous Type 2 policy which stated that “whether funded or not” the progress report contained in the Type 2 application may serve in lieu of a separate final progress report. NIH now requires that organizations submit an Interim-RPPR while their Type 2 is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution’s F-RPPR.

See the F-RPPR Instructions for more information. Recipients should also review the information found in Final Research Performance Progress Report.

8.4.1.5 Financial Reports

PMS will pre-populate the cash transaction section (lines 10a through 10c) of the FFR using recipient real-time cash advance information from PMS, and adjust recipient-reported disbursements to equal cash

advance drawdowns on all non-closed sub-accounts. Recipients will be required to certify at the time of each drawdown whether the cash drawdown request is for reimbursement of actual expenditures or is an advance for immediate disbursement; recipients must assert that award funds, including those issued to subrecipients, are used in compliance with all award conditions and federal statutory requirements.

8.4.1.5.1 Financial Expenditure Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient organization. NIH requires all financial expenditure reports to be submitted using the Payment Management System. This includes all initial FFRs being prepared for submission and any revised FFRs being submitted or re-submitted to NIH. The eRA Commons and Payment Management systems allows participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH through PMS. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted the FFR Reconciliation and Financial Closeout Support Center (FFR-C) within the Office of Policy for Extramural Research Administration (OPERA). NIH IC grants management staff also review these expenditure reports.

Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. When required on an annual basis, 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 ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date.

In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

Before submitting FFRs to NIH, recipients must ensure that the information submitted is accurate, complete, and consistent with the recipient's accounting system. When submitting the FFR through the Payment Management System, as applicable, the AOR or the individual designated to submit this report on behalf of their institution, certifies that the information in the FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties.

8.4.1.5.2 Revised Financial Reports and Expenditures

Revisions for Indirect Cost Changes. Each Federal Financial Report submitted by the recipient shall reflect the proper amount of indirect costs applicable to the grant period. If a provisional or an earlier period's permanent rate is used in the report, a subsequent adjustment to the FFR is necessary if a lower permanent rate(s) applicable to the grant is established, except for Institutions of Higher Education (IHEs) subject to 2 CFR 200.

Revised Expenditure Reports. NIH requires all financial expenditure reports (domestic and foreign) to be submitted using the Payment Management System. This includes the initial FFR and any FFR

revisions being submitted or re-submitted to NIH. In some cases the recipient may have to revise or amend a previously submitted annual or final FFR. When the revision results in a balance of $20,000 or greater due to NIH, the recipient must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report, and post the refund to the PMS document if the funds have not expired and are reconciled and closed in PMS. All refunds under $20,000 on closed PMS documents should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. PMS refund instructions may be found on the Program Support Center webpage. Revised expenditure reports representing additional expenditures by the recipient that were not reported to NIH within the 90-day time frame may be submitted electronically with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but no later than one year from the due date of the original report for annual FFRs and no later than 60 calendar days from the due date of the original report for final FFRs (i.e., 180 days from the project end date).

8.4.1.5.3 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See Administrative Requirements—Changes in Project and Budget for NIH approval authorities for unobligated balances.) Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FFR for awards other than those with authority for the automatic carryover of unobligated balances, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the NIH share of the approved budget for the current budget period. If the funds available exceed the NIH share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the recipient, revise the current NoA to authorize the recipient to spend the excess funds for additional approved purposes.
- Offset the current award or a subsequent award by an amount representing some or all of the excess.

8.4.1.5.4 Recipient Reporting of Subrecipient Data and Executive Compensation Information for Federal Funding Accountability and Transparency Act (FFATA)

A component of Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires most recipients of new Federal funds to report on sub-awards/subcontracts/consortiums equal to or greater than $30,000. This includes awards that are initially below $30,000 but subsequent grant modifications result in an award equal to or greater than $30,000.

Subaward reports are submitted in SAM.gov with subaward data ultimately distributed for publication and display on www.USASpending.gov. Recipients are required to register with SAM.gov, collect the necessary data from subrecipients, and file subaward reports by the end of the month following the month in which the pass-through entity awards any subaward greater than $30,000.

FFATA specifies the data that should be captured for each pass-through entity and first-tier subrecipient of Federal awards, regardless of award type. To promote data consistency and reduce reporting burdens, existing agency data sources will be leveraged to pre-populate reports for pass-through entities as well as for subrecipients when available. Recipients are responsible for confirming the pre-populated data and providing any additional required information.

Included in these requirements is the need to report the names and total compensation of the five most highly compensated officers of the entity if the entity as part of their registration profile in SAM in the preceding fiscal year: 1) received 80 percent or more of its annual gross revenues in Federal grants, subawards, contracts, and subcontracts; and 2) received $25,000,000 or more in annual gross revenues from Federal grants, subawards, contracts, and subcontracts; and 3) had gross income, from all sources, of $300,000 or more; and 4) the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1). Additionally, recipient organizations may be required to verify the following information in SAM.gov:

- Organization UEI
- Name and Address of organization
- Parent UEI
- Assistance listing number
- FAIN
- Federal Awarding Agency of the grant

8.4.1.6 Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14. The requirements also are specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing continuation progress report must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the recipient must also indicate whether they were reported.

The recipient also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of grant funds or other enforcement actions, including the imposition of specific terms and conditions.

Bayh-Dole regulations allow recipients to report inventions electronically (37 CFR 401.16). NIH requires electronic reporting through an Internet-based system, Interagency Edison. To meet the objectives of the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), recipients are required to submit invention reports to NIH using iEdison. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Recipients also may contact the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER. See Part III for contact information.

8.4.1.7 Financial Conflict of Interest Reports

Information related to FCOI reporting requirements can be found within Public Policy Requirements -- Financial Conflict of Interest.

8.4.1.8 Research Securities

In alignment with the CHIPS and Science Act of 2022 (P.L. 117-167) and National Security Presidential Memorandum-33 (NSPM-33), NIH has established a series of requirements to strengthen research security across NIH-funded projects.

8.4.1.9 NIH Disclosure Requirements

As part of the application preparation and submission process, and annual progress report submission, all individuals designated in an application as senior/key personnel are required to certify and submit information to assist reviewers and NIH staff in making informed recommendations and funding decisions.

Details on all required disclosures can be found in the NIH Disclosure Table. It is vital that submission of such disclosure information be taken seriously. Failure to comply with terms and conditions related to disclosure requirements may cause NIH to take action(s) to remedy non-compliance, such as disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action (see Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).. Further, violations that are potentially criminal will be referred to the NIH Office of Management Assessment for consultation with the HHS Office of Inspector General, the Department of Justice, or other law enforcement agencies, as appropriate.

8.4.1.10 Malign Foreign Talent Recruitment Program

In accordance with the CHIPS and Science Act of 2022 (P.L. 117-167) , individuals who are a current party to a Malign Foreign Talent Recruitment Program (MFTRP) are not eligible to serve as a senior/key person on an NIH grant or cooperative agreement.

8.4.1.11 Research Security Training

In accordance with the CHIPS and Science Act of 2022 (P.L. 117-167), each senior/key personnel listed on an NIH grant application must certify that they have completed Research Security Training (RST) within 12 months of the date of application submission. This individual certification is required at the time of the application submission, through the Biographical Sketch in SciENcv.

The Act also requires applicant institutions to certify that each covered individual who is employed by the institution and listed on the application has completed RST. The AOR, via their signature on the face page of the application, certifies the applicant institution’s compliance with this requirement.

Completion of RST and the individual and institutional certifications is required for applications submitted for due dates on or after May 25, 2026.

8.4.2 Record Retention and Access

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH.

Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH. See 2 CFR Part 200.334 for exceptions or qualifications to the 3-year retention requirement exist (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period), the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Maintain the information for the retention period for other types of grant-related records, including indirect cost proposals and property records. See 2 CFR Part 200.334 and 2 CFR Part 200.337 for record retention and access requirements for contracts under grants.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

NIH, pass-through entities, Inspectors General, the Comptroller General of the United States, or any of their authorized representatives, must have the right of access to any records of the recipient or subrecipient pertinent to the NIH award, to perform audits, execute site visits, or for any other official use. This right also includes timely and reasonable access to the recipient's or subrecipient's personnel for the purpose of interview and discussion related to such documents or the NIH award in general. NIH's rights of access are not limited to the required retention period of this part but lasts as long as the records are retained. Pass-through entities must not impose any other access requirements upon subrecipients.

8.4.3 Audit

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

NIH recipients (other than Federal institutions) are subject to audit requirements in 2 CFR Part 200 Subpart F and in the NIHGPS (for types of organizations to which 2 CFR Part 200, Subpart F-Audit Requirements do not directly apply). In general, 2 CFR Part 200, Subpart F- Audit Requirements requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $1,000,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts are required to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign recipients and for-profit recipients are addressed in the chapters of this NIHGPS that provide specific requirements for those types of recipients. In accordance with 2 CFR 200.101(a)(2), HHS has established for-profit audit requirements at 2 CFR 300.218. See NIHGPS 18.4.5 for details on NIH's implementation of the for-profit audit requirements.

As specified in the NoA, all awards issued by NIH meet the definition of "Research and Development" at 2 CFR Part 200.1. As such, NIH grant awards are subject to the R&D cluster of program requirements in the compliance supplement. NIH recognizes that some awards may have another classification for

purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Exhibit 10. Summary of Audit Requirements

Recipient Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Colleges & Universities (IHEs)	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Non-Profits	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Hospitals	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
For-Profits	NIH Grants Policy Statement	Audit Resolution Division (See contact information in Part III)
Foreign	NIH Grants Policy Statement (same as For-Profits)	Audit Resolution Division (See contact information in Part III)

When a recipient procures audit services, the procurement must comply with the procurement standards of 2 CFR Part 200, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, women's business enterprises, and veteran-owned enterprises. Recipients should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the criteria to be used for selection of the firm. Recipients' written agreements with auditors must specify the rights and responsibilities of each party.

2 CFR Part 200, Subpart F-Audit Requirements explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this regulation are as follows:

- Covered organizations expending $1,000,000 or more per year in Federal awards are required to have an audit performed in accordance with the regulation. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions of 2 CFR Part 200.507. NIH identifies one program as all awards funded by one IC. Prior to electing a program-specific audit, the recipient must obtain written prior approval from the relevant NIH awarding IC. Covered organizations expending less than $1,000,000 in any year are exempt from these audit requirements in that year but must have their records available for review as required by Administrative Requirements—Monitoring—Record Retention and Access.

- The reporting package must contain the following:
  - Financial statements and schedule of expenditures of Federal awards.
  - Independent auditor's report, including an opinion on the financial statements and the schedule of expenditures of Federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
  - A schedule of findings and questioned costs.
  - If applicable, a summary of prior audit findings and a corrective action plan.
- An audit under 2 CFR Part 200, Subpart F-Audit Requirements is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal law or regulation. Any additional audits will build upon work performed by the independent auditor.
- The data collection form (SF-SAC) and a copy of the Single Audit reporting package must be submitted electronically to the FAC at the address provided in Part III.
- A senior level representative of the auditee (e.g., state controller, director of finance, chief executive officer, or chief financial officer) must sign a statement to be included as part of the data collection that says that the auditee complied with the requirements of this part, the data were prepared in accordance with this part (and the instructions accompanying the form), the reporting package does not include protected personally identifiable information, the information included in its entirety is accurate and complete, and that the FAC is authorized to make the reporting package and the form publicly available on a web site. Exception: An auditee that is an Indian tribe or a tribal organization (as defined in the Indian Self- Determination, Education and Assistance Act (ISDEAA), 25 U.S.C. 450b(l)) may opt not to authorize the FAC to make the reporting package publicly available on a web site, by excluding the authorization for the FAC publication. If this option is exercised, the auditee becomes responsible for submitting the reporting package directly to any pass-through entities through which it has received a Federal award and to pass-through entities for which the summary schedule of prior audit findings reported the status of any findings related to Federal awards that the pass-through entity provided. Unless restricted by Federal statute or regulation, if the auditee opts not to authorize publication, it must make copies of the reporting package available for public inspection.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS or NIH award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS or NIH award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary. Audit reports should not be sent directly to the GMO. The threshold for reporting questioned costs is described in 2 CFR Part 200.516.

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by NIH or HHS. At the completion of the audit resolution process, the recipient will be notified of the Action Official's final decision. The recipient may appeal this decision if the adverse determination is of a type covered by NIH or HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM.

It is imperative that recipients submit required 2 CFR Part 200, Subpart F audits within the time limits specified in the regulation. If recipients are delinquent in complying with the provisions of the regulation, NIH will take one or more actions that may result in the loss of Federal funds. No audit costs will be allowed either as indirect costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of 2 CFR Part 200, Subpart F.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of audit costs.

8.5 SPECIFIC AWARD CONDITIONS AND REMEDIES FOR NONCOMPLIANCE (SPECIFIC AWARD CONDITIONS AND ENFORCEMENT ACTIONS)

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the recipient an opportunity to correct the deficiencies before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing specific conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

8.5.1 Specific Award Conditions: Modification of the Terms of Award

During grant performance, the GMO may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When specific conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR Part 52.9 and 2 CFR Part 200.339.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing specific award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

NIH may implement specific award conditions if a recipient or subrecipient fails to comply with the U.S. Constitution, Federal statues, regulations, or the terms and conditions of award., When NIH determines that noncompliance cannot be remedied by imposing specific conditions, NIH may take one or more of the following actions:

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference and post-conference follow-up, usually 1 year. A conference grant made to a permanently sponsoring organization for conferences held annually or biennially on a recurring topic may be awarded for up to a total of 5 years and will be funded annually, based on the availability of funds. Continued funding beyond the first year will be contingent on a report of satisfactory progress submitted in accordance with SNAP instructions. A change in conference focus requires NIH awarding IC prior approval.

14.9 ACKNOWLEDGMENT OF FUNDING SOURCE AND DISCLAIMER

When a conference is funded by an NIH grant or cooperative agreement, recipients must include the following statement on conference materials (including promotional materials, agenda, and internet sites):

> *"Funding for this conference was made possible (in part) by (Insert Grant/Cooperative Agreement #) from (insert name of NIH IC). The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of NIH; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government."*

Appropriate use of the NIH or HHS logo on conference materials is of particular importance. Neither logo should be displayed if it would cause confusion as to the source of the conference or give the false appearance of government endorsement. Accordingly, unless specifically authorized by the award, any use of the HHS and/or NIH logo requires prior approval. Unauthorized use of the HHS or NIH name or logo may result in imposition of civil monetary penalties (as provided in 42 CFR Part 1003).

14.10 ALLOWABLE AND UNALLOWABLE COSTS

The following highlights allowable and unallowable costs under conference grants. No costs other than those specified in this subsection as allowable, including any qualifications on their allowability, are permitted under conference grants.

14.10.1 Allowable Costs

In general, consistent with 2 CFR Part 200.432, conference hosts/sponsors must exercise discretion and judgment in ensuring that conference costs are appropriate, necessary and managed in a manner that minimizes costs to the Federal award.

Conference Services. Grant funds may be used for necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.

Consultant Services. Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem or, where applicable, subsistence).

Equipment Rental. Grant funds may be used for the rental of necessary equipment.

Federal Employees. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter.

Meals. When meals are justified by the applicant as an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. See Travel below.

EXHIBIT 3

U.S. Department of Health and Human Services | National Institutes of Health
An official website of the United States government Here's how you know

NIH GRANTS & FUNDING

NEW TO NIH

FUNDING

New to NIH

As you begin your journey in search of NIH grant funding, the information in this section can help you understand the structure of NIH and why it's important to successfully navigate the grants process.

NIH Grants Process: A Video Walk-Through for Beginners

What We Do

The National Institutes of Health is the largest public funder of biomedical research in the world.

Our 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.

NIH provides financial assistance for projects that advance this mission in a variety of broad research and research-related funding categories

- Research Training and Career Development
- Research and Development
- Small Business
- Supplemental Funding
- Construction and Modernization
- Loan Repayment Programs
- Contracts
- Other Transactions
- Challenges and Prizes

Want to learn more?
Visit Funding Categories.

Where is the Money

FY 2025 Investments in Research



NIH's institutes, centers, and offices (ICOs) award 80-85% of the NIH budget to support extramural research conducted outside of NIH. About 10% of NIH's budget supports intramural scientists in our own laboratories, most on our NIH campus in Bethesda, Maryland.

NIH is made up of 27 institutes and centers (ICs) and the Office of the Director (OD).

- Each IC has a distinct mission that focuses on a specific disease area, organ system, or stage of life.
- The OD, including the Office of Extramural Research (OER), is the central office responsible for setting NIH policy and for planning, managing, and coordinating programs and activities across NIH.
- Twenty-four of the 27 ICs and several offices within the OD post extramural funding opportunities and make awards.

Each IC has a separate appropriation from Congress. The director of each IC makes Funding Decisions for which grants the IC will fund, taking into consideration the results of the scientific peer review of the grant application, input from NIH staff, public health need, scientific opportunity, and the need to balance its scientific portfolio. Since awards are made through the ICOs, prospective recipients should identify the ICOs that might be interested in their area of study.

Want to learn more?
Visit Find a Fit for Your Research for highlighted topics and NIH ICO profiles.

A Highly Competitive Process

Funding is a highly competitive process.

NIH has three application, review, and award cycles per year. Unless a funding opportunity specifically indicates money has been set aside for awards, all applications compete for the same funds.

Tip
Funding opportunities with set-aside funds are designated as Requests for Applications (RFA) or Program Announcements with set-aside funds (PAS). You can easily identify them by the first three characters of their notice numbers (e.g., RFA-HL-25-123 or PAS-CA-25-123).

NIH receives a lot of applications and there simply aren't enough funds to go around. The overall chance a research project application would be funded in 2025, referred to as success rate, was around 13%. Still, NIH made a considerable number of research project awards - over 8,000!

Be persistent and learn from each application experience. Many investigators who were not initially successful go on to secure funding on subsequent attempts.

