EXHIBIT 29

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF APHA MEMBER 2

I, [redacted], pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is [redacted] and I serve as the Managing Director for [redacted] a small company dedicated to providing world-class education focused on pain research and neuroscience. In this position, I develop and coordinate educational modules, including webinars, conferences, and lectures for the continuing education of clinicians and researchers. I have held this position since I began working for [redacted] at the beginning of 2016.

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

3. I have 20 years of experience working on accreditation systems and instructional design, and I have been working in pain and neuroscience for the last decade. I began my career in this field at [redacted], where I served as the [redacted], and then worked at [redacted] as the [redacted]. I have also served as a [redacted] for the [redacted] for the last five years. My professional goal is to help other people do their jobs better.

4. Helping people who experience chronic pain is something I'm passionate about because it is one of the largest public health crises that is rarely discussed. Nearly 25% of American adults experience chronic pain and over 8% of American adults have chronic pain that frequently

limits their life or work. Children are also vulnerable to the impacts of chronic pain; they experience it at similar rates and it critically impacts their development and their lifelong relationship to healthcare. The economic burden of pain in the United States is more than the annual costs (in 2010 dollars) of heart disease ($309 billion), cancer ($243 billion), and diabetes ($188 billion) and nearly 30% higher than the combined cost of cancer and diabetes. Adjusted for inflation, chronic pain costs the United States nearly $1 trillion annually. I am also passionate about solving the problem of chronic pain because of its close relationship to the devastating effects of the opioid crisis. Almost one in four American adults know someone struggling with an opioid addiction. These are issues that affect almost all of us, and they deserve close attention.

5. I am a member of APHA and pay $230 in annual dues.

6. I am the Program Director for an R24 grant awarded by the National Institute of Health ("NIH"). R24 grants are issued by NIH to provide tools and resources in support of ongoing research. The grant award number is [redacted].

7. The grant funds the development and operation of a Coordinating Center for National Pain Scientists ("Coordinating Center"). As described in the Notice of Funding Opportunity ("NOFO") [redacted], the Coordinating Center is designed to be "a central facilitator for integrating training and mentoring across a network of mentors and early-stage investigators funded by the NIH," including NIH trainees, fellows, and others. The purpose of the Coordinating Center is to "enhance the training experience of new pain researchers across the continuum of basic, translational, and clinical research and create a vast network of NIH-funded pain researchers to promote multidisciplinary collaborations in pain research." A true and correct copy of [redacted] is attached hereto as Exhibit A.

8. The creation of the Coordinating Center is in direct response to the NIH Helping to End Addiction Long Term ("HEAL") Initiative®'s goal of building the pain workforce because there are not enough pain researchers to enhance and develop evidence-based approaches for pain management. The NIH has described this as an "urgent need" and has identified several factors that have contributed to a leaky workforce pipeline to pain research, including: challenging research environments for clinicians, a high departure rate from the field among senior researchers who serve as mentors for more junior researchers, a lack of structure for early-stage investigators to learn from experienced investigators, and a lack of collaboration between pain management researchers across disciplines. Furthermore, the Coordinating Center fills a gap in

NIH's structure because there is no NIH Institute for Pain that would normally serve as the coordinating and centralization entity for pain-related research and resources.

9. The Coordinating Center also responds to the priorities of other NIH Institutes and Centers ("ICs"). There are currently 27 ongoing clinical pain studies within the HEAL Initiative and there are thousands of more pain-related research programs across the ICs. This has led to a disjointed and uncoordinated approach which is a hinderance to the effective, multidisciplinary, and collaborative research that is needed to address such a grave public health problem. The Coordinating Center serves the function of connecting these researchers, educating them about the developing science of each other's studies, and helping to accelerate innovate approaches to pain management and treatment.

10. The Coordinating Center is also aligned with President Trump's Make America Healthy Again Executive Order and Commission which is tasked with addressing the key health priority of chronic disease. As described above, chronic pain is a largely silent public health crisis.

11. Applicants to this NOFO and all training-related grants were required to include elements from the Notice of NIH's Interest in Diversity NOT-OD-20-031. Specifically, the NOFO said,

> In addition to scientific diversity, applicants should strive to incorporate diversity in their team development plan. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust. Please refer to Notice of NIH's Interest in Diversity NOT-OD-20-031 for more details.

A true and correct copy of NOT-OD-20-031 is attached hereto as Exhibit B.

12. Because of this requirement, the grant application for the Coordinating Center that I prepared described how the Coordinating Center would be open and available to all pain researchers, including those from underrepresented backgrounds, such as women, Black, and Latinx researchers, as well as researchers with a low socioeconomic status and researchers with disabilities. The goal of the Coordinating Center is to improve mentorship and collaboration among pain researchers and clinicians, so it is critical that *all* researchers feel welcome. However, explicit mention of underrepresented groups in the grant application was only included

because it was an NIH requirement at the time, and the proposed budget did not dedicate any financial resources to this ancillary aim of diversifying the workforce. The operation of the Coordinating Center complies with federal, state, and local laws. We have never performed any preferential hiring, nor have we distributed any travel scholarships based upon demographic categories.

13. Putting together the grant application for the Coordinating Center was extremely time intensive. During the final weeks, I worked 196 hours over 11 days. I stopped going into the office, slept some nights but not all, and at times forgot to eat for many hours. I met with software platform vendors and other vendors so I could pull together a budget justification that was accurate to the dollar. Because instructional design methodology is my specialty, I dedicated roughly half the application to describing the innovative approaches I developed to meet the needs of NIH. I also spent hours meeting with NIH program officers during the application process so I could fully understand NIH needs, including the scale of the Coordinating Center. During the competitive review process, NIH followed up with me for additional information, and the responses to those requests were also time intensive.