Want to learn more?

Visit Funding Decisions to learn how funding decisions are made and Write Application for tips on preparing a strong application. Our Fiscal Year 2025 By the Numbers: Extramural Grant Investments in Research Nexus post also provides context for our 2025 numbers.

How NIH Announces Funding Opportunities

Our institutes, centers, and offices (ICOs) issue notices of funding opportunities (NOFOs) to look for grant proposals of high scientific caliber that are within mission and relevant to public health needs.

You can Explore NIH Grant Opportunities and search with NIH-specific filters to quickly identify potential funding opportunities of interest published at Grants.gov .

NIH offers both investigator-initiated and targeted funding opportunities.

Investigator-Initiated Research

- Much of what NIH supports are *investigator-initiated* or *unsolicited* research and training applications that originate from your research idea or training need, yet also address the scientific mission of the NIH and one or more of its ICOs.
- Consider NIH's centralized list of Highlighted Topics representing selected research priority areas within one or moe ICO.
- Investigator-initiated applications are submitted through centrally managed NIH "parent announcements" or broad ICO-issued funding opportunities.

Targeted, NIH-requested Research

- NIH ICOs regularly identify specific research areas and program priorities to carry out their scientific missions. They issue funding opportunities to encourage and stimulate research and the submission of research applications in these areas.
- These funding opportunities may be issued to support research in an understudied area of science, to take advantage of current scientific opportunities, to address a high scientific program priority, or to meet additional needs in research training and infrastructure.

Want to learn more?
Visit Find Your Opportunity, Contacts, and Due Dates.

Who is Eligible

Eligibility requirements vary by program and can be further restricted within individual funding opportunities but follow some general principles.

Organization Eligibility

NIH recognizes the applicant organization as the recipient for most programs. The applicant organization, represented by an authorized organization representative (AOR), has overall responsibility for compliance with all terms and conditions of award.

In general, organizations eligible to receive NIH grants can be

- Domestic or foreign
- Public or private
- Non-profit or for-profit

Want to learn more?
Check out these resources
- NIH Grants Policy Statement: Eligibility
- NOT-OD-26-084: Reminder - Definition of Foreign Components
- Acknowledging Foreign Components throughout NIH Application and Award Processes (Nexus, June 2026)

Foreign Eligibility

Foreign and international organizations are eligible to apply for most NIH research project grants but are not eligible to apply for institutional training, program project, center, resource, small business, or construction grants.

The Foreign Organizations eligibility section of each funding opportunity states whether the following types of organizations **are** or **are not** eligible to apply

- Non-domestic (non-U.S.) Entities (Foreign Organizations)
- Non-domestic (non-U.S.) components of U.S. Organizations
- Foreign components, as defined in the NIH Grants Policy Statement

In addition to standard review criteria, applications from foreign and international organizations are assessed on the following

- Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.
- Whether the proposed project has specific relevance to the mission and objectives of the ICO and has the potential for significantly advancing the health sciences in the United States.

Want to learn more?
Visit NIH Grants Policy Statement: Foreign Eligibility.

Individual Eligibility

The applicant organization must designate one or more project director/principal investigators (PD/PIs) to direct the project or program supported by the award.

The career stage of the PD/PI varies by program. NIH supports scientists at various stages in their careers, from pre-doctoral students on research training grants to investigators with extensive experience who run large research centers.

Generally, PD/PIs and other personnel supported by NIH research grants are not required to be U.S. citizens; however, some NIH programs have a citizenship requirement.

Carefully read the Eligible Individuals (Program Director/Principal Investigator) section of your funding opportunity for any citizenship requirement or other individual eligibility restrictions.

Are you an early stage investigator?

An early stage investigator (ESI) is a principal investigator who has completed their terminal research degree or end of post-graduate clinical training, whichever is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award.

NIH is committed to supporting ESIs.

- Reviewers give early stage investigators special consideration
- Applications with meritorious scores may be prioritized for funding
- NIH has programs targeted specifically for this population (e.g., Stephen I. Katz Early Stage Investigator Research Project Grant)

Want to learn more?
Visit NIH Early Stage Investigators Policy.

Meet the NIH Team

Your success with NIH funding requires an understanding of who your contacts are here at NIH.

Since applications are reviewed by the Center for Scientific Review (CSR) and awards are made through NIH institutes, centers, and offices (ICOs), most of your interactions with NIH will be with staff from CSR and ICOs, including scientific review officers, program officials, and grants management officers or specialists.

Scientific Review Officer (SRO)

Responsible for managing peer review meetings, evaluation procedures, and the determinations and management of conflicts of interest during review.

Program Official (PO)

Responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement.

Grants Management Officer/Specialist (GMO/GMS)

Responsible for the business management aspects of awards, including evaluation of administrative compliance with requirements, negotiating awards, and interpretation of policies and provisions.

Want to learn more?
Learn more about NIH staff roles and responsibilities, who to contact when, how to find appropriate contacts at various stages of the grants process, and tips for reaching out at Understand Staff Roles.

Interacting with NIH Systems –

Key Systems

Throughout your journey with NIH you will be interacting with a variety of systems that require registrations, some at the level of the institution, and others require registrations or permissions for institutional officials or individual investigators.

- **System for Award Management (SAM)**
  - A federal-wide (non-NIH) system. All organizations (referred to as "entities" in SAM) must register in SAM and establish a unique entity identifier (UEI) prior to doing business with the U.S. federal government.
  - The UEI serves as a common identifier across federal systems. Be sure to use the same UEI within all organization registrations and grant applications.
  - SAM is also the central location to search for contract opportunities from federal agencies.
- **Grants.gov**
  - Another federal-wide (non-NIH) system. Grants.gov is a central portal used by all federal grant-making agencies and their applicants to find and apply for federal grant funding.
  - Agencies post funding opportunities on Grants.gov. You can Explore NIH Grant Opportunities and search with NIH-specific filters to quickly identify potential funding opportunities of interest published at Grants.gov. Grants.gov receives application submissions on behalf of NIH and other agencies, and forwards those applications to the agency for processing.
- **eRA Commons** The eRA Commons is an NIH system that allows applicants, recipients, and federal staff to securely share, manage and process grant-related information. It allows principal investigators and institutional officials to track submission status, application assignment and review information, award information, and it supports post award reporting, amongst other things.
- **ASSIST**
  - NIH's Application Submission System & Interface for Submission Tracking (ASSIST) is one of several submission options available to prepare and submit grant applications electronically to NIH and other Public Health Service agencies.

Key Roles

There may be quite a few people involved in the preparation, submission, and administration of your grant application.

Grants.gov and eRA Commons use roles to determine which tasks each user is authorized to perform. At the time of organization registration, your organization designates one or more people with the authority to legally bind your organization in grants administration matters. Those designated individuals (Signing Officials in eRA Commons or E-Business Points of Contact in Grants.gov) can assign roles to other user accounts to define the functions they are authorized to perform.

Most electronic interactions with NIH are done through eRA Commons.

Key eRA Commons Roles

- **Signing Official (SO)**

- Holds authority to legally bind your institution and assume responsibility for adhering to all federal grant administration requirements referenced in the NIH Grants Policy Statement
- Registers the institution and maintains institutional profile data
- Accesses information for all applications and grants within your institution, including status and award information
- Creates and administers user accounts including additional SO and account administrator (AA) accounts

- **Project Director/Principal Investigator (PD/PI)**
  - Holds eRA Commons PI role as the designated project director/principal investigator (PD/PI) of an application or grant
  - Directs the project or activity being supported by the grant and is accountable to the recipient organization for the proper conduct of the project or activity
  - Performs or delegates tasks such as maintaining person profile information, checking application status, checking assembled application image used for review and performing post-submission administrative functions
  - Accesses information for their own grants and applications, including summary statements, scores, and notices of award

Want to learn more?
Visit eRA Commons Roles (PDF) for a detailed list of eRA Commons roles and Accounts Module Online Help System for instructions for creating accounts.

Get Registered −

Organizations

If your organization is new to working with NIH, multiple organization registrations are required including eRA Commons, System for Award Management (SAM), Grants.gov, and Small Business Administration (if applicable).

The full registration process in each system is typically completed once and then maintained as organization information changes.

The person who registers your organization must be authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

This individual may be referred to as an entity administrator, signing official (SO), or authorized organization representative (AOR) depending on the system. They are responsible for initial registration, maintaining organization information, and authorizing other individuals to serve similar functions on behalf of their organization.

Want to learn more?
Learn more about required organization registrations.

Note

NIH typically makes awards to organizations, not individuals. In rare cases, an individual who is not affiliated with a research organization may need to register in eRA Commons. For example, the Loan Repayment Program (LRP) supports contracts with individuals. LRP applicants who are not affiliated with a research organization may need to register in eRA Commons as an organization and an individual user. See Special Registration Instructions for Unaffiliated/Independent Applicants (PDF).

System Accounts for Investigators and Other Individuals

Once organization registrations are complete, the individuals responsible for maintaining your organization's information can assist in creating any additional individual user accounts needed to perform specific tasks. For example, creating or affiliating principal investigator accounts with the PI role in eRA Commons.

Want to learn more?
See System Accounts for Investigators and Other Individuals to learn who needs an account in systems like eRA Commons, Grants.gov, SAM, and Login.gov.

Resources

General

Information For pages – links and resources of interest to specific audiences

- Researchers
- Research Administrators
- Reviewers
- Small Business
- Foreign Grants
- Media and the Public

See Also

Documents

- How to Apply – Application Guide — Use these general application instructions along with the guidance in funding opportunities to submit grant applications to NIH.
- NIH Grants Policy Statement (GPS) — The NIH GPS outlines the policy requirements that serve as the terms and conditions of NIH grant awards.
  - New policies or updates to existing policies are announced through the NIH Guide for Grants and Contracts and later incorporated into the NIH GPS on a yearly basis.

Utility links

We have several handy utility links in the upper right corner of every page.

- Glossary — NIH, like most organizations, uses a lot of acronyms and nuanced terminology. Refer to our glossary to find acronym expansions and the meaning of many grant terms. A link to the glossary can be found at the top of each page under the search box.
- Frequently Asked Questions (FAQs) — Find the answers to questions on a wide range of grants administration policies, programs, and processes. The main FAQ page is a compilation of the topic-specific FAQ sets you'll find towards the bottom of our topic pages.

Contact

Check online guidance and direct your questions to your sponsored programs office or grants administrators. If you still need assistance, find NIH contacts at Need Help?

This page last updated on: May 19, 2026
For technical issues E-mail OER Webmaster

Did you find this page helpful?

- ○ Yes
- ○ No

Next

Form Approved OMB# 0925-0648 Exp. Date 7/2027

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EXHIBIT 4

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),[1] 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

Matthew J. Memoli, M.D.
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 5

From: Smith, Brad M. EOP/DOGE
To: Memoli, Matthew (NIH/OD) [E]
Subject: [EXTERNAL] RE: NOFOs
Date: Saturday, February 22, 2025 4:34:04 PM

Matt,

Thanks for the update. We are all very grateful for your leadership.

Best,
Brad

From: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Sent: Saturday, February 22, 2025 12:05 PM
To: Smith, Brad M. EOP/DOGE <Brad.M.Smith@doge.eop.gov>
Subject: Re: NOFOs

Hi Brad,

After my review these all need to come down. Some of the projects may be able to be modified to properly address our current priorities, but in their current form they are not in line with what NIH would like to be doing right now. I have instructed OER to take them all down.

Thanks,
Matt

Get Outlook for Mac

From: Smith, Brad M. EOP/DOGE <Brad.M.Smith@doge.eop.gov>
Date: Saturday, February 22, 2025 at 11:36 AM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Subject: [EXTERNAL] NOFOs

Matt,

Thanks so much for your time yesterday. Per our conversation, below are a number of NOFOs that it may be worth your team reviewing to make sure they align with your directive and priorities. We 100% defer to your team on whether each of these align with your directive, but I thought you might find this list helpful as you consider where to focus your review:

https://grants.nih.gov/grants/guide/pa-files/PAR-23-112.html
https://grants.nih.gov/grants/guide/pa-files/PAR-22-145.html

https://grants.nih.gov/grants/guide/pa-files/PAR-23-309.html
https://grants.nih.gov/grants/guide/pa-files/PAR-23-292.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-077.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-109.html
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https://grants.nih.gov/grants/guide/pa-files/PAR-25-098.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-201.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-237.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-240.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-241.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-317.html
https://grants.nih.gov/grants/guide/pa-files/PAR-26-001.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-003.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-NR-25-004.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-005.html

Best,
Brad

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EXHIBIT 6

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

STATE OF WASHINGTON, et al., Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States, et al., Defendants.

NO.2:25-cv-00244-LK

Washington, D.C.
Friday, April 4, 2025

Deposition of LIZA Q. BUNDESEN, a witness herein, was called for examination by counsel for Plaintiffs in the above-entitled matter, pursuant to notice, the witness being first duly sworn by BESS A. AVERY, a Notary Public in and for the District of Columbia, taken at the offices of B&A Litigation Services, 1029 Vermont Avenue, N.W., Washington, D.C., commencing at 9:06 a.m., when were present on behalf of the respective parties:

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF STATE OF WASHINGTON:

WILLIAM MCGINTY, ESQ.
LAURYN K. FRAAS, ESQ.
Assistant Attorneys General
Attorney General of Washington
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(360) 709-6027
william.mcginty@atg.wa.gov
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ON BEHALF OF THE DEFENDANTS:

VINITA B. ANDRAPALLIYAL, ESQ., SR. COUNSEL
CHRISTIAN S. DANIEL, ESQ., TRIAL ATTORNEY
ROBERT C. BOMBARD, ESQ., TRIAL ATTORNEY
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Civil Division, Federal Programs Branch
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Washington, DC 20530
(202) 305-0845
Vinita.B.Andrapalliyal@usdoj.gov
Christian.S.Daniels@usdoj.gov
Robert.Bombard2@usdoj.gov

ALSO PRESENT: Miranda Berge, Esq. - HHS
Anna Jacobs, Esq. - HHS

I N D E X

Witness: Page

LIZA Q. BUNDESEN

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- - -

E X H I B I T S

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E X H I B I T S

(Exhibits attached to transcript)

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that right?

A Yes.

Q That's the same day that you talked with Rachel Riley?

A Yes.

Q Was this the only termination letter that went out on February 28th?

A No.

Q How many termination letters went out on February 28th?

MS. ANDRAPALLIYAL: Objection, assumes facts not in evidence.

THE WITNESS: I don't remember.

BY MR. McGINTY:

Q Do you know if it was more or less than ten?

A I think it was more than ten, less than 30.

Q Okay. And do you know how the decision to make the grants that were terminated was made?

A I do not.

Q Okay. Do you know who made the decision?

A I do not.

Q Do you recollect the circumstances that led up to the termination of those grants on

February 28th?

A Can you please clarify.

Q How did you first learn that grants were going to be terminated on February 28th?

A I received a text message over Microsoft Teams from James McElroy. He said, Liza -- something to the effect of: Liza, can you please get in touch with Rachel Riley ASAP, she's been trying to reach you.

I'm paraphrasing.

I said, James, I'm sorry, I do not know who Rachel Riley is. And then shortly thereafter, James called me over a Microsoft Teams video call, and so he was there and Rachel Riley was there. She 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 an e-mail, a list of grants in an e-mail shortly thereafter.

Q Did she explain why the grants were being terminated?

A No.

Q Did you ask?

A She explained that -- excuse me, let me

clarify.

She said that the current administration's OGC has a different opinion from the previous administration's OGC on grant termination and, therefore, we will need to terminate grants by the end of the day.

I did not ask what, you know, what grants because I just literally was a little bit confused and caught off guard. And so I waited to see what I would receive by e-mail.

Q And then what did you receive by e-mail?

A I received an e-mail from Matt Memoli that said something to the effect of: Liza, the attached list of grants need to be terminated by COB today. And there was an Excel file attached to the e-mail.

Q And did you look at the Excel file?

A Yes.

Q And can you describe it for me.

A It was a list of grants -- well, you know, I'm trying -- I don't exactly remember all of the cells in the Excel file, but it was a list of grants. I can't remember if it had the grant numbers, the titles, the institutions. It had some combination.

Q Did it give any reason why the grants were

being terminated?

A No.

Q And what did you do next after you got that memo from Matt Memoli?

A And please allow me to clarify.

Also attached in the e-mail, I forgot to mention, Matt said attached is an OGC-approved termination letter, which was the template. So then after I received the e-mail, I took a look at the list and then I called Ms. Michelle Bulls to talk through next steps.

Q And what did you say to Michelle?

MS. ANDRAPALLIYAL: Objection, calls for the provision of deliberative information. I'd ask the witness not to answer insofar that it would divulge deliberative information.

THE WITNESS: Also, in addition to talking with Michelle, I also talked with, on the same phone call, Teams call, with our Office of General Counsel.

MR. McGINTY: Okay. So I'm just going to say for the record that the deliberative process exemption applies to communications made prior to a decision that's made and only to the extent that they are, in fact, deliberative communications. So

here a decision had already been made, so I don't think the deliberative process exemption applies. If you make an offer of proof, want to put that on the record.

MS. ANDRAPALLIYAL: Again, the deliberative process privilege routinely applies to protect pre-decisional and deliberative communications about a decision even if -- regardless of whether it has already been made, for example, in employee cases where deliberative process privilege is routinely invoked to protect documents about decisions that have already come to pass. And the purpose of the privilege is to protect agency deliberations decision making to ensure that folks can frankly discuss their concerns without being concerned about that information making its way out of the government.

So I am happy to provide case law shortly. If we could take a break, and if we could do that now?

BY MR. McGINTY:

Q Ms. Bundesen, when you got the e-mail from Matt Memoli was it your understanding that the decision to terminate the grants had already been made?

EXHIBIT 7

From:	Memoli, Matthew (NIH/OD) [E]
To:	Bundesen, Liza (NIH/OD) [E]
Cc:	Smith, Brad M. EOP/DOGE; Rachel.Riley@hhs.gov; Keveney, Sean (HHS/OGC)
Subject:	Grants for immediate termination today
Date:	Friday, February 28, 2025 2:35:29 PM
Attachments:	28 FEB Grants for Cancellation.xlsx NIH Termination Letter 022625[42].docx

Liza,

Please terminate the grants on the attached spreadsheet by COB today. Attached is an OGC cleared termination letter.

Thank you,
Matt

--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

Project Abstract
Abstract
A plethora of research exists highlighting the disproportionate
disparities faced by sexual and gender
minorities (SGM) of all ages, such as increased levels of homelessness,
lack of access to healthcare, and
negative physical and psychological outcomes. While there have been
significant efforts to address
systemic racism and social determinants of health (SDOHs) at the
PROJECT SUMMARY
No changes being proposed.

INTRODUCTION
This application is for an Administrative Supplement for Research on
Sexual and Gender Minority (SGM)
Populations (NOT-OD-22-032) to the parent award, ""Effects of Social
Networks and Policy Context on Health
7. Project Summary/Abstract
Consistent with NIAAA's expressed goal to understand sex differences
in risk of problem alcohol use and
target mechanisms that contribute to known disparities within high-risk
communities, the current proposal
seeks to examine the role of internal sources of minority stress (i.e.,
stress unique to those from marginalized
communities) in potentiating heavy alcohol use, particularly among
PROJECT SUMMARY
Mobile health (mHealth) interventions are a promising modality for
overcoming barriers and providing culturally
appropriate treatment among transgender individuals. mHealth
interventions may be appropriate among
transgender individuals, as emergent evidence suggests that virtual
spaces are used to access gender affirming
support and resources. Moreover, mHealth interventions may enable
ABSTRACT
Age is the greatest risk factor for Alzheimer's disease and related
dementia (AD/ADRD) and an estimated 2.7
million LGBTQ+ Americans are older adults. LGBTQ+ older adults face
discrimination and persecution
throughout their lives, with only some recent legal protections for their
sexual orientation and/or gender
identification statuses in the United States. LGBTQ+ individuals with
Transgender individuals are disproportionately burdened by chronic
(e.g., interpersonal rejection) and acute
(victimization) discrimination. According to minority stress theory, both
forms of discrimination are associated
with adverse mental health outcomes including PTSD, a stress sensitive
disorder that may arise from exposure
to life-threatening events, serious injury, or sexual assault. While PTSD
effects an estimated 6.8% of the U.S.

Project Summary
Sexual minority women (SMW) consistently report higher rates of alcohol use than heterosexual women. In fact, SMW are more likely to be current alcohol users, binge drinkers, and heavy drinkers than heterosexual women1 and are 11 times more likely to meet the threshold for alcohol use disorder.1-6 While research on SMW's alcohol use has grown in recent years, a scoping review of the

Abstract
By 2030, there will be nearly six million sexual and gender minority (SGM) older adults aged 50 and older in the U.S. who identify as lesbian, gay, bisexual, transgender, and/or queer. This number will more than double by 2050. Approximately 350,000 SGM older adults in the U.S. currently are living with Alzheimer's disease and related dementias (ADRD), with projections nearing one million by

ABSTRACT
Black and Latino trans women and men who have sex with men – or sexual and gender minorities of color (SGMoC) - account for at least half of all new HIV infections in the United States (U.S.). At the same time there is a significant disparity in knowledge of, access to and uptake of pre-exposure prophylaxis (PrEP) among SGMoC is disproportionately low compared to white MSM and trans

PROJECT SUMMARY
Transgender and gender nonbinary (TGNB) people are diverse and have distinct healthcare needs, yet demonstrate lower levels of healthcare utilization and greater likelihood of delaying needed care than their cisgender counterparts. Further, TGNB young adults experience more barriers to healthcare utilization and are more likely to delay care than TGNB adolescents and older adults.

ABSTRACT
Older sexual and gender minority (SGM) populations experience significant disparities in morbidity and disability compared with their heterosexual and cisgender counterparts. There are two primary explanations as to why physical health, mental health, and disability outcomes may differ for older SGM adults compared to older heterosexual and

PROJECT SUMMARY
The use of virtual sociosexual networking venues (e.g., mobile apps and websites) to find intimate partners is near ubiquitous among young sexual minority (SM) men. However, little attention has been paid to the unique discriminatory phenomena that occur in online spaces, and how these experiences impact the mental health of young sexual minority men of color (YSMMoC). One such phenomenon

PROJECT SUMMARY/ABSTRACT

During the COVID-19 pandemic, up to 81% of adults in the United States experienced worsening mental health. A major cause was the social isolation triggered by the pandemic due to quarantining, loss of family or friends, and loss of work. For individuals who lost social connections or were unable to adapt to maintain their connections, social support decreased and loneliness worsened,

Project Summary

Our study seeks to advance methods to measure and analyze multiple types of discrimination for population health research. We will compare novel implicit vs. conventional explicit (self-report) measures of exposure, investigate different approaches to modeling exposure to multiple types of discrimination, and test novel hypotheses using causal mediation analyses. We are motivated by

Abstract

By 2030, there will be nearly six million sexual and gender minority (SGM) older adults aged 60 and older in the U.S. who identify as lesbian, gay, bisexual and transgender. Approximately 350,000 SGM older adults in the U.S. currently have Alzheimer's disease and related dementias (ADRD), with projections nearing one million by 2030. Yet, almost nothing is known about the prevalence or

Abstract

Public awareness of the diversity of experiences of gender identities has climbed sharply. The specific issues of those with gender dysphoria (GD) related to self-identity, body image, and medical interventions are challenges for the 21st century, particularly given the high risk of suicide. Gender identity is tightly linked to one's bodily features, particularly readily observable sexual

Project Title	Administer	Project End Date	FIPS
Leveraging a community-driven approach to address the impact of social determinants of health on structural inequities among Miami-Dade County's intergenerational LGBTQ+ Community	OD	09/20/2028	US
Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	NIA	06/30/2025	US
Internal Sources of Minority Stress and Alcohol Consumption	NIAAA	07/31/2025	US
TRANSforma Tu Salud Dejando de Fumar: Advancing smoking cessation among transgender individuals	NCI	08/31/2025	US
SilverBills: A Legal, Technical and Financial Tool for Aging LGBTQ+ Individuals with Impaired Cognition.	NIA	08/31/2025	US
Trajectories of Adaptation to Traumatic Stress in a Vulnerable Population	NIGMS	08/31/2025	US

Health Effects of Intersectional Stigma among Sexual Minority Women	NIAAA	08/31/2025	US
Building Community and Research Engagement among Sexual and Gender Minority Older Adults at Risk for Alzheimer's Disease and Related Dementias	NIA	08/31/2025	US
One Ballroom: Understanding Intersectional Stigma to Optimize the HIV Prevention Continuum among Vulnerable Populations in the United States	NIAID	08/31/2027	US
Facilitators of and barriers to healthcare utilization among racially and ethnically diverse transgender and gender nonbinary young adults	NIMHD	02/28/2025	US
Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	NIA	06/30/2025	US
Racialized Sexual Discrimination (RSD) and Psychological Well-being among Young Sexual Minority Men of Color (YSMMoC)	NIMHD	02/28/2025	US

Improving mental health among the LGBTQ+ community impacted by the COVID-19 pandemic	NIMH	08/31/2025	US
Advancing novel methods to measure and analyze multiple types of discrimination for population health research	NIMHD	01/31/2026	US
The Epidemiology of Alzheimer's Disease and Related Dementias in Sexual and Gender Minority Older Adults: Identifying Risk and Protective Factors	NIA	06/30/2025	US
Personalized 3D avatar tool development for measurement of body perception across gender identities	NIBIB	03/31/2025	CA

Organization Name	Total Cost IC
URBAN HEALTH PARTNERSHIPS	$ 1,125,000
VANDERBILT UNIVERSITY	$ 99,998
TEXAS TECH UNIVERSITY	$ 397,892
UNIVERSITY OF ROCHESTER	$ 2,000
SILVERBILLS INC.	$ 1,080,149
HUNTER COLLEGE	$ 117,000

UNIVERSITY OF CALIFORNIA SA	$	180,704
EMORY UNIVERSITY	$	727,284
UNIVERSITY OF CALIFORNIA-IR	$	426,660
UNIVERSITY OF CENTRAL FLOR	$	188,746
VANDERBILT UNIVERSITY	$	362,818
UNIVERSITY OF ILLINOIS AT UR	$	159,646

BROWN UNIVERSITY	$ 2,368,492
HARVARD SCHOOL OF PUBLIC	$ 648,444
UNIVERSITY OF NEVADA LAS V	$ 126,738
CENTRE FOR ADDICTION AND I	$ 120,174

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED APRIL 2024-SEPTEMBER 2024 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. [INSERT EXPLANATION—EXAMPLES BELOW

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

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

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number [INSERT] is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to [the NIH Director or his designee] no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, [the NIH Director or his designee] may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

[insert sig block]

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2022-MARCH 2024 (TO BE DELTED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2022 National Institutes of Health ("NIH") Grants Policy Statement,[13] and 2 C.F.R. § 200.340(a)(2) (2023). This letter constitutes a notice of termination.[14]

The 2022 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[15]

The 2022 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[16] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[17] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. [INSERT EXPLANATION—EXAMPLES BELOW

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the

[13] https://grants.nih.gov/grants/policy/nihgps/nihgps_2022.pdf.
[14] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[15] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[16] 2022 Policy Statement at IIA-1.
[17] *Id.* at IIA-153.

health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

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

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[18] no corrective action is possible here. The premise of Project Number [INSERT] is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[19] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[20]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[21] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[22]

You must submit a request for such review to [the NIH Director or his designee] no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, [the NIH Director or his designee] may grant an extension of time.[23]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[24]

Sincerely,

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[18] 2022 Policy Statement at IIA-154.
[19] *See* 2 C.F.R. § 200.343 (2023).
[20] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[21] *See* 45 C.F.R. § 75.374.
[22] See 42 C.F.R. Part 50, Subpart D.
[23] *Id.* § 50.406(a).
[24] *Id.* § 50.406(b).

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[insert sig block]

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2021-NOVEMBER 2022 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2021 National Institutes of Health ("NIH") Grants Policy Statement,[25] and 2 C.F.R. § 200.340(a)(2) (2022). This letter constitutes a notice of termination.[26]

The 2021 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[27]

The 2021 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[28] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[29] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. [INSERT EXPLANATION—EXAMPLES BELOW

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the

[25] https://grants.nih.gov/grants/policy/nihgps/nihgps_2021.pdf.
[26] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[27] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[28] 2022 Policy Statement at IIA-1.
[29] *Id.* at IIA-152.

health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

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Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[30] no corrective action is possible here. The premise of Project Number [INSERT] is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[31] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[32]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[33] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[34]

You must submit a request for such review to [the NIH Director or his designee] no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, [the NIH Director or his designee] may grant an extension of time.[35]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[36]

Sincerely,

---

[30] 2021 Policy Statement at IIA-154.
[31] *See* 2 C.F.R. § 200.343 (2022).
[32] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[33] *See* 45 C.F.R. § 75.374.
[34] See 42 C.F.R. Part 50, Subpart D.
[35] *Id.* § 50.406(a).
[36] *Id.* § 50.406(b).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

[insert sig block]

EXHIBIT 8

From:
To:
Cc:
Subject: Re: Grants for immediate termination today
Date: Friday, February 28, 2025 7:46:09 PM
Attachments:

Hi Michelle,
As we discussed, there are 5 more projects, listed immediately below. I think one is the AHRQ grant you mentioned earlier. Rachel is trying to work on the letters (see an example attached), but please handle as you see fit.
I'm going drive home soon myself, but I'll log back on.
I appreciate you,
Liza

From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:34 PM
To: Burdeson, Liza (NIH/OD) [E]; McElroy, James (NIH/OD) [E]
Subject: RE: Grants for immediate termination today
(LETTER ATTACHED)
5 grants:
An intervention to promote healthy relationships among transgender and gender expansive youth – 5R21HD107311-02 (DRAFT LETTER ATTACHED)
Antigen discovery for transmission-blocking vaccines in Plasmodium vivax - 5R01AI156533-05 (I WILL DO NOW)
China Health and Retirement Longitudinal study - 5R01AG037037-14 (I WILL DO NOW)
TransHealthCUIDE: Transforming Health for Gender-Diverse Young Adults Using Interventions to Drive Equity – 5U01MH136558-03
Using telehealth to improve access to gender-affirming care for BIPOC and rural gender diverse youth - 5K08HS029028-02

From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:27 PM
To: Burdeson, Liza (NIH/OD) [E]; McElroy, James (NIH/NIMH) [E]
Subject: RE: Grants for immediate termination today
First letter attached.

From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:18 PM
To: Burdeson, Liza (NIH/OD) [E]; McElroy, James (NIH/NIMH) [E]
Subject: RE: Grants for immediate termination today

From: Bundesen, Liza (NIH/OD) [E]
To: Bulls, Michelle G. (NIH/OD) [E]
Cc: Jacobs, Anna (NIH/OD) [E]
Subject: FW: Grants for immediate termination today
Date: Friday, February 28, 2025 7:46:09 PM
Attachments: NIH Termination Letter 5R21HD107311-02.docx

Hi Michelle,

As we discussed, there are 5 more projects, listed immediately below. I think one is the AHRQ grant you mentioned earlier. Rachel is trying to work on the letters (see an example attached), but please handle as you see fit.

I'm going drive home soon myself, but I'll log back on.

I appreciate you,

Liza

From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:34 PM
To: Bundesen, Liza (NIH/OD) [E] ; McElroy, James (NIH/OD) [E]
Subject: RE: Grants for immediate termination today

(LETTER ATTACHED)

5 grants:

An intervention to promote healthy relationships among transgender and gender expansive youth – 5R21HD107311-02 (DRAFT LETTER ATTACHED)

Antigen discovery for transmission-blocking vaccines in Plasmodium vivax - 5R01AI150533-05 (I WILL DO NOW)

China Health and Retirement Longitudinal study - 5R01AG037031-14 (I WILL DO NOW)

TransHealthGUIDE: Transforming Health for Gender-Diverse Young Adults Using Interventions to Drive Equity = 5U01MH136558-03

Using telehealth to improve access to gender-affirming care for BIPOC and rural gender diverse youth - 5K08HS029028-02

From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:27 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; McElroy, James (NIH/NIMH) [E] <james.mcelroy@nih.gov>
Subject: RE: Grants for immediate termination today

First letter attached.

From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:18 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; McElroy, James (NIH/NIMH) [E] <james.mcelroy@nih.gov>
Subject: RE: Grants for immediate termination today

An intervention to promote healthy relationships among transgender and gender expansive youth
Antigen discovery for transmission-blocking vaccines in Plasmodium vivax
China Health and Retirement Longitudinal study
TransHealthGUIDE: Transforming Health for Gender-Diverse Young Adults Using Interventions to Drive Equity
Using telehealth to improve access to gender-affirming care for BIPOC and rural gender diverse youth

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From: Riley, Rachel (OS/ASA)
Sent: Friday, February 28, 2025 7:14 PM
To: 'Bundesen, Liza (NIH/OD) [E]' <lbundese@mail.nih.gov>; McElroy, James (NIH/NIMH) [E] <james.mcelroy@nih.gov>
Subject: RE: Grants for immediate termination today