14. In September of 2022, NIH issued a Notice of Award ("NOA") for $6,882,205 for a period of three years (to end August 31, 2025) to fund the Coordinating Center. It was communicated to me that I would be able to apply for a Type 4 Non-Compete Renewal at the close of the grant to continue funding the Coordinating Center for at least another two years. A true and correct copy of that NOA is attached hereto as Exhibit C.

15. Since its launch, the Coordinating Center has been a massive success. It is the first and only mechanism for consolidating the entirety of pain researchers across the spectrum of basic, clinical, and translational research, at all career stages. This is primarily accomplished through an online hub that—among other things—indexes research studies, provides up-to-date contact information to enhance collaboration opportunities, connects researchers with clinical doctors who may have ready study participants, and aggregates funding and job opportunities. For example, a user of the hub who is interested in understanding pain associated with fibromyalgia can type the term into the network and instantly be connected with all the researchers who are doing this work. The Coordinating Center acts as a digital resource center and provides tools and support for other NIH-funded pain research programs, consolidating their resources into one

location while reducing the need for redundant, more costly infrastructure at each study site. To date, the online platform has nearly 5,000 users and the number is growing daily.

16. Another major way the Coordinating Center achieves its goals is through an annual conference that gathers pain researchers together to accelerate "bench to bedside" treatment, which is the process of translating scientific discoveries made by researchers into practical applications and improved patient care. At the conference, researchers have the opportunity to hear directly from people who have the conditions they aim to treat, which helps them develop new hypotheses or narrow in on hypotheses worth further testing. This annual meeting also serves as a required in-person investigator meeting for pain research programs funded under the HEAL Initiative and through individual ICs. It is the only place for many of these investigators and their research teams to meet in-person, collaborate, and connect with other NIH-funded pain researchers. By centralizing the in-person meetings for various studies and programs, the Coordinating Center has helped to reduce redundancy for multiple meetings, centralize planning resources, and approach pain research efforts as a holistic group instead of the status quo of individual meetings for each study. This has reduced overall costs for affiliated meetings, while enhancing efficacy. Overwhelmingly, participants say that they were "able to network with researchers from across the continuum of basic, translational, and clinical research," and that they now "plan to collaborate with at least one other researcher from a discipline different than their own."

17. To make the Coordinating Center as successful as it's been, I've had to hire three dedicated staff people: a Conference and Community Coordinator, a Community Engagement Coordinator, and a Digital Media Specialist. One hundred percent of their time is allocated to the Coordinating Center. I also spend approximately 55% of my time on the Coordinating Center.

18. And, in 2024 NIH issued a NOA to [redacted] for a Supplemental Award to support the HEAL PAIN Researcher Cohort Program ("PAIN Cohort Program"), an interdisciplinary training program among postdoctoral researchers pursuing careers in pain and addiction science. The Supplemental Award was a 5-year grant that required an annual Non-Compete Renewal. The first-year award was for $850,595, and because it is a Supplemental Award, the budget and project period end dates are the same as the parent award, described in paragraph 14 above. The Supplemental Award number is [redacted]. A true and correct copy of the NOA reflecting the Supplemental Award is attached hereto as Exhibit D.

19. The PAIN Cohort Program utilized the Coordinating Center to help foster collaboration and a shared learning experience across six universities: the University of Utah, Mass General Brigham, Stanford University, University of Michigan, University of Florida, and Washington University in St. Louis. Each university, in turn, recruited four trainees under the Ruth L. Kirschstein National Research Service Awards ("NRSA") program (T90 awards) and one trainee under the R90 grant program to bring postdoctoral researchers from various disciplines together to learn from one another. For example, one postdoctoral trainee might be from the school of dentistry and another from the school of engineering and through the program, they have the opportunity to develop innovative treatments and translate research findings into clinical practice.

20. The PAIN Cohort Program emphasizes mentorship, career development, and hands-on research experience, and the Coordinating Center is a critical tool for achieving those goals. The Coordinating Center provides the necessary infrastructure for trainees to coordinate with one another across institutions. Through the Coordinating Center, trainees can do their own research planning and develop materials to support that research. To support this collaborative effort, I redesigned a training curriculum so that it could work on a national scale and so trainees could learn in a timely and effective manner, including a weekly webinar series on pain research and soft skills. An added benefit of using the Coordinating Center as the central hub for the PAIN Cohort Program is that the materials and resources developed through the PAIN Cohort Program are also available to the larger Coordinating Center network. Additionally, the Coordinating Center establishes an enduring archive of this critical work.

21. I spend about 30% of my time working on the PAIN Cohort Program, meaning that 85% of my time is spent working on these two NIH-funded projects.

22. Given the success of the Coordinating Center, there has never been any indication that the Non-Compete Renewal I was set to apply for this year would not be granted. In fact, just last year I was awarded the NIH [redacted] Award for the work I've done on the Coordinating Center.

23. However, on March 21, 2025, before that renewal application was due, I received a termination letter from the NIH notifying me that my award was terminated. The letter said:

> This award no longer effectuates agency priorities. 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.

A true and correct copy of the termination letter is attached hereto as Exhibit E.

24. The reasons given in the termination letter are inconsistent with the work of the Coordinating Center. The Coordinating Center does not spend any money on diversifying the biomedical research field. The Coordinating Center aims to enhance the field for all pain researchers, regardless of their race, gender, sexual orientation, or any other identity that might be understood to fall into that classification.