An intervention to promote healthy relationships among transgender and gender expansive youth	PROJECT SUMMARY Transgender and gender expansive (TGE) youth identify as a gender different from their sex at birth. Research tends to define this group based on high rates of sexually transmitted infections (STIs), sexual risk behaviors, violence exposures, and other health outcomes. Little work has used a supportive, resilience-based framework or a human-centered approach. We conducted preliminary qualitative/co-design studies to understand sexual health content needs and format/design preferences. Content areas recommended by TGE youth, their families, providers, and/or advocates include: a) Youth/ providers noted that puberty can produce dysphoria for TGE adolescents and that information/tools would be beneficial; b) Participants asked for non-judgmental information about STI risks and prevention; c) Youth/providers asked for content around contraception that clarifies that gender-affirming medical interventions do not prevent unintended pregnancies; d) Participants recommended destigmatizing and normalizing diversity in sexual attractions and desires; e) TGE youth raised disclosure of TGE identity as a unique challenge and asked for communication skills training to help them maintain agency over when and how to disclose; and f) Participants described difficulties navigating partner consent because it is often described in heteronormative, binary terms in sexual education classes. TGE youth also described favoring written materials for more fact-based content on contraception and STIs, interactive formats for content that requires personalization by gender and/or degree of medical transition, and multimedia approaches emphasizing lived experience perspectives for information around desire, gender identity disclosure, and consent. Participants also provided design guidance (e.g., use of a covert color palette that would not unwantedly disclose users' transgender status in public) and specific features (e.g., blacklisting functions to protect the user from triggering content; robust search and filter system to easily locate information specific to an individual's needs). Based on these themes, we co-designed a paper intervention prototype with TGE youth. In this proposal, we will engage a Youth Advisory Board and Community Consultants to co-design a fully functional online interactive sexual education tool (OISET) with TGE youth (Aim 1a) and conduct cognitive interviews to refine select survey tools and ensure gender-affirming intervention effect measurement in a future R01 (Aim 1b). We will then conduct an unbalanced, randomized controlled pilot study with 40 youth (30 intervention:10 control) to refine content and establish feasibility of the OISET and data collection protocols/procedures (Aim 2). Primary outcomes will be intervention usability/feasibility/appropriateness/ acceptability and study feasibility. We will collect baseline, post-intervention, and 3 month data on knowledge; general/sexuality-specific self-efficacy; partner communication; risky sexual behaviors; social support; and resilience. This project is innovative, rigorous, and responsive to NICHD/NINR/SGMRO priorities. It will result in the first evidence- and strengths-based online sexual health intervention for TGE youth.	NICHD	10697301	09/06/2023	PA-20-194	5R21HD107311-02	5	R21	HD	107311	02	POPKIN, RONNA	09/05/2022	08/31/2025	Health Promotion in Communities Study Section[HPC]	9730435	AHRENS, KYM R	Not Applicable	048682157	SZ32VTCXM799	048682157	LMAWH591NFK5; SZ32VTCXM799	US	47.66243	-122.282291	1531401	SEATTLE CHILDREN'S HOSPITAL	SEATTLE	WA	Independent Hospitals	981053901	UNITED STATES	09/01/2023	08/31/2025	865	Non-SBIR/STTR	2023	240544	NICHD	185415	55129	240544
Antigen discovery for transmission-blocking vaccines in Plasmodium vivax	Project Narrative Development of transmission-blocking vaccines against the human malaria parasite Plasmodium vivax is urgently needed for malaria elimination. This project seeks to use a comprehensive antigen discovery pathway, including antigen identification through genome-wide immunological screening, validation in rodent malaria model, and further evaluation in P. vivax, to identify new transmission-blocking vaccine candidates for vivax malaria.	NIAID		06/21/2024	PAR-17-142	5R01AI150533-05	5	R01	AI	150533	05	MO, ANNIE X. Y.	04/06/2020	03/31/2025	Special Emphasis Panel[ZRG1-PSE-D(55)]	15224411	CAO, YAMING	Not Applicable	529786253	KN4BZNFH4GR4	529786253	KN4BZNFH4GR4	CH	41.79222	123.43278	2818101	CHINA MEDICAL UNIVERSITY	SHENYANG		Unavailable	110122	CHINA	04/01/2024	03/31/2025	855	Non-SBIR/STTR	2024	$ 135,000	NIAID	126600	8400	135000
China Health and Retirement Longitudinal study	Project Narrative The China Health and Retirement Longitudinal Study (CHARLS) has already begun to enrich the international landscape of aging studies. CHARLS follows closely the existing Health and Retirement Studies around the world in order to provide the capability for scholars to engage in comparative studies as well as studies of the special conditions in China. The first four national waves of CHARLS were fielded in 2011, 2013, 2015 and 2018 and waves 5 and 6 are planned for 2021 and 2024; including updates of the CHARLS Harmonized Cognitive Assessment Protocol (HCAP) of Alzheimers Disease and Related Dementias (ADRD).	NIA		05/22/2024	PA-19-056	5R01AG037031-14	5	R01	AG	037031	14	CHATTERJI, MINKI	06/15/2020	04/30/2025	Social Sciences and Population Studies B Study Section[SSPB]	78743006	WANG, YAFENG	STRAUSS, JOHN A;ZHAO, YAOHUI	653934935	K3AYKJKUF6M3	653934935	K3AYKJKUF6M3	CH	39.9075	116.39723	10008779	PEKING UNIVERSITY	BEIJING		Unavailable	100871	CHINA	05/01/2024	04/30/2025	866	Non-SBIR/STTR	2024	$ 1,739,936	NIA	1612231	127705	1739936

PROJECT SUMMARY
No changes being proposed.

INTRODUCTION
This application is for an Administrative Supplement for Research on Sexual and Gender Minority (SGM) Populations (NOT-OD-22-032) to the parent award, ""Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South," (R01AG063771). This application proposes to extend the parent award's existing data collection among a panel of older sexual and gender minority (SGM) adults to include new objective measures of cognitive functioning. The parent award already includes self-reported cognitive functioning and analyses of cognition-related outcomes are within the scope of the parent award. As such, this proposal seeks to extend the range of SGM-related data and research questions on health and aging through the expansion of measures that are not available in this population. As we note in the strategy, there are currently no studies that directly measure cognitive functioning in self-identified SGM older adults regardless of relationship status and only one cross-sectional study has tested cognitive abilities across gender and sexual orientation in a sample inclusive of older adults (age 20-65). 1 Very little work on self-reported cognitive aging in SGM populations is able to disaggregate the experiences and outcomes of SGM people by identity or other exposures (e.g., negative life experiences) due to small sample sizes. Several recent reports, including the 2023 Federal Evidence Agenda on LGBTQI+ Equity, highlight the lack of data on SGM populations that can be disaggregated to consider within-group variation in outcomes and

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

Dr. Ronna Popkin
4800 Sand Point Way NE
Seattle Children's Hospital
Seattle, WA

Dr. Popkin:

Funding for Project Number 5R21HD107311-02 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 1, 2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5R21HD107311-02 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matthew Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Matthew Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

[insert sig block]

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT 9

From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]; Bulls, Michelle G. (NIH/OD) [E]
Subject: Grants for termination
Date: Monday, March 24, 2025 10:23:10 AM
Attachments: Memorandum - Covid-19 Termination.pdf
For termination 3-24.xlsx

Good morning,

We have been asked to terminate the list of approximately 120 grants by COB today. The memo from HHS OGC defines the reason for the termination so our letter should mirror this memo. Attached Is an excel sheet with the grants for termination. These have already been reviewed, so please terminate them all.

Thanks,

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

EXHIBIT 10

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

Background

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

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

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

- Action: ICs must not issue the award.

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

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

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

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

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

Appendix 1

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

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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

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

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

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

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

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

Dorothy A. Fink

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

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

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

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

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

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

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

Term and Condition of Award

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

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

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

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

approved

Matt

Get Outlook for iOS

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

Hi Matt,

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

Thank you,
Liza

EXHIBIT 11

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]
Subject: Award Revision Guidance and List of Terminated Grants via letter on 3/12
Date: Thursday, March 13, 2025 4:03:00 PM
Attachments: Termination Categories 3.13.25.docx
Terminated Grants 3-12_no subprojects.xlsx

Chiefs,

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

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

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

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

        It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.
        NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a

copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Thanks,
Michelle

Termination Categories

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

EXHIBIT 12

INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT

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

Issue Date: March 25, 2025

Background

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

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

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

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

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

    Term of Award:

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

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other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

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

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

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

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

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are

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ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award in Section IV of the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

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

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

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

  This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes

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[select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa., etc.] or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

- **Unable to remove activities that are not an NIH/HHS priority/authority:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Category 4.
- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICs must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the DEI Term and Condition of Award in Section IV of the NOA of the parent grant. The IC must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the IC must revise the prior year award to remove references to those outyear commitments.
- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific topics that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the IC must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the IC must terminate the award following the process in Category 4.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICs receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICs must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICs do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

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Category 2B:

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

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

- Resource Section
- Biosketch
- RPPRs

Category 2C:

Subprojects terminated by HHS.

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

Category 3: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

Category 4/HHS Departmental Authority Terminations:

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

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- OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICs.

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

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

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

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

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

Category 5: Awards to Entities in certain foreign countries

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

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- Office of Foreign Assets Control Sanctions List

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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Appendix 1

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

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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

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

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

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

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

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

Dorothy A. Fink

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

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

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

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

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

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Appendix 4 - Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

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

approved

Matt

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

Hi Matt,

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

Thank you,
Liza

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Appendix 5 – Notice of Funding Opportunity (NOFO) Guidance

[pending]

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Appendix 6 – Frequently Asked Questions

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

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

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

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

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

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

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

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

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

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

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

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

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards, when termination letter is issued.

Recipients are required to request approval from OPERA before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare. These are the only approvals that will be issued. OPERA will work with the IC to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS.

Recipients are required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

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EXHIBIT 13

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity, etc. after the priorities memo is issued), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For second and third NCE's, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's may use the following term of award when approving/disapproving NCEs:
  - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
  - **Term of Award (disapproved extension**): The no cost extension request for this project has been denied. Please proceed with orderly phaseout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

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

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

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

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

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

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the ICO must terminate the award following the process in **Category 1**.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICO's receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICO's must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

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

Examples below, and in these cases, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

  [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: HHS Departmental Authority Terminations.

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the ICO is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

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

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

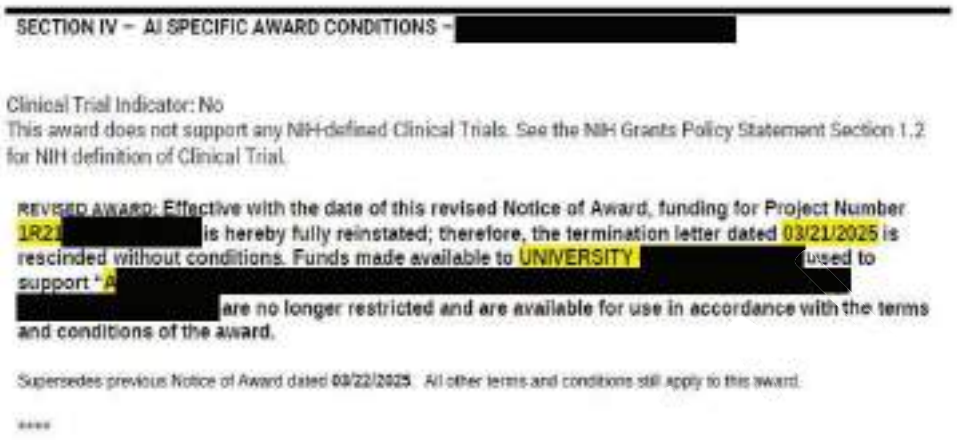
- eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type OD NIH



SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated 03/22/2025. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be

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terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

- Include the following Termination Term in the revised NOA:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

      Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
  - Include the following Termination Term in the revised NOA:

    This award is bilaterally terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

Impacts on the Biomedical Workforce:

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- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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

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

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

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

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

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

Dorothy A. Fink

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

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

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

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

- China: "Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives."
- DEI: "Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- Vaccine Hesitancy: "It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."
- COVID (to be used for HHS/NIH OD directed terminations only): "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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

approved

Matt

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

Hi Matt,

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

Thank you,
Liza

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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Appendix 6 – Frequently Asked Questions

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

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

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

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

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

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

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

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

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. **Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

    The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. **If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

    No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. **For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

    Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. **For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

    Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. **If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

    No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. **If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

    Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. **For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

    In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. § 200.340(a)(4). This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement". This "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."

According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time your grant was issued, 2 C.F.R. § 200.340(a)(4) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This project no longer effectuates agency priorities. [insert termination category language (e.g., DEI) verbatim]. Therefore, there is no modification of the project that would align with agency priorities.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §200.344. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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Termination Categories

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

EXHIBIT 14

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity, etc. after the priorities memo is issued), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For all NCE requests, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's may use the following term of award when approving/disapproving NCEs:
  - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
  - **Term of Award (disapproved extension**): The no cost extension request for this project has been denied. Please proceed with orderly phaseout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

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

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

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

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

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

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award**.**

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the ICO must terminate the award following the process in **Category 1**.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICO's receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICO's must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

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

Examples below, and in these cases, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: HHS Departmental Authority Terminations.

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the ICO is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

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

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

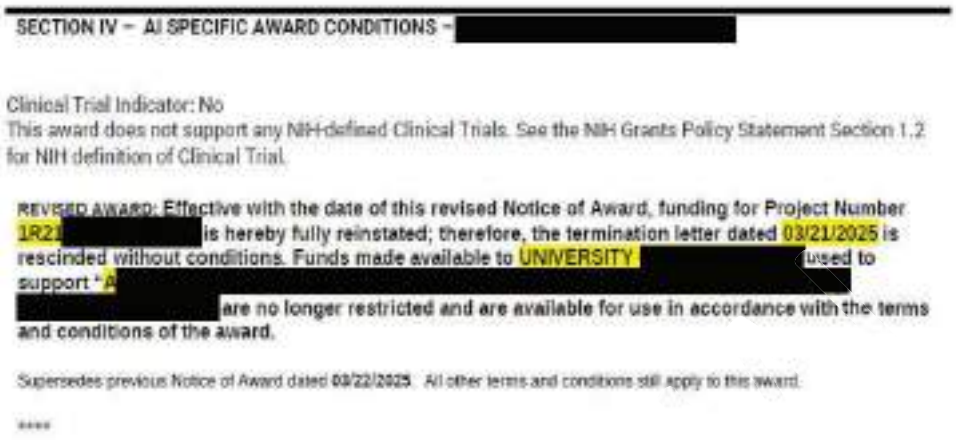
- eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type OD NIH



SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated 03/22/2025. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be

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terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

- Include the following Termination Term in the revised NOA:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

      Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
  - Include the following Termination Term in the revised NOA:

    NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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Impacts on the Biomedical Workforce:

- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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

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

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

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

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

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

Dorothy A. Fink

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

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

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

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

- China: "Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives."
- DEI: "Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- Vaccine Hesitancy: "It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."
- COVID (to be used for HHS/NIH OD directed terminations only): "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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

approved

Matt

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

Hi Matt,

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

Thank you,
Liza

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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Appendix 6 – Frequently Asked Questions

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

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

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

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

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

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

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

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

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. **Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

    The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. **If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

    No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. **For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

    Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. **For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

    Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. **If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

    No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. **If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

    Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. **For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

    In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. § 200.340(a)(4). This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement". This "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."

According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time your grant was issued, 2 C.F.R. § 200.340(a)(4) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This project no longer effectuates agency priorities. [insert termination category language (e.g., DEI) verbatim]. Therefore, there is no modification of the project that would align with agency priorities.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §200.344. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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EXHIBIT 15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

DATE: August 15, 2025

TO: Institute and Center Directors, Scientific Directors, Clinical Directors, Division Directors, and all Office of the Director Staff

FROM: Jay Bhattacharya, M.D., Ph.D.
Director, National Institutes of Health

SUBJECT: NIH Priorities and Internal Review of Intramural and Extramural Programs

Dear Colleagues:

I am sending this memo to clarify our priorities and ensure efforts to fulfill our mission are aligned across the agency. I want to start by expressing my gratitude for your advice and input thus far, and I look forward to our continued collaboration. I have had the opportunity now to visit labs and meet with teams across the agency, and I am constantly impressed. It is a privilege to work with such a dedicated and talented staff.

I recognize that several new initiatives and policies have been implemented in a short period of time, and there has been some confusion due to inaccurate media reports and rumors. Therefore, I have outlined select agency priorities at the end of this note to ensure you have a clearer picture of our rationale and objectives. I do not mean this memo to be an exhaustive list of all agency priorities, but rather a select list of topics that require our particular attention and focus while continuing the other important work you are all doing. This memo will help to ensure NIH supports only high-quality projects selected based on the merit of the science and that are aligned with our mission to generate data that can improve the health of all of the American people. I ask each of you to use this guidance when reviewing your intramural and extramural research portfolios and making decisions about your future programs.

In recent weeks, it has come to my attention that some at NIH and in the scientific community believe that there are "banned words" or some level of censorship of science ongoing or planned. This is simply untrue. I have advocated for academic freedom throughout my career, with a particular public focus in the last five years. My position has not changed; scientists must be allowed to pursue their ideas free of censorship or control by others. They must be able to express their scientific opinions and challenge scientific dogma. This does not mean everything scientists want to do can or will be funded, but rather that they will be free to propose and discuss these ideas freely in public scientific debate.

The NIH is committed to this. We have already taken steps in this direction by taking scientific review out of the ICs and moving it into the agnostic Center for Scientific Review, minimizing the possibility of gatekeeping within an institute or center. In the coming weeks, we will be taking further steps with an intramural academic freedom policy, and we have formed working groups to evaluate and change how notices of funding for extramural programs are designed and grants are funded to allow for more of a bottom-up research approach.

These changes will allow the scientific community to drive science in a field rather than the government dictating what should be done. They will create an environment that allows for the increased diversity of thought in every field, more opportunities for new or previously sidelined investigators, and expansion of the scientific enterprise into previously unexplored areas. The result will be breakthroughs that really can make America healthy again.

We must continue to ensure our research and training programs are free from fraud, abuse, duplication, and are implemented and administered in a manner consistent with federal law. The NIH is powered by public funds. It is our job to ensure we are good stewards of taxpayer money and create a high return on investment by improving the health of all Americans. Many people across the country have lost trust in NIH because they no longer believe we are working in their best interests. The reforms we're implementing aim to repair this trust. Academic freedom, scientific integrity, transparency, and accountability—gold-standard science – will continue to guide our approach.

Thank you for your efforts and dedication to the great mission of NIH.

All the best,

Jay Bhattacharya, M.D., Ph.D.
Director of the National Institutes of Health

Priorities:

This document has been prepared in furtherance of the NIH Director's responsibility to provide the overall direction of NIH, to establish and implement general policies respecting the management and operation of NIH programs and activities, and to coordinate and oversee the operation of NIH's institutes, centers, and offices. See 42 U.S.C. § 282(b)(1) & (2). Please note that this is not an exhaustive list of all agency priorities. This document is intended to clarify specific issues that currently require additional guidance. NIH continues to support projects across the full spectrum of biomedical research topics. Through an executive order on Gold-Standard Science and the Make America Healthy Again Commission Report, the President has directed the NIH to close critical research gaps and guide efforts to better combat chronic disease in America and improve the health of all Americans through gold-standard science. To meet these requirements and fulfill our mission, NIH is prioritizing research in the following areas:

Training future biomedical scientists:

NIH training programs should focus on training future physicians and scientists to lead American preeminence in biomedical research in the 21st century. Programs should allow trainees to design and conduct the highest quality scientific studies. Importantly, these programs should be based on merit, follow civil rights law, and not discriminate against anyone. NIH and the institutions we support must also uphold safe, equal, and healthy working and learning conditions conducive to high-quality research and free inquiry.

Replication and reproducibility:

Replicable, reproducible, and generalizable research must serve as the basis for truth in biomedical science. The "publish or perish" culture favors the promotion of only favorable results, and replication work is little valued or rewarded. NIH is prioritizing research that produces robust, reproducible results. We are exploring various mechanisms to support scientists focused on replication work, to publish negative findings, and to elevate replication research.

Real-World Data Platform:

NIH is establishing a robust and secure national infrastructure to integrate and link data from various real-world sources consistent with a deep respect for individual privacy rights. This new Real-World Data Platform will provide advanced computational analysis resources for investigators across numerous research areas, including neurodevelopmental disorders and chronic diseases.

Artificial intelligence:

Artificial intelligence breakthroughs provide exciting new possibilities for science and medicine, but require careful, rigorous research to fulfill their promise. The NIH will develop an AI Strategic Plan to enhance transparency in AI models, develop replication standards for AI use in research, and expedite the research, development, and translation of AI discoveries to benefit patients. The plan will consider strategic architecture, high-impact AI use cases, new opportunities to use AI for agency operations, and best practices for validating AI in healthcare delivery.

Nutrition:

NIH will champion initiatives rigorously exploring the role of poor diets in causing common chronic conditions and the identification of healthy diets that can prevent and better manage these conditions. We will prioritize projects focusing on the role of maternal and infant dietary exposures on health outcomes across the lifespan. NIH will also work to initiate long-term studies to understand the impacts of certain foods and diets on obesity and insulin resistance in children.

Furthering our understanding of autism:

NIH is supporting initiatives to understand the etiology and the treatment and care needs of the broad spectrum of people with autism. The new autism data science initiative will support investigators in identifying and addressing data gaps in scientific understanding of the etiology of autism and commonly co-occurring conditions. Activities supported will include creating new data resources and integrating existing data resources into state-of-the-art analyses on autism etiology. The program aims to develop knowledge to improve health outcomes for people on the autism spectrum.

Alternative testing models:

NIH is establishing the Office of Research Innovation, Validation, and Application under the Division of Program Coordination, Planning, and Strategic Initiatives, to develop, validate, and scale the use of human-biology-based new approach methodologies (NAMs) to complement animal models and enhance investigations. This office will coordinate with NIH institutes, centers, and offices to explore and prioritize ways to reduce our reliance on animal testing to advance technologies that improve translation to humans. Accordingly, all new funding opportunities that include support for animal models will also incorporate language on the consideration of NAMs. The office will serve as a hub for interagency collaboration and expand funding opportunities and infrastructure for non-animal approaches.

Promoting research focused on scientifically valid, measurable health outcomes:

NIH will continue to support research that advances the health of all Americans, regardless of their age, race, ethnicity, sex, sexual orientation, or other characteristics. To conduct meaningful biomedical research, scientists must consider both individual and external factors that influence health outcomes, guided by the needs of the specific research question. Some relevant personal characteristics may include demographic indicators such as race and sex, while some contextual factors, like environmental exposures and socioeconomic conditions (e.g., poverty), may also be scientifically significant. Any distinctions made in study design must be directly relevant to the health outcomes under investigation. NIH will support scientifically rigorous research that considers these factors when they are scientifically justified and aligned with the study's objectives.

In contrast to research that considers race or ethnicity when scientifically justified (described in the paragraph above), research based on ideologies that promote differential treatment of people based on race or ethnicity, rely on poorly defined concepts or on unfalsifiable theories, does not follow the principles of gold-standard science. Such studies divert

resources away from projects that advance the health and longevity of all Americans, including minority populations. The NIH will always prioritize gold-standard science.

Investigators must employ specific and measurable concepts in health disparities research. For example, redlining and housing discrimination are clearly defined practices that can measurably impact the health of minority populations. The NIH will support scientifically rigorous research programs that explore such causes as one reason among many for poor health outcomes for Americans.

However, broad or subjective claims—such as attributing worse health outcomes in a particular population to poorly measured factors like systemic racism—should not be presented as established background facts without clearly defining measurable variables that are part of the research question.

Relatedly, research involving participant volunteers should be based on appropriate population descriptors and categories that use precise language to define participant attributes, comparator group attributes, and to whom the study findings apply. Research based on overly broad and scientifically imprecise goals is of low value and off-mission.

Shifting to solution-oriented approaches in health disparities research:

NIH has invested substantially in health disparities research, focusing mainly on identifying and documenting worse health outcomes for minority populations. The field has made significant progress in mapping the breadth and depth of differences in health outcomes across populations, but this research has not always translated into measurable improved health for minority populations.

Going forward, the NIH will prioritize research that goes beyond measuring health disparities to focusing on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative evidence-based interventions and treatments that address poor health outcomes.

Improving oversight of NIH funds going to foreign research institutions:

The NIH will continue to support research collaborations with institutions and scientists outside the U.S. Many critical breakthroughs that improve the health of Americans have resulted from global partnerships, so foreign scientific research collaborations often have clear scientific value. However, we must take action to ensure better oversight of our funding abroad.

All NIH institutes, centers, and offices should consider whether there is a scientific justification for conducting a research program at a foreign site rather than a domestic one. The NIH should prefer the latter over the former when scientifically justified. We should also consider whether each project involving foreign collaboration will likely lead to better health for Americans, since American taxpayers fund NIH research.

We must also assess risks to national security, biosecurity, and waste, abuse, or fraud at foreign sites where NIH has substandard or no oversight. To address this goal, we have established a new award structure for foreign collaboration. Foreign institutions receiving funds for work on a funded project will henceforth be considered independent awards linked to the parent project. This system will allow the NIH to directly track funds awarded to all foreign

components receiving NIH funding and hold all institutions receiving NIH funding to grant terms and conditions regardless of where they are in the world.

Ensuring evidence-based health care for children and teenagers identifying as transgender:

The state of the scientific literature regarding optimal care and support approaches for children and teenagers identifying as transgender and those diagnosed with gender dysphoria is described in the recent HHS review of treatment for pediatric gender dysphoria. In accordance with these data, there are clearly more promising avenues of research that can be taken to improve the health of these populations than to conduct studies that involve the use of puberty suppression, hormone therapy, or surgical intervention to treat gender dysphoria, gender identity disorder, or gender incongruence in minors. By contrast, research that aims to identify and treat the harms these therapies and procedures have potentially caused to minors diagnosed with gender dysphoria, gender identity disorder, or gender incongruence, and how to best address the needs of these individuals so that they may live long, healthy lives is more promising.

Implementing advances in HIV/AIDS research:

Ending the HIV epidemic in the United States remains a key priority. For more than 40 years, NIH support has enabled significant advances in antiretroviral therapies, transforming the landscape of care and prevention approaches. Recent breakthroughs in simpler-to-take treatments and long-acting prophylactics, and many other recent breakthroughs, provide us with the technological tools needed to finally win this long battle. To take advantage of this opportunity, the NIH will support implementation science and other research directions to improve the uptake of and access to existing medical and behavioral interventions that can significantly limit and eventually eradicate HIV infection from the United States. Research on HIV/AIDS prevention, treatment, and cure will continue as needed to support this goal.

Guidance for internal review:

Effective immediately, relevant NIH personnel (including but not limited to directors of extramural research, program officers, directors of intramural research, and intramural investigators) must conduct an individualized review of all current and planned research activities, including:

- Contract solicitations and funding opportunity announcements
- Applications for new (Type 1) and competing renewal (Type 2) awards
- Active grants and contracts
- Cooperative agreements and other transactions
- Intramural research and research training programs

Please identify all research or training programs that do not align with these agency priorities described in this memo and indicate where there are gaps in your portfolio. This individualized review should follow the NIH's normal process of identifying research opportunities that meet the NIH's mission to advance the health and longevity of all of the American people. Please continue to adhere to the NIH Grants Policy Statement. Programs and projects determined not to

align with agency priorities may be restricted, paused, not renewed, or terminated (in whole or part) consistent with the law. Where possible, ICs are encouraged to renegotiate programs and projects to ensure their compliance with agency priorities. These actions must comply with all applicable laws, regulations, court orders, and required notice procedures. Please consult with the Office of the Director and the Office of the General Counsel before taking any actions on existing grants, contracts, and agreements to ensure that all actions comply with all current laws and court orders. The legal landscape changes daily, and we will continue to offer guidance, so please reach out to us at any time.

Please ensure the directives in this memo are implemented without delay.

EXHIBIT 16

NIH Websites Are Changing

NIH is moving the launch of its new website to the fall to ensure the best possible experience for everyone who relies on our websites for health information, research, funding opportunities, and other resources.

Get the Latest Updates and FAQs

National Institutes of Health
Turning Discovery Into Health

STATEMENT Friday, August 15, 2025

Advancing NIH's Mission Through a Unified Strategy

THIS STATEMENT WAS UPDATED ON JULY 2, 2026.

As stewards of taxpayer funds, NIH must dedicate public funds toward medical and scientific research that promises the greatest benefit to the public. Today, I'm pleased to announce that NIH is moving toward a unified strategy that aligns our priorities and funding approaches to fulfill this commitment. Through this strategy, we will better leverage the synergistic missions of each NIH Institute, Center and Office (ICO) to fund the most meritorious science, address urgent health needs, and sustain a robust biomedical research workforce.

A central pillar of this approach is balancing scientific opportunity with mission-critical objectives. NIH is sharpening its focus on chronic health issues that affect Americans, including chronic childhood diseases and nutrition. We are also prioritizing next-generation tools such as artificial intelligence, alternative testing models, and real-world data platforms.

To improve public trust, NIH is enhancing oversight of funded research abroad and reinforcing its commitment to responsible stewardship of taxpayer dollars. We will expand support for replication studies and strengthen our capacity to advance groundbreaking science. At the same time, NIH remains dedicated to fostering open, competitive, and accountable science and supporting investigators regardless of controversy as they pursue innovative research grounded in rigorous methodology.

A core function of NIH ICOs is to assess scientific merit within the context of NIH's broader strategic goals and develop appropriate research funding plans accordingly. In an environment where NIH receives more meritorious applications than it can fund, this review process is increasingly critical. To that end, NIH will empower its ICOs to make funding decisions that reflect agency and institute priorities, scientific opportunity, program balance, workforce needs, and other core principles that will be consistently applied across the agency.

Taxpayer dollars are a finite resource, entrusted to NIH officials to invest in the nation's future. By transparently establishing priorities and aligning our goals, we aim to demonstrate to the American people that we take this commitment seriously—and that we are doing all we can to honor their trust.

Jay Bhattacharya, M.D., Ph.D.
Director, NIH

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

NIH…Turning Discovery Into Health®

Priorities:

This document has been prepared in furtherance of the NIH Director's responsibility to provide the overall direction of NIH, to establish and implement general policies respecting the management and operation of NIH programs and activities, and to coordinate and oversee the operation of NIH's institutes, centers, and offices. See 42 U.S.C. § 282(b)(1) & (2). Please note that this is not an exhaustive list of all agency priorities. This document is intended to clarify specific issues that may require additional guidance. NIH continues to support projects across the full spectrum of biomedical research topics. Through an executive order, Restoring Gold Standard Science, and the Make America Healthy Again Commission Strategy, the President has directed the NIH to close critical research gaps and guide efforts to better combat chronic disease in America and improve the health of all Americans through gold-standard science. To meet these requirements and fulfill our mission, NIH is prioritizing research in the following areas:

Training future biomedical scientists:

NIH training programs should focus on training future physicians and scientists to lead American preeminence in biomedical research in the 21st century. Programs should allow trainees to design and conduct the highest quality scientific studies. Importantly, these programs should be based on merit, follow civil rights law, and tolerate no unlawful discrimination. NIH and the institutions we support must also uphold safe, fair, and healthy working and learning conditions conducive to high-quality research and free inquiry.

Replication and reproducibility:

Replicable, reproducible, and generalizable research must serve as the basis for truth in biomedical science. The "publish or perish" culture favors the promotion of only favorable results, and replication work is little valued or rewarded. NIH is prioritizing research that produces robust, reproducible results. We are exploring various mechanisms to support scientists focused on replication work, to publish negative findings, and to elevate replication research.

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NIH will champion initiatives rigorously exploring the role of poor diets in causing common chronic conditions and the identification of healthy diets that can prevent and better manage these conditions. We will prioritize projects focusing on the role of maternal and infant dietary exposures on health outcomes across the lifespan. NIH will also work to initiate long-term studies to understand the impacts of certain foods and diets on obesity and insulin resistance in children.

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Promoting research focused on scientifically valid, measurable health outcomes:

NIH will continue to support research that advances the health of all Americans, regardless of their age, race, ethnicity, sex, or other characteristics. To conduct meaningful biomedical research, scientists must consider both individual and external factors that influence health outcomes, guided by the details of the specific research question. In certain cases where scientifically justified, personal characteristics such as race and sex may be relevant, while some

contextual factors, like environmental exposures and socioeconomic conditions (e.g., poverty), may also be scientifically significant. Any distinctions made in study design must be directly relevant to the health outcomes under investigation. NIH will support scientifically rigorous research that considers these factors when they are scientifically justified and aligned with the study's objectives.

In contrast to research that considers personal characteristics when scientifically justified (described in the paragraph above), research based on beliefs that promote differential treatment or unnecessary classification of people based on race or ethnicity, or on poorly defined concepts or on unfalsifiable theories, does not follow the principles of Gold-Standard science. Overly broad or subjective assumptions —such as attributing, without evidentiary basis, worse health outcomes in a particular population to poorly measured or unproven factors like systemic racism—should not be presented as established background facts or otherwise included in proposed research. Funding research containing such poorly defined concepts and unfalsifiable theories would divert resources away from projects that advance the health and longevity of all Americans, including minority populations. The NIH will always prioritize gold-standard science.

Relatedly, research involving participant volunteers should be based on appropriate population descriptors and categories that use precise language to define participant attributes, comparator group attributes, and to whom the study findings apply. Research based on overly broad and scientifically imprecise goals is of low value and off-mission.

Shifting to solution-oriented approaches in health disparities research:

In the past, the NIH invested substantially in health disparities research that has not resulted in tangible improvements in health outcomes for the populations it purports to benefit. Going forward, the NIH will prioritize research that goes beyond measuring health disparities outcomes to focus on solution-oriented approaches. This includes actively testing, advancing, scaling, and implementing innovative evidence-based interventions and treatments that address poor health outcomes. The NIH, of course, will continue to fund research into health issues that are more likely to affect particular populations, such as genetically inherited disorders.

Improving oversight of NIH funds going to foreign research institutions:

The NIH will continue to support research collaborations with institutions and scientists outside the U.S. Many critical breakthroughs that improve the health of Americans have resulted from global partnerships, so foreign scientific research collaborations often have clear scientific value. However, we must take action to ensure better oversight of our funding abroad.

All NIH institutes, centers, and offices should consider whether there is a scientific justification for conducting a research program at a foreign site rather than a domestic one. The NIH should prefer the latter over the former when scientifically justified. We should also consider whether each project involving foreign collaboration will likely lead to better health for Americans, since American taxpayers fund NIH research.

We must also assess risks to national security, biosecurity, and waste, abuse, or fraud at foreign sites where NIH has substandard or no oversight. To address this goal, we have established an award structure for foreign collaboration. Foreign institutions receiving funds for work on a funded project will are considered independent awards linked to the parent project. This system will allow the NIH to directly track funds awarded to all foreign components receiving NIH funding and hold all institutions receiving NIH funding to grant terms and conditions regardless of where they are in the world, and will follow all government-wide policies regarding dangerous gain-of-function research.

Ensuring evidence-based health care for children and teenagers diagnosed with gender dysphoria:

When funding research into care for children and teenagers diagnosed with gender dysphoria, NIH will prioritize the most promising avenues of research. The state of the scientific literature regarding optimal care and support approaches for children and teenagers diagnosed with gender dysphoria is described in the recent HHS review PDF of treatment for pediatric gender dysphoria. In accordance with these data, there are clearly more promising avenues of research than conducting studies that involve the use of puberty suppression, hormone therapy, or surgical intervention for gender dysphoria, gender identity disorder, or gender incongruence in minors. By contrast, research that aims to identify the utility these interventions, therapies, and procedures have for minors diagnosed with gender dysphoria, gender identity disorder, or gender incongruence, and how to best address the needs of these individuals so that they may live long, healthy lives, is more promising.

Implementing advances in HIV/AIDS research:

Ending the HIV epidemic in the United States remains a key priority. For more than 40 years, NIH support has enabled significant advances in antiretroviral therapies, transforming the landscape of care and prevention approaches. Recent breakthroughs in simpler-to-take treatments and long-acting prophylactics, and many other recent breakthroughs, show the benefit of NIH investment. To take advantage of this opportunity, the NIH will support implementation science and other research directions to improve the uptake of and access to existing medical and behavioral interventions that can significantly limit and eventually eradicate HIV infection from the United States. Additional research on HIV/AIDS prevention, treatment, and cure will continue as needed to support the ambitious goal of ending the epidemic.

NIH will implement these priorities consistent with applicable laws, regulations, court orders, and any required procedures.

This page last reviewed on July 2, 2026

National Institutes of Health

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EXHIBIT 17

Reminder of Compliance Requirements for NIH Extramural Recipients Related to Renegotiated Aims, Objectives, Titles, and Abstracts

Notice Number:
NOT-OD-26-007

Key Dates

Release Date: November 18, 2025

Related Announcements

None

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

Reminder to NIH awardees that changes in scope represent new terms and conditions, with which recipients must comply. This reminder applies to grants, cooperative agreements, and other transactions.

Background

NIH grants management staff are responsible for the business management of awards, which has always included negotiating grant budgets and scope, where appropriate. NIH GPS, 2.1.1. A change of scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. NIH GPS, 1.2. This can include changes to Aims, Objectives, Titles, and Abstracts. One type of scope change that has arisen beginning with Fiscal Year (FY) 25, is a change to bring an NIH funded grant, cooperative agreement, and other transaction into alignment with NIH's agency priorities. For details related to NIH's priorities effective August 15, 2025, please see the NIH Director's Statement of Priorities, entitled "Advancing NIH's Mission Through a Unified Strategy."