25. The termination letter also did not define the terms within it. Because the terms do not describe the work that the Coordinating Center does, it is unclear to me what criteria NIH used to determine that the Coordinating Center "no longer effectuates agency priorities."

26. When I reached out to my Program Officer to get clarity about why the funding had been terminated, I was informed that the IC had not been consulted about the termination of the grant and my Program Officer had also not been informed.

27. The next weekday after receiving the termination letter, on March 24, 2025, I appealed pursuant to the instructions in the termination letter. In drafting the appeal, I was left to guess how NIH applied the terms used in the letter to the Coordinating Center. I received an acknowledgment of receipt of the appeal, two weeks later, on April 7, 2025.

28. After submitting my appeal, I received a revised NOA with a revised project period end date of March 21, 2025. The revised NOA stated that the award is "related to DEI" and "no longer effectuates agency priorities" and was terminated for those reasons. A true and correct copy of the revised NOA is attached hereto at Exhibit F.

29. Because the Supplemental Award is connected to the Coordinating Center award, it has also been terminated. I received a revised NOA with a new project period end date of March 21, 2025. My Supplemental Award Program Officer told me that they had not been informed about the termination of my Supplemental Award. A true and correct copy of the revised Supplemental NOA is attached hereto at Exhibit G.

30. The impact of this termination is severe and dire. In a conversation with my grants manager at NIH, I was told that NIH would not cover unliquidated obligations that have already

been made in reliance on this funding. I have asked for this policy in writing, but have not yet received it.

31. If this is true, I may be faced with up to $1 million to pay for obligations already committed for the upcoming annual conference currently scheduled for June. For example, for almost two years, we've had a nearly $500,000 contract with the hotel that is set to host the conference. We also have a $120,000 planned expense for audio/video services for the conference. Additional food and beverage costs are also potentially on the line. If [redacted] is forced to pay these costs out-of-pocket, it would bankrupt the business.

32. Conference travel support was also funded through the grant. To date, approximately 100 people have applied for this travel support, and I must now determine who has been approved for that support and contact them to find out if they've purchased tickets that they now may not be reimbursed for. This poses a particularly upsetting challenge, since those attendees applied for travel support because they are unable to afford the costs on their own. Relatedly, many other grant programs throughout the NIH include requirements that their researchers attend the conference. If the conference is cancelled because of the termination, all the researchers who have already purchased plane tickets or made other travel arrangements have now wasted those federal funds. Likewise, it is unclear to me what will happen regarding faculty member reimbursements.

33. Even if NIH provides funding to cover these obligated costs, the conference cannot move forward, and all these expenditures will be wasted.

34. Additionally, the day that I received the termination letter, I had to furlough the three staff people who work with me on the Coordinating Center because 100% of their time was spent supporting this program.

35. I also am no longer receiving a salary, despite the time and costs associated with closing out the grant and resolving the financial burden caused by NIH's abrupt grant termination.

36. [redacted] does not have a fallback plan. As the Coordinating Center work scaled up over the years, our other educational programs have necessarily had to scale back. Other budget lines that kept us afloat in the past are no longer there.

37. Perhaps most concerning is the impact the virtually overnight disappearance of the Coordinating Center will have on the prospect of responding to the public health crisis of chronic pain and addiction. Without the Coordinating Center, researchers will go back to being siloed,

critical studies will struggle to find collaborators, promising developments in the field will not be shared broadly, and the scientists tasked with finding a solution to this critical problem will no longer hear from people with chronic pain in such an effective manner.

38. I am seeking to file this declaration under seal because I am scared for my own security, especially that I will get doxed. The current climate is particularly hostile and even though I believe NIH still intends to do good work, my association with this case could make it seem like I am oppositional to NIH's interests or biomedical research in general, when that is not the case. I am also worried that involvement in this case may jeopardize future NIH funding opportunities. Finally, I am also worried that my involvement in this case could have longer term negative consequences on my career because broad knowledge that my funding was terminated by NIH may suggest that I was not good at developing and providing continuing education, when that too is not the case.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 23 day of April, 2025.

[redacted]

EXHIBIT A

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

National Institute of Neurological Disorders and Stroke (NINDS (https://www.ninds.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))

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

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

Funding Opportunity Title

Emergency Awards: HEAL Initiative: Coordinating Center for National Pain Scientists Career Development (R24 Clinical Trial Not Allowed)

Activity Code

R24 (/[redacted]_results.htm?text_curr=[redacted]

Announcement Type

Reissue of [redacted]

Related Notices

None

Funding Opportunity Announcement (FOA) Number

[redacted]

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

[redacted]

Funding Opportunity Purpose

HEAL is issuing this FOA in response to the declared public health emergency issued by the Secretary, HHS. Please see Determination that a Public Health Emergency Exists Nationwide as the Result of the Opioid Crisis (https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx) as renewed in Renewal of the Determination that a Public Health Emergency Exists Nationwide as the Result of the Continued Consequences of the Opioid Crisis (https://www.phe.gov/emergency/news/healthactions/phe/Pages/Opioids-6Oct2021.aspx).

There is an urgent need for more research to establish best practices in the pain management field, however, there is a limited workforce pipeline of pain researchers to meet NIH's long-term goals of providing effective non-opioid options for the treatment of pain conditions and better pain management overall. The Interagency Pain Research Coordinating Committee (IPRCC) has identified the workforce problem as a barrier for new pain research, and has identified factors that contributed to it, including challenging environments for clinicians to practice research and a high departure rate among senior investigators and mentors. The IPRCC also identified a need for more structured opportunities for early-stage investigators to learn from experienced investigators. The pain management field has further recognized that basic, translational, and clinical researchers do not regularly collaborate when developing grant applications. If pain management researchers across all disciplines were to work together, it would enhance the innovation, relevance, and practical application of pain management research.

To support the NIH HEAL Initiative's response supporting new investigators, promoting multidisciplinary collaborations among pain researchers, and identifying innovative treatments to manage pain, this FOA invites applications for the Coordinating Center for National Pain Scientists (CCNPS). The CCNPS will be a central facilitator for integrating training and mentoring across a network of mentors and early-stage investigators funded by NIH (e.g., NIH trainees, NIH fellows, and Career Development Awardees). The main purpose of the CCNPS is to enhance the training experience of new pain researchers across the continuum of basic, translational, and clinical research and create a vast network of NIH-funded pain researchers to promote multidisciplinary collaborations in pain research. The CCNPS will create and run a coordination center to connect NIH-funded pain researchers with each other with the goal of enhancing the innovation, relevance, and practical application of pain management research, as well as increase communication among pain management researchers across all disciplines.

Key Dates

Posted Date

May 05, 2022

Open Date (Earliest Submission Date)

June 15, 2022

Letter of Intent Due Date(s)

30 days before application due date

Application Due Date(s)

07/15/2022

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

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

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

Not Applicable

Advisory Council Review

Not Applicable

Earliest Start Date

December 2022

Expiration Date

July 16, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.php?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

There is an urgent need for more research to establish best practices in the pain management field, however, there is a limited workforce pipeline of pain researchers to meet NIH's long-term goals of providing effective non-opioid options for the treatment of pain conditions and better pain management overall. The Interagency Pain Research Coordinating Committee (IPRCC) has identified the workforce problem as a barrier for new pain research, and has identified factors that contribute to it, including challenging environments for clinicians to practice research and a high departure rate among senior investigators and mentors. The IPRCC also identified a need for more structured opportunities for early-stage investigators to learn from experienced investigators. The pain management field has further recognized that basic, translational, and clinical researchers do not regularly collaborate when developing grant applications. If pain management researchers across all disciplines were to work together, it would enhance the innovation, relevance, and practical application of pain management research.

This FOA invites applications to develop a Coordinating Center for National Pain Scientists (CCNPS) that will support the NIH HEAL Initiative's goal of supporting new investigators, promoting multidisciplinary collaborations among pain researchers, and identifying innovative treatments to manage pain. The CCNPS will be a central facilitator for integrating training and mentoring across a network of mentors and early-stage investigators funded by NIH (e.g., NIH trainees, NIH fellows, and career development awardees). The CCNPS will also synergize the specific efforts of NIH HEAL Initiative's two previously released FOAs (a K24 (NOT-NS-21-026 (https://grants.nih.gov/grants/guide/notice-files/NOT-NS-21-026.html)) to support mentors and a K12 (RFA-NS-22-045 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-22-045.html)) to develop a structured mentorship/career development program) which are in response to the need to increase the clinical research workforce. The main purpose of the CCNPS is to enhance the training experience of early-career researchers and investigators who are new to pain research across the continuum of basic, translational, and clinical research and create a vast network of NIH-funded pain researchers to promote multidisciplinary collaborations in pain research. The CCNPS will create and run a

coordination center to connect NIH-funded pain researchers with each other with the goal of enhancing the innovation, relevance, and practical application of pain management research, as well as increase communication among pain management researchers across all disciplines.

Coordinating Center for National Pain Scientists Career Development

This program would serve as a central facilitator to integrate training and mentoring across a network of all early-stage pain investigators funded by NIH (e.g., NIH trainees, NIH fellows, and Career Development Awardees) and pain mentors funded by Institutes. The goal is to enhance the experience of all newly funded NIH pain researchers across the spectrum of basic, translational, and clinical research and to promote multidisciplinary research that is meaningful for those living with pain. The CCNPS should ultimately be an engaging network where: 1) all NIH funded early-stage pain investigators can connect and learn from NIH funded pain mentors across the U.S.; 2) early-stage NIH funded investigators can learn from and collaborate with each other; 3) collaboration along the continuum of pain research is facilitated. Additionally, the CCNPS wouldbe required to organize and host an annual meeting that should be widely attended by NIH funded pain researchers across the entire research continuum (i.e., basic, clinical and translational researchers) and acrosscareer levels. Attendance at this meeting will be mandatory for the scholars funded by an accompanying K12 (RFA-NS-22-045 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-22-045.html)). Attendance at this meeting will be recommended for all NIH-funded pain early-stage investigators (researchers on K grants, T grants, F grants, etc.). The CCNPS will be responsible for promoting this meeting and networking opportunities to NIH-funded early-stage investigators and mentors.

Key components of the program:

- Create a governing body composed of multidisciplinary pain researchers and pain patients from across the United States.
- Create a networking system to connect pain researchers across the continuum of pain research, from all disciplines, and at all career levels.
- Create a medium that facilitates communication between basic, translational, and clinical researchers.
- Plan and host an annual meeting for all NIH-funded pain trainees and mentors.
- Disseminate information about the annual meeting, collaboration and education events, accomplishments of trainees, etc.
- Regular hosting of collaboration and educational events to connect early-stage investigators among themselves and with more experienced investigators on a regular basis.
- Assess educational courses offered for trainees and mentors, and then develop and offer courses that would help enhance the field of pain management, if necessary.
- Conduct an external evaluation of the accompanying K12 program's effectiveness in its last year (RFA-NS-22-045 (https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-22-045.html)).
- Create and utilize objective criteria to 1) measure success of the network (e.g. participation, engagements, publications with multiple network participants); and 2) evaluate the impact of the network on career success and development (e.g. correlate network participation with traditional criteria for assessing accomplishments such as publications or promotions).