Policy

NIH seeks to remind awardees that all changes in scope that were agreed upon by NIH and the Authorized Organizational Representatives (AOR) become new terms and conditions of award, and the recipient must comply with those changes. This includes changes in scope that were renegotiated to align with the agency's priorities. As such, NIH fully expects recipients to comply with the new terms and conditions, unless otherwise stated in the Notice of Award, or unless NIH has been enjoined by court order from imposing or enforcing such terms while that court order is in effect. If recipients have questions related to the new terms and conditions of the awards, the recipient must seek clarification from the Grants Management Official, prior to drawing down on the funds. Once the funds are drawn down from the HHS payment system, the recipient agrees to the terms and conditions of the award and must fully comply with them.

Please be advised that if NIH discovers that recipients have not complied with the new terms and conditions of their award, NIH can immediately take an enforcement action under 2 CFR 200, as appropriate, which includes termination for non-compliance under 2 CFR 200.340(a)(1). For terminations for non-compliance with the revised scope, NIH will provide appeal rights to recipients at the time of the termination and, in accordance with 2 CFR Part 200.340 (c), will report the terminations in SAM.gov, as appropriate.

Inquiries

Please direct all inquiries to:

NIH Office of Policy for Extramural Research Administration/OER
OPERAleadership@mail.nih.gov

EXHIBIT 18

Staff Guidance – Reviewing Grants for Priority Alignment
Issue Date: December 12, 2025

This Staff Guidance establishes procedures for the NIH Institutes and Centers (ICs) to review grants for alignment with the priorities set forth in the August 15, 2025, NIH Director's Priorities Statement, "Advancing NIH's Mission Through a Unified Strategy" and its addenda, if any ("Priorities Statement"). See https://www.nih.gov/about-nih/nih-director/statements/advancing-nihs-mission-through-unified-strategy. The August 15, 2025, Priorities Statement superseded the February 21, 2025, statement of the Acting NIH Director, "Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards." The February 21, 2025, statement is no longer in effect. This Staff Guidance supersedes the Staff Guidance issued by OPERA in March 2025 through May 2025 that implemented the February 21, 2025, statement. The prior Staff Guidance is no longer in effect.

Applicability

This Staff Guidance applies to all existing and new awards for grants, cooperative agreements and Other Transactions; however, it does not apply to any grant that is flagged in eRA as the subject of litigation or court orders. ICOs must not subject those grants to the priority alignment policies and procedures described below. Additional guidance will be provided regarding these flags.

Background

On August 15, 2025, the NIH Director issued a Statement of NIH Priorities to provide the overall direction of NIH, to establish and implement general policies respecting the management and operation of NIH programs and activities, and to coordinate and oversee the operation of NIH's Institutes, Centers, and Offices.

Beginning in FY26 ICs must review their full portfolio of ongoing awards for alignment with these NIH August 15, 2025, priorities (and any subsequent addenda). No competing or non-competing awards may be issued until the project has been assessed, and all areas of non-alignment have been addressed.

To assess projects, ICOs must first conduct an evaluation using a computational text analysis tool to scan for terms that may potentially be associated with misalignment with the agency's priorities.

- This review must be conducted for **all** competing applications to be awarded and ongoing projects in the ICO's portfolio, including projects currently in a no-cost extension.
- If the initial text analysis review finds no concerns, ICOs may proceed with the award following standard procedures.
- Any projects that are identified by the text analysis tool as potentially unaligned with agency priorities must be manually reviewed, renegotiated or, if renegotiation is not possible, terminated as outlined below.
- Grants should be reviewed by ICO staff on a case-by-case basis, according to the principles described below and without reference to whether or not the NOFOs under which they were funded are still active. The state of the NOFO can be used as part of the automated scanning process (see below) to help identify applications and grants that are potentially out of alignment because they came in under a NOFO that was taken down and might contain elements that need to be remediated (e.g., Recruitment Plans, etc.). However, after the scanning process is completed, staff should examine each flagged application or grant individually.

Procedures

Project Assessment

As projects approach the next Type 5 or a Type 1 or 2 is moving to To Be Paid status, ICOs must assess each project for alignment with NIH priorities.
ICOs should review awards that are nearing the end of the project period and may be preparing to initiate no-cost extensions to determine if the extension should be allowed.
ICOs are responsible for their respective portfolio reviews.
First, the ICO must use the computational text analysis tool to evaluate the award. This tool is currently maintained for ICO use by NIGMS and looks for terms that have been found to be associated with grants that are not aligned with the NIH's priorities.
If the text analysis tool identifies any potential aspects of the project that do not align with NIH priorities, the appropriate ICO staff must manually evaluate the award using the August 15, 2025 NIH Director's Statement of NIH Priorities and its addenda, if any. The determinations must be linked to the appropriate priority and the ICO must document the specific areas of the project that do not align with the NIH's priorities in their determination. A few clarifying points to note are:

- Pay particular attention to the use in grants of poorly defined, non-scientific or subjective terms and variables, as defined in the August 15, 2025 NIH Director's Statement of NIH Priorities and its addenda, to frame or justify the research. Frequent examples are "health equity" and "structural racism." If these can be replaced with well-defined, scientific concepts that have objective and measurable variables, then the grant can likely be renegotiated to focus on those instead. For example, framing around "health equity" might be refocused to emphasize studying and ameliorating a particular health disparity. In some cases, however, the entire premise of the grant relies on subjective or poorly defined, non-scientific terms, in which case it might not be possible to renegotiate it.
- Health disparities research is within the NIH's priorities as long as it is scientifically justified and the interventions or potential interventions relate to areas that can be directly influenced by healthcare or biomedical science. Examples of areas that would not be directly influenced by healthcare or biomedical science include (but are not limited to) poverty, employment, and immigration.
- NIH-funded research can focus on or include specific populations - such as racial or SG minorities - if it is scientifically justified. For example, the disease/condition could be more prevalent in a certain group, or that group is not currently sufficiently represented in studies of a potential therapeutic to make conclusions about its efficacy or side effects in the group.
    - Specific groups included in research studies should be described using clearly defined, standardized terms. For racial and ethnic groups, OMB's reporting categories (SPD 15) should be used: https://www.census.gov/newsroom/blogs/random-samplings/2024/04/updates-race-ethnicity-standards.html. Terms such as LatinX

that are not consistent with these categories should not be used. Gender should not be used as a synonym for biological sex.

- A clinical study that says it plans to increase the diversity of its patient base is within the NIH's priorities as long as the need for increased patient diversity is scientifically justified.
- Grants intended to increase workforce diversity by granting preferential treatment to individuals based on protected characteristics such as race or ethnicity are not consistent with the NIH's priorities. If they are focused on trainees early in their careers (e.g., undergraduates) they can often be renegotiated because their goals are not tailored to specific groups. Programs to promote diversity in the workforce at later careers stages, such as faculty members, are often harder to renegotiate particularly if they are tailored towards specific groups (e.g., underrepresented populations). Limiting program eligibility or giving preferential eligibility to members of specific groups based on protected statuses such as race, ethnicity or sex is not consistent with the NIH's priorities and is likely to be legally problematic.
  - Grants that are aimed at building research capacity at certain types of institutions, states or regions are within the NIH's priorities if there is a clear need and justification. Examples include resource-limited institutions and IDeA states.
  - Grants supporting research involving federally recognized American Indian or Alaska Native Tribes are within the NIH's priorities.
- Direct foreign awards must be strongly justified in terms of providing unusual talent, resources, populations, or environmental conditions that are not readily available in the United States and must provide the opportunity to significantly advance health sciences in the U.S.
- Please keep an eye out for grants that are overtly political in nature – for instance, take a clear political side rather than adopting a neutral, scientific approach to answering a question – and for grants that contain work that could be construed as lobbying. These grants could violate the NIH's Terms and Conditions of Award: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.5_lobbying_-_appropriation_prohibition.htm?Highlight=lobbying.

- The ICO must ensure the award program aligns with the granting authorities (can consult OPERA as needed). See Item 13 on page one of the Notice of Award. The most common granting authorities that are used include but are not limited to:
  - Research, Career Development, Conference Grants, Research Education Awards: 42 USC 241; 42 CFR 52
  - Training and Fellowship: 42 USC 288; 42 CFR 66
  - NIEHS Hazardous Materials Training: 42 USC 9660a; 42 CFR 65
  - International Research Training Grants:42 U.S.C. 287b; 42 C.F.R. Part 63a
- Internal approval processes may be managed at the ICO level, as long as all decisions are fully documented in the grant file.

- If the ICO determines that the award fully aligns with NIH priorities, the ICO may proceed with issuing the award.
- After the manual review, any projects that are identified as potentially unaligned with agency priories must be renegotiated to bring them into alignment or, if renegotiation is not possible, terminated or not awarded.

Renegotiation

- Please remember that the ICs will need to substantively renegotiate the projects with the recipients; they are not just "changing words." In most cases, some underlying components of the work also need to be altered. Once these renegotiations are done, all changes in scope that were agreed upon by NIH and the Authorized Organizational Representatives (AOR) become new terms and conditions of award, and the recipient must comply with those changes. If NIH discovers that recipients and/or subrecipients have not complied with the new terms and conditions of their award, NIH can immediately take an enforcement action under 2 CFR 200, which includes termination for non-compliance under 2 CFR 200.340(a)(1).
- For awards that can be renegotiated, ICOs must document their determination in a decision memo that outlines the specific areas of the project that do not align with the NIH priorities, and the actions taken to resolve them. In general, 2-3 sentences should suffice for this memo.
- To initiate the updates to the project, the Program Official (PO) must send a written request to the recipient Authorized Organization Representative (AOR) and copy the Grants Management Specialist (GMS).
- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit revised documents as appropriate (e.g., face page, specific aims, abstract, budget, title, etc.) via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO approves the renegotiation, the ICO must upload the updated documentation into the Additions for GM section of the grant folder. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.
- All awards that are identified as out of alignment with NIH priorities **must** be renegotiated before the competing award or the next Type 5 is issued.
- Internal approvals may be managed at the ICO level, as long as all decisions are fully documented in the grant file.
- After NIH and the AOR complete the negotiations, the ICO releases the award. The revised NOA must include a term of award stating that award has been renegotiated, and the recipient must comply with the changes. If the ICO determines that recipients have not complied with the new terms and conditions of their award, the ICO must contact OPERA to determine appropriate remedies for noncompliance (See NIH GPS 8.5.2).
- Grants that have been released for award by the ICOs will then be scanned by eRA.
    - Grants that are flagged by eRA will be sent to the DDER Review Team for further assessment.
    - Reviewers will assess each flagged grant and return a spreadsheet to the IC noting the following categories:
        - In alignment with the NIH's priorities (no highlights).
        - Partially out of alignment and needs additional renegotiations to be in alignment (highlighted in yellow). ICOs must start/restart the renegotiation process to address the issues identified by the DDER Review Team.

- Fully out of alignment and unlikely to be renegotiable (highlighted in red). These are expected to be rare and will be sent to OER for a final determination, to be handled centrally.
- ICOs will be instructed to perform "Stop Release" action for all highlighted grants and eRA will put highlighted grants (yellow or red) on hold until resolved.

Termination

- For awards that are fully out of alignment with NIH priorities and cannot be renegotiated, the award must be terminated. Prior to terminating, ICOs must send OPERA Leadership and copy Jon Lorsch the information identified under Appendix 1 for each award that the IC proposes to terminate. The required information outlines the specific areas of the project that do not align with the NIH priorities, why negotiation is not possible, and an assessment of countervailing reliance factors.
- OPERA will then prepare a draft decision memo on behalf the IC that analyzes each proposed termination and will submit the draft to the IC for concurrence. Once the IC concurs, the memo will be transmitted on behalf of the IC to the NIH Director through Jon Lorsch. The NIH Director must approve the termination before the ICO may proceed with termination.
- OER has updated the NOA templates for all awards issued after October 1 to state that the awards are subject to 2 CFR 200, and to specify the termination provisions of 2 CFR 200.340, including .340(a)(4), which permits terminations for non-alignment with agency priorities. Therefore, prior to terminating the project, the ICO must first ensure that the current NOA being terminated contains this new language prior to proceeding with terminating the award. If it does not, then the IC must wait until the next budget period to issue a NOA (i.e., the next Type 5 award) which will include the updated termination provision.
- If the award is in its final year, the ICO must notify the recipient that NIH will not allow the first automatic no-cost extension (NCE) and notify OPERA so that OPERA can work with eRA to remove the automatic notifications to the recipient. IC's may not terminate the award but must allow it to end naturally.
- For awards currently in an NCE, the ICO must notify the recipient that NIH will not allow any additional NCEs and notify OPERA Leadership. OPERA will place a red bar to award to prevent future NCEs.
- When issuing the NOA to terminate the award, the ICO must use the "Terminated – No longer effectuates the program goals or agency priorities" post-award revision type.

Appendix 1– Information to Provide OPERA for a Decision Analysis

1. IC Designated Official

2. Award Number and Title

3. Cite relevant granting authority (e.g., 42 USC 241and 284 as implemented under 42 CFR Part 52).

4. Insert language from granting authority that outlines the purpose of the award program. Select one of the following options, as applicable. If ICOs identify any activities not covered here, contact OPERA.:

a. Research projects: the statutes authorize NIH to support research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases. Research Project Grants offer support to U.S. domestic institutions as well as foreign entities/components, where appropriate, and are NIHs most commonly used grant for independent research projects.

b. NRSA Training and Fellowship Awards: The statute authorizes NIH to make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards (NRSA) for research (and training to undertake biomedical and behavioral research) in the matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health are directed. The purpose of the Ruth L. Kirschstein NRSA Individual Predoctoral (Parent F31) award is to enable promising predoctoral students to obtain individualized, mentored research training from appropriate faculty sponsors while conducting biomedical research in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training must address the candidate's identified research training and career goals and enhance the candidate's potential to successfully transition to the next phase of their biomedical research career.

c. International Research Training Grants: The statute authorizes NIH to provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences; and provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries. The purpose of this program is to support research training programs for US and foreign professionals and students to strengthen global health research and international research collaboration.

5. Describe the specific award that is being terminated. Include award objectives and any other specific details that are relevant to the termination decision, citing the specific priorities in the NIH Director's statement.

6. Budget period start and end date.

7. Project period start and end date.

8. Confirm that the award states the following:

This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

Any term or condition in this Notice of Award, including those incorporated by reference, that NIH is enjoined by court order from imposing or enforcing, shall not apply or be enforced as to any recipient or subrecipient to which that court order applies and while that court order is in effect.

9. Quote the relevant language from the August 15, 2025, priority statement that relates to the nonalignment identified under the award

10. Describe how the award is not in alignment with agency priorities for NIH. Be as specific as possible. If there are aspects of the award that might weigh in favor of not terminating it (e.g., an aspect might support advancement of a different agency priority), address how terminating the award overall outweighs those aspects.

11. Describe why renegotiation is not possible.

12. Address reliance interests of recipients, beneficiaries of the award program and/or award, and the public generally. Reliance interests include reasonable actions the grantees took based on their expectations for continuation of the award, such as hiring or student recruitment. Also address potential impacts on public health and subrecipients.

EXHIBIT 19

nature

NEWS | 11 August 2026

NIH limits funding for research on the health effects of public policy

US biomedical agency no longer considers policymakers 'mission relevant', leaving dozens of grants in limbo.

By Max Kozlov

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Research about how pollution regulations affect people's health is relevant to policymakers, but the US National Institutes of Health is shifting away from funding such work. Credit: Brandon Bell/Getty

The US National Institutes of Health (NIH) has begun turning away research grant applications for which the "primary function" is informing policymakers and legislators, according to internal documents seen by *Nature*. This means that the agency is likely to fund fewer projects assessing how public policies affect human health.

RELATED



It's a major departure for the world's largest public funder of biomedical research. The NIH has a strong reputation for funding projects relevant to policymakers, including those evaluating the health impacts of firearm regulations, abortion limits and

Inside the new political screening that's stalling NIH grants

environmental protections.

"Policymakers are not considered a stakeholder group within the scope of NIH's mission," the internal documents say. "NIH-funded research must empower decision-making by NIH mission-relevant stakeholder groups", which the documents list as including patients, health-care workers, hospitals and scientists. The change has not yet been formally announced, and there is a lack of clarity inside the agency about how it will be implemented, say NIH officials, who requested anonymity because of the risk of retaliation.

Removing policy-focused projects from the agency's portfolio ignores the reality that policies and social factors fundamentally shape human health, some scientists say. Even the most advanced medical breakthroughs cannot help people if poorly designed distribution policies or social barriers prevent them from reaching the individuals who need them, they say.

"Public policy that is blind to current evidence risks safety and effectiveness," says Meredith Matone, a health-services specialist at the University of Pennsylvania in Philadelphia.

The NIH did not respond to *Nature*'s queries about the change or the agency's rationale for the move.

'Policy' removal

Some NIH staff members learnt about the change in May, when political appointees inside the NIH and those at its parent agency, the Department of Health and Human Services (HHS), began flagging and freezing policy-focused grant applications that had been previously approved by peer reviewers and agency employees. (In an unprecedented move, the administration of US President Donald Trump has added

political appointees to the grant-approval process, *Nature* reported in June.)

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NIH pivots away from agency-directed science

Dozens of applications have since been sent back to NIH programme officers in charge of the proposals, instructing them to remove the word 'policy' and its derivatives and determine whether the proposals can be salvaged, two NIH officials say. More than 3,700 projects funded during the 2025 fiscal year include these words in the project title or abstract, according to the NIH's project database.

The NIH leadership has not provided its employees with a rationale for the shift, but top officials have characterized some of the flagged proposals as 'lobbying', defined by the agency as using federal funds to pay someone to influence a federal employee or member of the US Congress, which violates NIH rules.

Michael Lauer — who for a decade ran the NIH's extramural research programme, which funds scientists across the United States — says he does not think that this type of work could be considered lobbying. "When people do a thorough scholarly assessment of whether heart-attack risk or gun deaths are related to various policies, that's not lobbying, that's science."

Marcia McNutt, a geophysicist who is the former president of the US National Academy of Sciences in Washington DC, is worried about the change at NIH, especially given the growing influence of political appointees in federal grant decisions. Targeting research related to policy, she says, could lead to selective scrutiny of projects, depending on whether they support the position of the Trump administration.