Elements of the CCNPS Program:

Administrative Coordination

There are several administrative coordination components of the CCNPS:

- Create a network/networking system for NIH-funded pain researchers. Specifically, the network should help connect early-stage investigators to established mentors around the country and should help enhance collaboration among early-stage investigators who are along the pain research continuum (i.e., basic, translational, and clinical researchers). It is required that the network have an online space/platform component that CCNPS uses to engage network participants regularly throughout the year.
- Survey early-stage investigators and NIH-funded mentors to obtain their input about the types of activities (e.g., social networking, pain seminars, leadership training, mentoring experiences) that should be incorporated into the network.
- Identify NIH-funded early-stage career investigators (e.g., those who have received a K grant, are on a T grant, etc.) as well as NIH-funded mentors to inform them about, and encourage their participation in, the network.
- Plan and implement activities that will enhance and facilitate communication across the pain research continuum with the goal of increasing multidisciplinary collaborations.
- Disseminate information about all CCNPS activities, including the annual meeting, collaboration events, education events, successes of trainees, etc., to all awardees of NIH pain grants.
- Assist early-stage NIH pain grant awardees in navigating systems (i.e., connecting to a senior mentor at an outside institution, identifying helpful courses and training, running webinars to provide information that might help early-stage NIH pain grant awardees progress to mid-stage investigators, etc.)
- Create and utilize criteria/methods to measure the success of the CCNPS at meeting its stated objectives. It is recommended that these methods include an element that can be used to compare success of network participants to non-participants
- There should be a clear logistical plan and timeline that explains how and when activities will occur within the coordinating center

Organization of an Annual Meeting and Networking Activities

A required element of this FOA is the planning and hosting of an annual meeting for all NIH-funded early-stage pain researchers (i.e., researchers on K grants, T grants, F grants, etc.) and NIH-funded mentors. The PD/PI, along with the governing board, will organize this meeting annually to serve a forum where mentoring and career development activities can be discussed and take place. The meeting should also serve the purpose of connecting investigators across the continuum of pain research to facilitate multidisciplinary collaborations. The main scope of the annual meeting should be to help build a network of pain researchers from across the United States, as well as across the scientific continuum, who are working towards the common goal of improving pain management by openly sharing and communicating their knowledge in a collegial atmosphere. The annual meeting should also povide enhanced mentorship opportunities, leadership courses, and any additional trainings that maybe ncessary for early-career scietistis. The CCNPS should encourage all NIH-funded early-stage pain investigators and NIH-funded mentors to attend the annual meeting. The CCNPS also should incorporate a mechanism to fund a portion of all NIH-funded early-career pain researcher trainees' travel to the annual meeting. Meeting attendance is required for K12 scholars, and it is expected that the K12 Advisory Committee members will attend.

The network also should include regular activities to keep pain scientists engaged in the network throughout the year and add value to the training experience of NIH pain early-stage researchers. These activities would support the overall goals of the CCNPS to 1) enhance the training experience of early-stage career researchers; 2) facilitate/enhance communication/collaboration between pain researchers across the continuum of scientific disciplines; and 3) enhance the access of trainees to more senior mentors. The CCNPS should seek out stakeholders' perspectives on what activities would be most useful to host throughout the year to achieve the CCNPS's goals and encourage maximum participation from NIH pain early-stage investigators and NIH-funded mentors.

Research education infrastructure

The CCNPS is expected to survey early-stage investigators, mentors, and the governing board to understand potential educational activities, webinars, training or courses that would maximize the potential of pain researchers. The CCNP should consider administering the educational activities, training and/or courses at the annual meeting, or make them available at regular intervals throughout the year. If necessary, the CCNPS will develop and administer the necessary courses and training. In addition, the CCNPS may decide to improve access to key trainings or courses, that are already available, by focusing on disseminating this information across the network.

Program Evaluation

The CCNPS would berequired to conduct an external review of the success of the K12 program (see accompanying K12 FOA; [redacted] The governing board and PD/PI would be required to create objective criteria by which to measure the success of the program. The governing board and PD/PI also would be responsible for conducting the review, preparing a report and presenting their findings to NIH program staff.

PD/PI Responsibilities

The PD/PI(s) would be expected to coordinate meetings and events, monitor and assess the program, and submit all documents and reports as required. The PD/PI(s) would be responsible for the day-to-day administration of the program, appointing members of the governing board, conceptualizing and establishing the network/networking system, designing an outreach plan to recruit eligible participants to the network, planning and leading governing board discussions, monitoring the success and reach of the CCNPS program, leading the development of the review criteria for the K12 program and dissemination of information about/promotion of the CCNPS. This R24 grant will provide PD/PI(s) 50% protected time in order to run the CCNPS. PD/PIs and NAC members from the K12 award cannot apply to be PD/PI(s) for the R24. PD/PI(s) also are responsible for hiring the program staff needed to execute CCNPS operations. This R24 grant would support an administrative staff member for up to 6 calendar months/year and one IT/web support staff for 4 months/year. In addition, if extensive coordination is required to achieve the goals of the CCNPS, an additional 6 month/year salary support may be requested to support a CCNPS administrative position designed to accomplish these goals.

It is expected that the PD/PI(s) will provide detailed information about the specific goals and expectations of the CCNPS to all governing board members, and when appropriate, department chairs of early-stage NIH grantees, and ensure that the governing board agrees with the goals, expectations, and requirements of the CCNPS. The PD/PI(s) may wish to assign significant programmatic roles

to faculty members (e.g., name co-directors) or administrative staff who do not serve as PD/PI(s). These individuals should agree to perform the described duties and should have documented, sufficient time to commit to the program.

The PD/PI(s) would be required to submit annual progress reports, in the Research Performance Progress Report (RPPR) (https://grants.nih.gov/grants/rppr/index.htm)format, and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/guide/url_redirect.php?id=11161)

Governing Board

The governing board, chaired by the PD/PI(s), is a select group of multidisciplinary scientists who have established records of research and mentoring, as well as pople with pain. The governing board should include approximately 10 members (eight established research investigators as well as at least two patients with lived experience). This committee must be diverse with respect to scientific interests, geographic location, clinical scientist and non-clinical scientists, and prior training affiliations (i.e., multidisciplinary). The committee also should have appropriate representation of experts with regard to gender, socioeconomic background, disability, and race/ethnicity. While the governing board will likely contain mostly mid-career and senior scientists, the PD/PI(s) may also wish to add additional individuals who are more junior scientists but are clearly outstanding for their career stage (i.e., individuals who have published high quality research and recently received their first R01). Note that not all members of the board must have identical roles in the program, and the PD/PI may wish to assign subcommittee roles to board members. The governing board will plan, design and help run CCNPS activities including the annual meeting, provide input on the quality of CCNPS activities to ensure that the goals are being met and help evaluate the K12 program. Due to the role of the governing board in evaluating the K12 program, PD/PI(s) and K12 AC members from the K12 program cannot serve on the governing board for the CCNPS. The duration of service of individuals on the board should be negotiated between individual members and the PD/PI and generally should be a minimum of three years.

A description of the governing board should be included in the grant application; however, board members need not be named in the grant application. The application should mention how the PD/PI(s) will propose to achieve the composition of the governing board. The application should include descriptions as to how the board will provide oversight and guidance within CCNPS. After the NOA has been issued, NIH must approve the composition of the governing board, including the individuals' names, expertise, current affiliation, and prior training affiliations, as well as their roles and responsibilities, and other relevant information. Board members should be paid a yearly honorarium for their participation in the CCNPS, and honorariums should be in line with NIH guidelines of a maximum of $400 per meeting.

HEAL

In addition to scientific diversity, applicants should strive to incorporate diversity in their team development plan. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust. Please refer to Notice of NIH's Interest in Diversity NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)for more details.

The *NIH HEAL Initiative* will require a high level of coordination and sharing between investigators. It is expected that *NIH HEAL Initiative* recipients will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting, as well as other activities.
See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

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

NIH intends to fund one award, corresponding to $1,893,240 direct costs in FY 2022. Future year amounts will depend on annual appropriations.

HEAL intends to commit approximately $2,499,120 (direct cost) in FY23, $1,893,240 (direct cost) in FY24, $1,893,240 (direct cost) in FY25, and $1,893,240 (direct cost) in FY26.

Award Budget

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

Award Project Period

The project period is 5 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Government

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

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

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

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are not** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) – Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. SAM registrations prior to fall 2021 were updated to include a UEI. For applications due on or after January 25, 2022, the UEI must be provided on the application forms (e.g., FORMS-G); the same UEI must be used for all registrations, as well as on the grant application.
    - Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) – Organization registrations prior to April 2022 require applicants to obtain a DUNS prior to registering in SAM. By April 2022, the federal government will stop using the DUNS number as an entity identifier and will transition to the Unique Entity Identifier (UEI) issued by SAM. Prior to April 2022, after obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- eRA Commons (https://era.nih.gov/) - Once the unique organization identifier (DUNS prior to April 2022; UEI after April 2022) is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.php?id=11126)

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar.))

Section IV. Application and Submission Information

1. Requesting an Application Package

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

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.php?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

[redacted]
National Institute of Neurological Disorders and Stroke (NINDS)
Email: [redacted]

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

Personnel Costs: Individuals designing, directing, and implementing the career development program may request salary and fringe benefits to support up to 6 person-months (50% effort total for all individuals) and 4 person-months of IT/web support. In addition, if extensive coordination is required to achieve the goals of the program, an additional 6 person-month salary may be requested to support a CCNPS administrative position designed to accomplish these goals. Salaries requested may not exceed the levels commensurate with the institution's policy for similar positions and may not exceed the congressionally mandated cap.

Other Program Related Expenses: Consultant costs, equipment, supplies, travel for key persons, and other program-related expenses may be included in the proposed budget. These expenses must be justified as specifically required by the proposed program and must not duplicate items generally available at the applicant institution. Honoraria for attending meetings and travel to meetings may be requested for members of the governing board. Honoraria also may be offered for planning the annual meeting and the evaluation of the K12 program.

The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met: (1) Administrative or clerical services are integral to a project or activity; (2) Individuals involved can be specifically identified with the project or activity; (3) Such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; and (4) The costs are not also recovered as indirect costs. When specifically identified and justified, these expenses must be itemized in Sections A and B, as appropriate, of the R&R Budget. It is anticipated that support will not exceed **16** person-months for administrative support, which can only be requested for work directly performed for the CCNPS program.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

Program Plan

Program Administration:

Describe the strengths, leadership and administrative skills, scientific expertise, and training experience of the CCNPS PD/PI(s). Particular attention should be paid to the qualifications of the PD/PI(s) to lead and oversee this national coordinating center. Describe the strategy and administrative structure that is intended to be used to plan, execute and monitor the program.