Relevant stakeholders

NIH director Jayanta Bhattacharya spoke about the agency's position on policy research at several health-economics conferences in June. According to a summary of these discussions that was distributed to NIH staff members afterwards, the agency is "setting forth three rules for all NIH research": it must be actionable, rigorous and 'in scope', meaning that it is for "NIH mission-relevant stakeholder groups", which excludes policymakers, the document says.

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NIH grant cuts disproportionately hit minority and female scientists

NIH employees tell *Nature* that there was confusion and backlash after the summary was sent to a group of the agency's scientists. This led to a follow-up e-mail from NIH leadership, clarifying that colleagues at other HHS agencies who set policy, such as at the US Food and Drug Administration, are still considered relevant stakeholders by the NIH. The e-mail adds "that there is still no formal guidance" on these changes.

Without such guidance, NIH employees tell *Nature* that it's challenging to know how to process grant proposals. "What feels hard to me is not really knowing what the people in the front office will find acceptable," one NIH programme official says.

Bhattacharya did not respond to *Nature*'s request for an interview.

Budget considerations?

This is not the first time that the NIH has narrowed the type of research it funds: in 2015, during the presidency of Barack Obama, the agency announced that "applications whose relationship to health is unclear or distantly removed do not fall within the NIH's mission". Such studies included those designed to understand individual financial well-being and those examining the financing of health care.

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NIH staffing shortage could slash number of new grants issued this year

Still, Lauer says that evaluating the health consequences of various policies has been an important part of the NIH mission. The US National Academies of Sciences, Engineering and Medicine, for example, has repeatedly recommended that researchers study how policies on topics such as cannabis legalization and housing affect the health of people in the United States. “Scientists shouldn’t be dictating policy, but scientists should certainly inform policy,” Lauer says.

Anupam Jena, a physician and health economist at Harvard University in Cambridge, Massachusetts, says that health-policy research has historically been incredibly useful. But he adds that the NIH operates on a finite budget, so an agency decision to shift funds away from research related to policy would be reasonable, freeing up money for basic science.

Much of the research that would be no longer in scope for the agency is likely to lie in the social and behavioural sciences, researchers say. These topics have been targeted anew by the NIH in the past two weeks: the agency has stopped funding several ongoing projects studying health disparities that affect disadvantaged groups, and more terminations are planned, according to *Science*.

How Trump 2.0 is reshaping science

Explore *Nature*'s coverage of the Trump administration and its impact on science globally.



1 September 2026

Canada recruits dozens of US scholars — including several science stars

US funding uncertainty was a key factor for several of the researchers heading to Canada. Observers predict more will follow.



20 August 2026

Exclusive: NSF set to issue lowest number of new grants in four decades

The US science-funding agency is withholding $1 billion of its budget so that the money can go to a special White House project.



18 August 202

NIH propo revamp of research g

Proponents ar system create precision, but change could interference.

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doi: https://doi.org/10.1038/d41586-026-02489-2

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Nature (*Nature*) | ISSN 1476-4687 (online) | ISSN 0028-0836 (print)

EXHIBIT 20

STAT PLUS
EXCLUSIVE

Hours after NIH director confirmed, the agency tackles one of his priorities — ending ‘censorship’ in science

Email directs NIH staff to identify grants related to ‘fighting misinformation’



Jay Bhattacharya testifies during his Senate confirmation hearing earlier this month. JIM WATSON/AFP via Getty Images

By Anil Oza March 26, 2025

General Assignment Reporter

In October, Jay Bhattacharya, then a health economist at Stanford University, posted on X: "If you favor government control of misinformation, you are an enemy of free speech."

On Wednesday, on the morning after his confirmation as director of the National Institutes of Health, the agency directed staff to compile a list of grants and contracts related to "fighting misinformation or disinformation" — a step that in recent weeks has preceded the termination of research funding in areas that run counter to the Trump administration's priorities.

The early morning email, marked "URGENT," asked contracting officers at the NIH to respond by "noon today" with information on any contract that "may be related to any form of censorship at all or directing people to believe one idea over another related to health outcomes." It goes on to list examples including contracts to promote vaccine uptake, or public health messages about the "dangers of Covid or not wearing masks."

Staff were also instructed to search for keywords such as media literacy, social media, social distancing, and lockdown. "This should address any contract that could be used to 'censor Americans,'" the email concluded.

Public health and misinformation researchers told of the memo were concerned the move will make vaccines less accessible to those who are susceptible to misinformation, but were largely unsurprised by the targeting of their work because Trump's appointees, including Bhattacharya, have publicly derided efforts to study misinformation.

"One critical component of public health is to work with the public to help them understand how to keep themselves safe and how to keep their neighbors safe. That's one of the most important things that we do in public health," said Carl Bergstrom, a biologist at the University of Washington. "This notion of conflating censorship with basic education and basic public health is very frightening, and very dangerous."

While there's no indication that Bhattacharya, who has yet to be sworn in, had a role in the email, it is consistent with his views. "For the past couple years, Jay Bhattacharya has portrayed himself as a victim of censorship," said Jonathan Howard, a physician who wrote a book on the anti-vaccine movement throughout the pandemic, and has written about Bhattacharya for the blog Science-Based Medicine.

During his confirmation hearing earlier this month, Bhattacharya stated one of his goals for his tenure was to foster a culture of dissent and free speech. “I personally was subjected to censorship by the actions of the Biden administration during the pandemic,” he said. “Science, to succeed, needs free speech, it needs an environment where there is tolerance for dissent.”

Bhattacharya was accused of spreading misinformation when he was at Stanford, including the publication of The Great Barrington Declaration, an open letter that he co-authored that challenged the need for most social distancing efforts and called for less stringent public health measures in the first year of the pandemic. Health and Human Services Secretary Robert F. Kennedy Jr., Bhattacharya’s new boss, has also spread misinformation regarding the risks of vaccinations. He has sued a number of media companies alleging that he was censored, and sued Meta over censorship of anti-vaccine posts by Children’s Health Defense, an anti-vaccine organization that he founded.

“Misinformation has found a home in this presidential administration, and that’s why they are taking action to make it difficult for us to do this research,” said Matthew Motta, a political scientist at Boston University who has researched anti-scientific attitudes.

In recent weeks, the NIH has begun purging its grant portfolio of topics that the Trump administration does not support. On Tuesday, the agency began terminating grants related to Covid-19, and earlier it terminated grants related to researching vaccine hesitancy, and the health of LGBTQ+ people, and diversity, equity, and inclusion.

Researchers who study vaccine misinformation stressed that their work is not akin to “censorship,” as the NIH email suggests, but an integral part of ensuring that people have access to the latest medicine and are aware of potential concerns.

“So much of what we do as vaccine promotion researchers, is trying to understand what real and perceived access barriers get in the way of people vaccinating, and then try to do something to fix that, to provide people with the information they need to make informed decisions,” said Motta. He noted that during his confirmation hearing, Kennedy stated he would not take away people’s access to vaccinations. But, “by taking away this research and by making it impossible for us to understand why it is that some people don’t vaccinate, we really are harming vaccine access. That, to me, does represent breaking the promise that he made under oath.”

The field of studying health misinformation took on a renewed importance during the pandemic, when people could see the effects of false or misleading information. In 2021, Surgeon General Vivek Murthy issued an advisory on health misinformation and the World Health Organization created resources to mitigate the "Covid-19 Infodemic." Throughout that time, however, there was pushback from conservative figures who felt that they were being disproportionately targeted by this work and by social media companies cracking down on misinformation. However, research published last year found that in recent years conservatives were more likely to share misinformation.

There has been a "broad smear campaign" targeting misinformation researchers, said Tim Caulfield, a health policy researcher at the University of Alberta in Canada who studies misinformation. He and colleagues have felt a chilling effect from this administration, even before it has directly cut funding for this research. In planning for a talk in the U.S., Caulfield said the organizers of the talk recommended removing the word "misinformation" from the title given how controversial the term has become.

Several researchers also pointed out the hypocrisy of the administration censoring the terms researchers can use in grants while accusing misinformation researchers of censoring others.

There is "irony in the administration putting this out at the same time that they're themselves on this massive censorship campaign," said Lisa Fazio, a cognitive psychologist at Vanderbilt, who was part of a panel that published a National Academies report on misinformation about science. "They're trying to control the speech that universities and students can and can't use. They're trying to do a lot of things to control free speech, and yet they keep talking about this misinformation, censorship industrial complex."

Fazio and others worry that young researchers will leave the country or stop studying misinformation entirely. Others pointed out targeting this research will ultimately make the NIH's goal of enhancing health more difficult.

"Why do biomedical research if you're not going to tell people what worked and what didn't?" Bergstrom, of the University of Washington, asked.

Correction: The story and headline have been updated to reflect that Bhattacharya has been confirmed as NIH director, though not yet sworn in.

EXHIBIT 21

NIH Director Remarks

NBER Coordinating Center on the Economics of AD/ADRD Prevention, Treatment, and Care
June 18, 2026

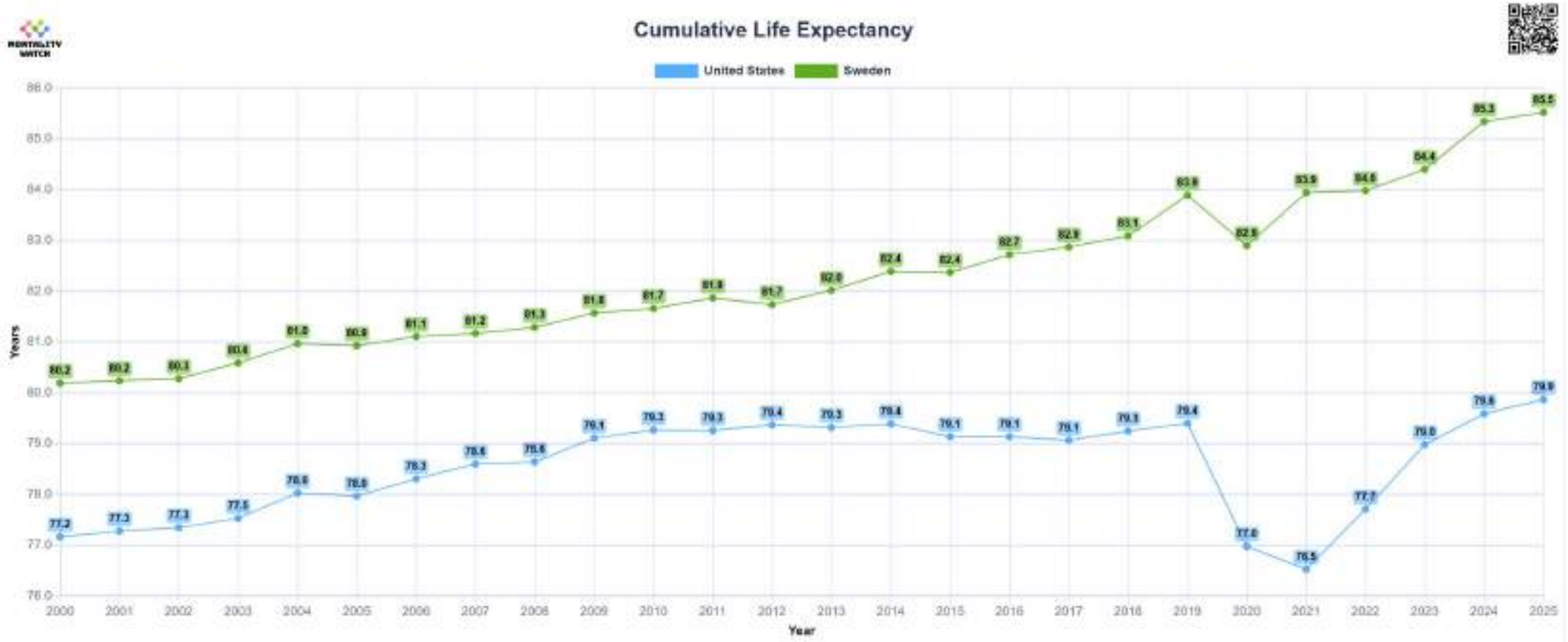
Jay Bhattacharya, M.D., Ph.D.
Director, National Institutes of Health

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems

and the application of that knowledge

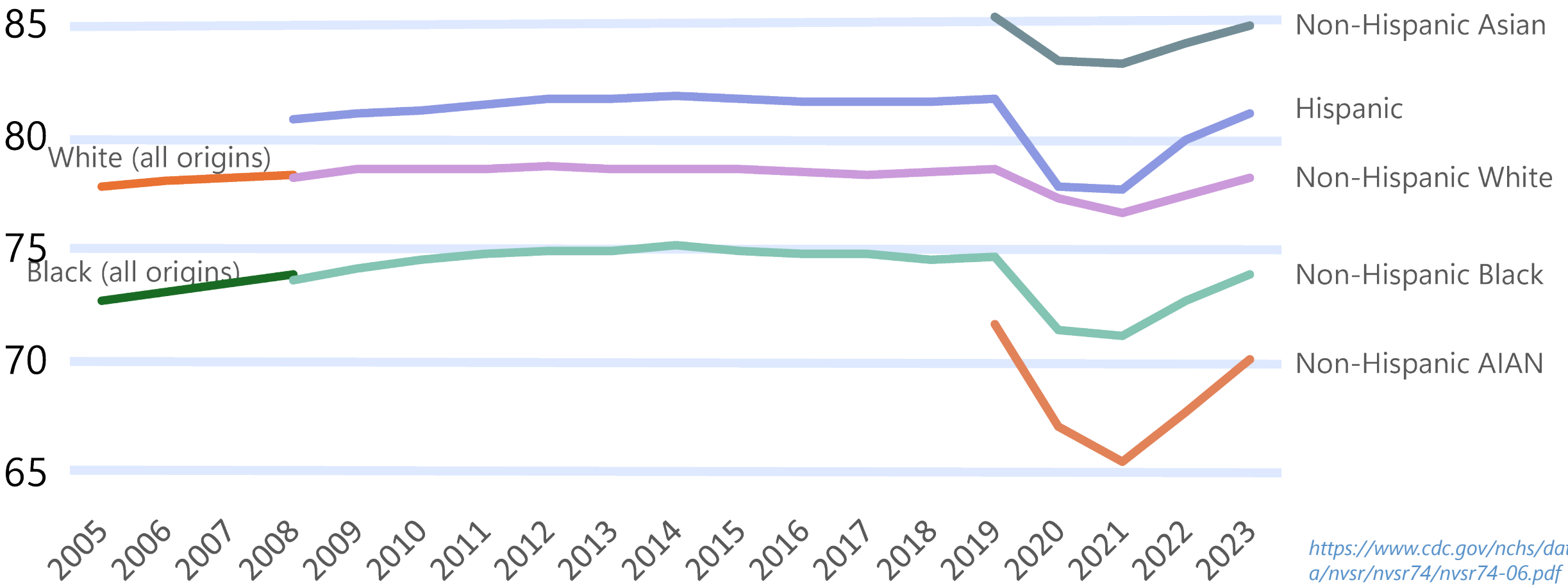
to **enhance health, lengthen life, and reduce illness and disability**

U.S. Longevity Progress is Too Slow



Source: Mortality Watch
https://www.mortality.watch/explorer/?c=USA&t=le&ct=yearly&e=0&cs=line&df=2001&bf=2011&sb=0&ce=1&m=0&sl=1&lg=0

America's Longevity Gap



https://www.cdc.gov/nchs/data/nvsr/nvsr74/nvsr74-06.pdf

Why Aren't We Making More Progress?

Too much **safe, incremental science**

Research doesn't **replicate**

Funding concentrated in few institutions

Solution: Democratizing Science

Too much **safe, incremental science**

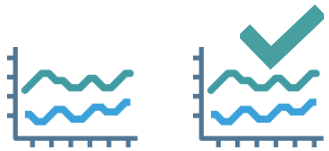




Unified Funding Strategy

Research doesn't **replicate**





Replication initiative

Funding concentrated in few institutions





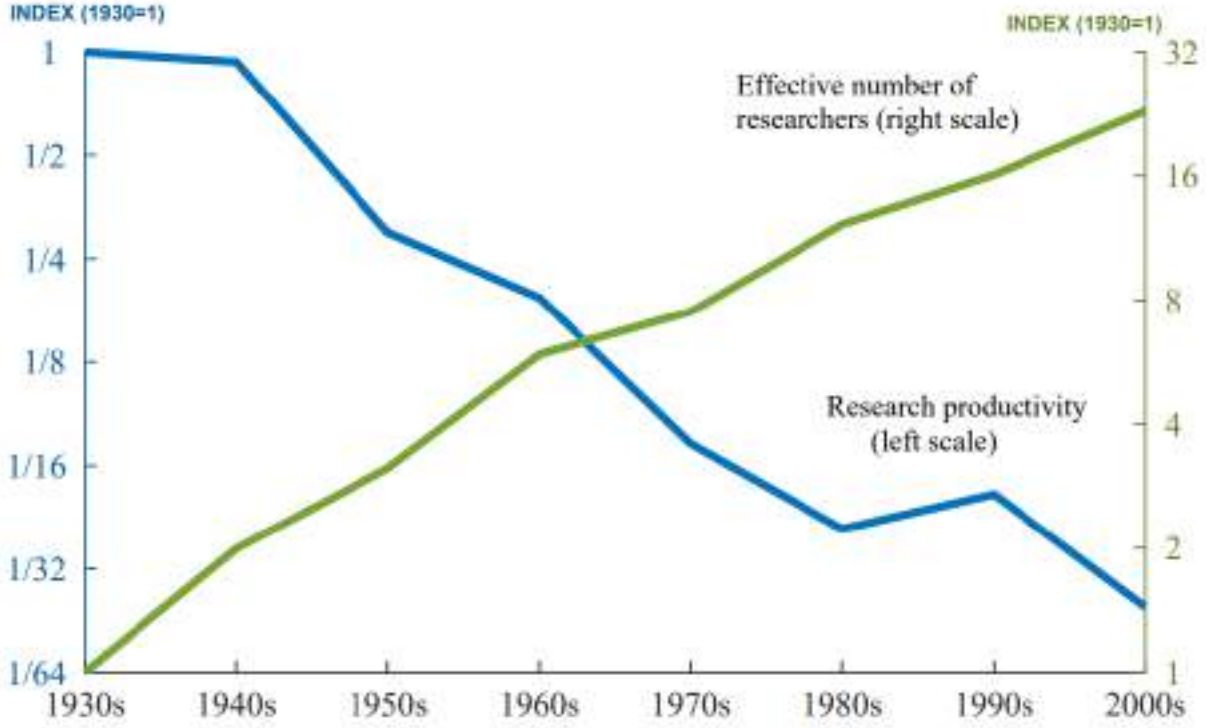
Competitive infrastructure support

Catalyzing Discovery

Two overarching strategies for improving research productivity

- Build opportunities for mission-driving research
- Rewire incentive structures

Figure 2: Aggregate Evidence on Research Productivity



Bloom et al. (2017) "Are Ideas Getting Harder to Find" NBER Working Paper #23782

Building Opportunities for Mission-Driving Research

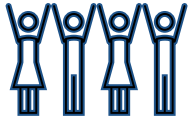
Unified Funding Strategy



Peer review stays
Scientific merit remains the primary standard. Nothing about that changes.