If the CCNPS program will have co-directors, these individuals, as well as their roles, should be identified, and qualifications to perform these responsibilities should be discussed. All PD/PI(s) should provide a letter documenting their willingness to serve in their proposed capacity. The letters should be included in the “Letters of Support” section.

Governing Board:

Describe the planned make-up of the governing board. Describe how the PD/PI(s) will identify and approach potential board members. Describe how the governing board will operate and how the input of patients with lived pain experience will be incorporated into board decision-making. Describe the proposed roles for patients with lived pain experience.

After the NOA has been issued, the PD/PI(s) needs to report the composition of the governing board, including name, expertise, current affiliation, and prior training affiliations, as well as their roles and responsibilities, and other relevant information. NIH program staff will have to approve the governing board composition and may make changes to the composition of the board, if necessary.

Proposed Activities:

Networking. Describe how the coordinating center will implement and design a network/networking system for NIH-funded pain early-stage investigators and NIH-funded mentors. NOTE that it is required that the network have an online component so that the network regularly engages participants throughout the year, across the U.S. Explain how the CCNPS program will enhance communication between scientists across the continuum of pain research. Describe how the program intends to recruit NIH-funded pain researchers from across the pain research continuum and how the program intends to connect researchers of different career stages. Delineate how the coordinating center intends to achieve buy-in from both early and late-stage investigators, as well as researchers from all levels across the pain research continuum (i.e., basic, clinical, and translational scientists) to participate in this network.

Annual Meeting. Describe the type of content and information that would be included in an annual meeting for all NIH-funded early-stage pain researchers (i.e., researchers on K grants, T grants, etc.) and NIH-funded mentors. Explain how the CCNPS would organize this meeting and how it would promote and build a network of pain researchers from across the United States and the scientific continuum, who are working towards a common goal of improving pain management. Describe how the CCNPS would promote the meeting and encourage all pain NIH-funded early-stage investigators and NIH-funded mentors to attend the annual meeting. Also, provide a proposal to fund a portion of all pain-focused NIH-funded early-career trainees travel to the annual meeting.

Research education infrastructure. Describe how the program will survey early-stage investigators, mentors, and the governing board to assess potential educational activities, webinars, trainings or courses that would maximize the potential of pain researchers. Explain how the program will provide educational activities, training and/or courses at the annual meeting or make them available at regular intervals. Detail how the CCNPS, if necessary, will develop and provide the necessary courses and trainings throughout the year. Discuss how the program will improve access to key training or courses that already are available, by disseminating this information across the network.

Program Evaluation. Describe how the governing board and PD/PI will create objective criteria by which to measure the success of the K12 program. Discuss how they will be responsible for conducting the review, preparing a report and presenting their findings to NIH program staff.

Stakeholder Engagement. Describe how the program will educate early-stage investigators on the role of stakeholder and community engagement across the continuum of scientific research. Discuss community stakeholder activities and trainings that are planned as part of the program. Explain how patients with lived experience will be utilized on the governing board. Describe how the program will engage NIH grant awardees to encourage participation in the network as well as gather input for the network's design.

Dissemination. Describe how the program plans to disseminate program information (i.e., information about the annual meeting, training, and networking events) as well as the successes of program participants across the network. Discuss how the program plans to ensure that the network is as expansive and diverse as possible and how the program plans to track the success, or limitations, of information dissemination strategies and engagement in research education activities.

Leadership. Describe the plan for using the CCNPS program to contribute to the development of future leaders within the pain management community.

Institutional Environment and Commitment to the CCNPS

The PD/PI's sponsoring institution must assure support for the proposed CCNPS program, including assurance that sufficient time will be allowed for the PD/PI(s) to contribute to the proposed program (a minimum of 6-person months per year, equivalent to 50% effort) will be maintained.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

HEAL

Datasharing: Under Research Strategy/Resource Sharing Plan

NIH intends to maximize the impact of HEAL Initiative-supported projects through broad and rapid data sharing. Consistent with the **HEAL Initiative Public Access and Data Sharing Policy** (https://heal.nih.gov/about/public-access-data (https://heal.nih.gov/about/public-access-data)), all applications, regardless of the amount of direct costs requested for any one year, are required to include a Data Management and Sharing Plan outlining how scientific data and any accompanying metadata will be managed and shared. The plan should describe data types, file formats, submission timelines, and standards used in collecting or processing the data. It is expected that data generated by HEAL Initiative-funded projects will be submitted to study-appropriate domain-specific or generalist repositories in consultation with the HEAL Data Stewardship Group to ensure the data is accessible via the HEAL Initiative Data Ecosystem (https://heal.nih.gov/about/heal-data-ecosystem). Additional guidance on data related activities can be found at https://www.healdatafair.org/. (https://www.healdatafair.org/)

To maximize discoverability and value of HEAL datasets and studies, and facilitate data integration and collaboration, applications submitted in response to this FOA are strongly encouraged to incorporate standards and resources where applicable:

- Applicants are encouraged to ensure that data collected by the study conform to Findable, Accessible, Interoperable, and Reusable (FAIR (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4792175/)) principles.
- Applicants are specifically encouraged to incorporate into their planning, an alignment with the guidelines, principles and recommendations developed by the HEAL Data Ecosystem, including but not limited to preparing data to store in selected specified repositories, applying minimal metadata standards, use of core HEAL Clinical Data Elements (CDEs, https://heal.nih.gov/data/common-data-elements (https://heal.nih.gov/data/common-data-elements)), and other necessary requirements to prepare data to connect to the HEAL Data Ecosystem.
- All new HEAL clinical pain studies are required to submit their case-report forms/questionnaires to the HEAL Clinical Data Elements (CDE) Program. The program will create the CDE files containing standardized variable names, responses, coding, and other information. The program will also format the case-report forms in a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C § 794 (d) (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title29/html/USCODE-2011-title29-chap16-subchapV-sec794d.htm)), which "require[s] Federal agencies to make their electronic and information technology accessible to people with disabilities." HEAL Initiative clinical studies that are using copyrighted questionaries are required to obtain licenses for use prior to initiating data collection. Licenses must be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. For additional information, visit the HEAL CDE Program (https://heal.nih.gov/data/common-data-elements).