More inputs considered
Score + critiques + portfolio balance + IC priorities + public health needs.



Better outcomes
High-risk ideas, emerging fields, and new investigators get fairer consideration.

✓**Expanding** how NIH uses peer review.

✓**Applying** a fuller picture of merit.

✓**Not** just about paylines. It's a framework shift.

✓**Still** investigator-initiated — **that's core to the purpose.**

Rewire Incentive Structures

Invest in the Science of Replication



Fund replication research



Establish a replication platform



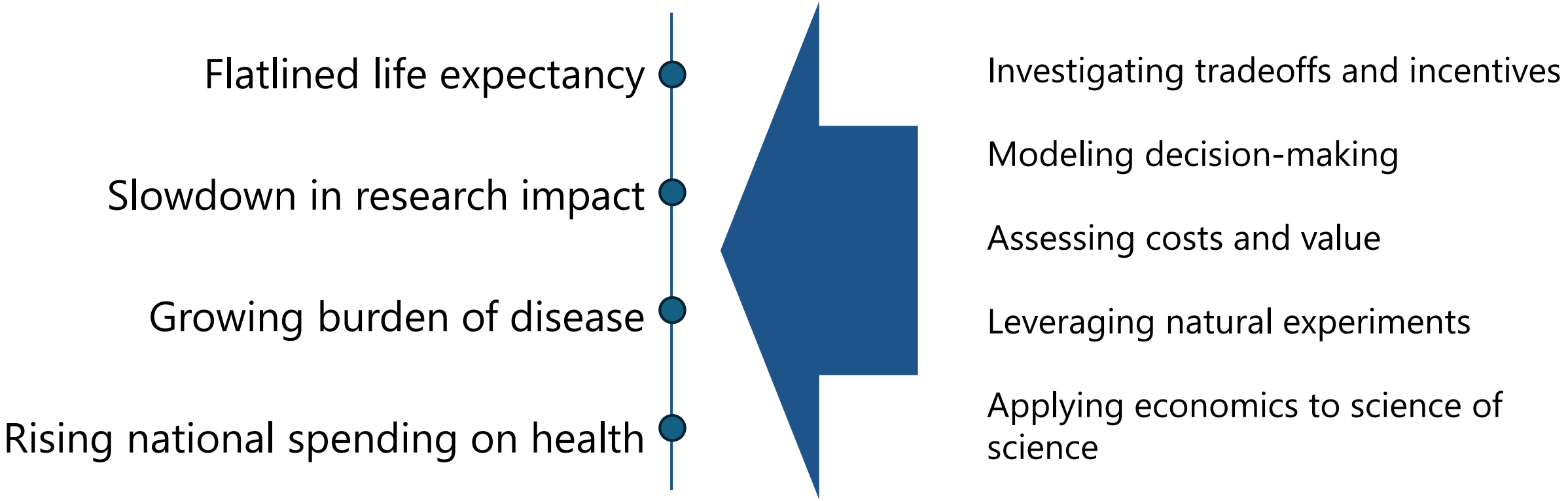
Enhanced visibility through PubMed



New metrics for scientific contribution

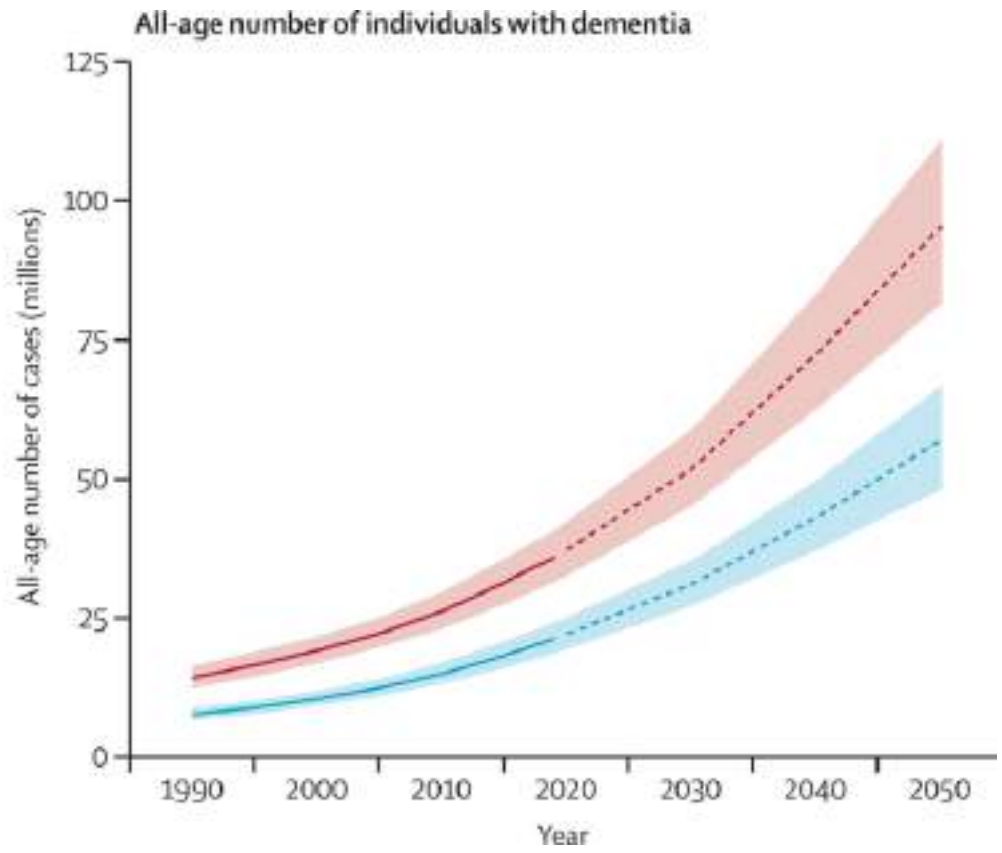
Deploying Health Economics Methods to Drive Forward NIH's Mission

Emerging and Growing Health Challenges Motivate the Deployment of Economic Methods



Use Case of Deploying Economic Methodology

Assessing Value of Lecanemab



GBD 2019 Dementia Forecasting Collaborators. (2022). "Estimation of the global prevalence of dementia in 2019 and forecasted prevalence in 2050: an analysis for the Global Burden of Disease Study". *The Lancet Public Health.*

Economics can identify high value treatments

Long-term value of lecanemab to individuals and families

Bryan Tysinger [1], Yifan Wei [2], Hanke Heun-Johnson [1], Julie M Zissimopoulos [1,✉]

▸ Author information ▸ Article notes ▸ Copyright and License information

PMCID: PMC12394178 PMID: 40895811

Alzheimer's & Dementia
Translational Research & Clinical Interventions

"Over time, lecanemab treatment reduced medical costs, hours of care required from care partners, and improved quality of life."

Use Case of Deploying Economic Methodology

Econometric Analysis Provides Causal Evidence

NIA and NINDS
Multidisciplinary Workshop
June 2026

"Zoster Vaccine and Dementia Risk Reduction: Evidence and Mechanisms"

Featured Paper:



Article | Open access | Published: 02 April 2025

A natural experiment on the effect of herpes zoster vaccination on dementia

Markus Eyting, Min Xie, Felix Michalik, Simon Heß, Seunghun Chung & Pascal Geldsetzer

Nature **641**, 438–446 (2025) | Cite this article

622k Accesses | **177** Citations | **7406** Altmetric | Metrics

"By taking advantage of the fact that the unique way in which the zoster vaccine was rolled out in Wales constitutes a natural experiment, and examining each possible remaining source of bias, our study ***provides evidence that is more likely to be causal in nature*** *than the existing, exclusively associational, evidence on this topic."*

Three Principles for NIH-Funded Research

NIH Research Must Adhere to Three Principles

In-Scope

Rigorous

Actionable

Three Principles: In-Scope

In-Scope

Research relates to (1) NIH's mission, goals, or priorities, and (2) variables that could be **influenced by biomedical research, healthcare, or public health.**

Considerations for economists

Clearly explain how your research **builds evidence for stakeholders within scope of the NIH mission**, which include:

- Individuals making health decisions.
- Patient populations.
- Healthcare professionals.
- Hospitals.
- Scientists and engineers/developers driving forward biomedical research and technology.

Note that research whose primary aim is to inform policymakers is **not in-scope** for NIH funding.

Three Principles: Rigorous

Rigorous

Methodological rigor includes testing falsifiable hypotheses, assessing outcomes that are clearly measurable, delineating between cause and correlation, and taking a collaborative approach.

Considerations for economists

Continue deploying research methods designed to **identify cause** and clearly emphasize the mechanism of interest.

This Coordinating Center is a beacon for **interdisciplinary applications of economic methods**. Connecting with other fields to collaboratively tackle health challenges is encouraged.

Three Principles: Actionable

Actionable

High-impact and takes a **solutions-oriented approach** to generating evidence.

Considerations for economists

Emphasize the ways in which findings may be **meaningfully deployed** to improve health.

Ensure that data, documentation, and code **enable replication**, which is essential for translating accurate evidence into action.

Principles Provide a Foundation for Advancing NIH's Mission

NIH National Institutes of Health
Turning Discovery Into Health

Actionable

Builds findings that can be readily deployed.

Rigorous

Propels forward discovery through gold-standard methods.

In-Scope

Ensures evidence is relevant for NIH objectives.

Questions? Ideas?

Contact us:

Health_Economics@nih.gov


NIH
National Institutes of Health
Turning Discovery Into Health

EXHIBIT 22

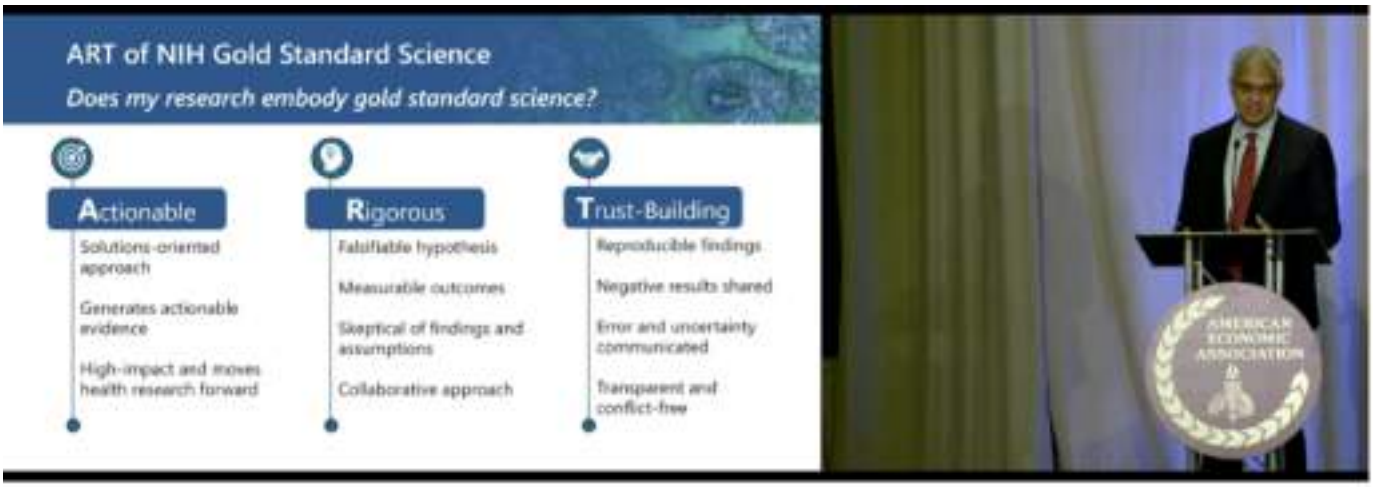
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Categories: Newsletter, Newsletter Issue 2026:1

NIH Signals New Era for Health Economics

By Kosali Simon

Highlights from Dr. Jay Bhattacharya's remarks at the 2026 AEA Meetings



At the 2026 AEA Meetings, NIH Director Dr. Jay Bhattacharya delivered a clear message to economists: **NIH is eager to engage health economics and interdisciplinary teams to achieve its mission** of advancing knowledge to improve health and longevity. He argued that stagnant US life expectancy, rising chronic disease burden, and unsustainable health spending cannot be solved by biomedical science alone. Health economics, he emphasized, must be a full partner.

Dr. Bhattacharya announced a major shift in NIH policy. He described prior restrictions that narrowed the scope of economics research eligible for NIH funding that are now removed. Going forward, health

economics proposals will be evaluated like any other science at NIH, based on rigor, relevance to health, and potential for impact.

He encouraged economists to submit work that is **actionable, reproducible, and testable (ART)**, particularly research that informs financing, incentives, workforce challenges, consumer decision making, and efficiency in care delivery. His message was both an invitation and a challenge: if economists want to shape the future of population health, NIH is now explicitly asking them to apply, and, to be involved in the review process. In his own words, "Biomedical discovery alone has not delivered population health gains. Economics is essential if we want longer, healthier lives".

More details

1. Goals as NIH Director

Dr. Bhattacharya framed his remarks around five goals for his tenure as NIH Director, focusing this talk on one priority: **improving population health**. He argued that despite decades of scientific breakthroughs, the US has failed to deliver sustained improvements in life expectancy or quality of life. Health economics, he said, is indispensable to understanding why. NIH is repositioning health economics from a peripheral or constrained activity to a core component of its mission.

2. The problem: health outcomes, productivity, and costs

Dr. Bhattacharya highlighted several trends motivating the policy change:

- US life expectancy has stagnated since about 2010, with COVID producing a sharp decline and only partial recovery.
- Chronic diseases such as diabetes, obesity, and Alzheimer-related dementias continue to expand, driving morbidity and long-term costs.
- Research productivity appears to be slowing, with greater investment yielding smaller marginal gains.
- Health spending continues to rise toward 20 percent of GDP without commensurate improvements in outcomes.

Together, these patterns suggest a system that generates innovation but struggles to translate it into broad, sustained health gains.

3. NIH's track record with economics

He emphasized that NIH already has a strong legacy of enabling economics research. He cited long-standing investments such as the Health and Retirement Study, SEER cancer registries, and Alzheimer's research infrastructure, which have supported decades of influential economic and policy analysis.

Economists have already shown their value within NIH-supported ecosystems, and expanding this role is both logical and necessary.

4. The policy shift: removing limits on health economics

The centerpiece of the talk was to announce that **NIH will remove prior limits that constrained health economics research.**

- Economics and health economics proposals will be judged under the same standards as other sciences.
- There are no blanket topic exclusions, provided the work advances NIH's mission to improve length and quality of life.
- Relevance to health outcomes must be explicit, but the pathway can be policy, delivery, financing, or behavior.

This was framed as a correction to earlier guidance that had unintentionally narrowed the scope of valuable research. According to Dr. Bhattacharya, "If the work advances health and is scientifically rigorous, it belongs at NIH".

5. What NIH wants to fund: ART expectations and standards

Dr. Bhattacharya outlined what successful NIH-funded health economics should look like. He emphasized three core attributes:

1. **Actionable:** Research should inform decisions, interventions, or policy design, not just describe problems
2. **Reproducible:** Clear hypotheses, transparent methods, data sharing, and openness to null results are essential
3. **Testable:** NIH favors work that generates falsifiable claims and evidence that can be validated or challenged.

He also stressed interdisciplinary collaboration when appropriate, particularly with clinicians, biomedical scientists, and public health researchers.

6. Illustrative priority areas

He offered examples of economic research domains that naturally align with NIH priorities:

- Financing and incentive design in health care
- Health care workforce supply, demand, and organization
- Consumer decision making and behavioral responses
- Cost, efficiency, and delivery system design

- Economic burden and value assessment for chronic and aging-related diseases

These examples were explicitly described as illustrative, not restrictive.

7. A direct call to economists

Dr. Bhattacharya closed with an unambiguous invitation. Economists, he said, should view NIH as a serious home for investigator-initiated health economics research. Addressing the chronic disease crisis and fiscal pressures in health care will require economists working alongside biomedical and clinical scientists. He emphasized that NIH is not seeking advocacy, but rigorous science that can inform real-world decisions.

What this means for ASHEcon researchers

1. NIH should now be considered a viable funding destination for work that links economic mechanisms to health outcomes. Successful proposals will clearly articulate health relevance, prioritize reproducibility, and aim for actionable insights
2. Projects that integrate economics with clinical, biomedical, or implementation expertise are likely to be especially competitive
3. This shift signals a broader recognition that improving population health requires not just new treatments, but better incentives, delivery systems, and decision environments

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