The NIH notices referenced below provide additional NIH guidance that should be considered in developing a strong data management and sharing plan. The list is instructive but not comprehensive.

- Elements of an NIH Data Management and Sharing Plan (NOT-OD-21-014 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-014.html))
- NIH has provided guidance around selecting a repository for data generated by NIH-supported research and has developed desirable characteristics for all data repositories (NOT-OD-21-016 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html)).
- NIH encourages the use of data standards including the PhenX Toolkit (www.phenxtoolkit.org (http://www.phenxtoolkit.org)) (for example, see NOT-DA-12-008 (https://grants.nih.gov/grants/guide/notice-files/NOT-DA-12-008.html), NOT-MH-15-009 (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html))
- NIH encourages researchers to explore the use of the HL7 FHIR® (Fast Healthcare Interoperability Resources) standard to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data (NOT-OD-19-122 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-122.html)). The FHIR® standard may be particularly useful in facilitating the flow of data with EHR-based datasets, tools, and applications.
- NIH encourages clinical research programs and researchers to adopt and use the standardized set of data classes, data elements, and associated vocabulary standards specified in the United States Core Data for Interoperability (USCDI) (https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi) standards, as they are applicable (NOT-OD-20-146 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-146.html)). Use of the USCDI can complement the FHIR® standard and enable researchers to leverage structured EHR data for research and enable discovery.

Recipientsconducting research that includes collection of genomic data should incorporate requirements under the NIH Genomic Data Sharing Policy (NOT-OD-14-124 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html), NOT-OD-15-086 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-086.html)).

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

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

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

4. Submission Dates and Times

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

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

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

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

Late applications will not be considered.

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

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

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

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential fieldof the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the unique entity identifier (DUNS number or UEI as required) provided on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

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

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

Webinar

In order to learn more about this RFA and to have the opportunity to ask questions, a pre-application webinar will be held on June 6th from 12:00-1:00pm EST (9:00-10:00am PST). Information on how to join the webinar is provided below.

[redacted]

To join the web presentation:

1.Go to

https://nih.zoomgov.com/j/1619140305?pwd=YkhXYTlISXVnTkp6M2E1UUUvRmFQZz09 (https://nih.zoomgov.com/j/1619140305?pwd=YkhXYTlISXVnTkp6M2E1UUUvRmFQZz09)

2. Click "Join Now"

For audio you can follow the prompts on your monitor, or

Call-in number (US): 646 828 7666

Meeting ID: 161 914 0305

Passcode: 103026

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299). Any instructions provided here are in addition to the instructions in the policy.

After the NOA has been issued, the PD/PI(s) needs to report the composition of the governing board, including name, expertise, current affiliation, and prior training affiliations, as well as their roles and responsibilities, and other relevant information. NIH program staff will have to approve the governing board composition and may make changes to the composition of the board, if necessary.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed coordinating center will create a network for researchers across the spectrum of pain research, bring early-stage investigators and mentors together, organize an annual meeting, and offer courses and trainings throughout the year to help enhance the field of pain management, in consideration of the following review criteria and additional review.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA:

- Is there evidence that an appropriate level of effort will be devoted by the program leadership to ensure program objectives?
- Are the PD/PI(s) research qualifications, scientific stature, previous leadership and mentoring experience, and track record(s) appropriate for the proposed coordinating center?
- Are the PD/PI(s) currently engaged in research relevant to the scientific area of the proposed program?
- For applications designating multiple PDs/PIs:
    - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the career development program and the scholars?
    - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, with and justified by the aims of the career development program and the complementary expertise of the PDs/PIs?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

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

Administrative Coordination

- Is there evidence that the proposed network/networking system can reach and disseminate information about the R24 activities to NIH-funded pain early-stage investigators who could benefit from receiving support from the network?
- Is the proposed program likely to entice NIH pain grant awardees (early-stage investigators and NIH funded mentors) across the research continuum to participate in the network?
- Are there proposed activities to ensure that NIH early-stage investigators will gain a thorough appreciation of how all levels of scientific research (i.e. basic/clinical/translational) interact?
- Is there a plan to effectively deliver or facilitate access to necessary educational courses/trainings to members of the network?
- Is there a thoughtful plan for maximizing the participation of pain researchers in the network who are diverse in the field by gender, socioeconomic background, training, geographic location, disability, as well as race and ethnicity?
- Are the guidelines proposed for oversight of didactic, training-related, and research-related activities of the program appropriate?
- Is there a plan to objectively evaluate the success of the network? Would the evaluation method permit the comparison of program participants to non-program participants?

Network

- Does the proposalapplication describe the creation of an innovative network that NIH-funded early stage-investigators and NIH-funded mentors will engage in?
- Does the proposalapplication describe an online or virtual networking system that engages participants regularly and semi-frequently throughout the year?
- Is the network an innovative way to engage the NIH trainee community and foster a collegial atmosphere that will facilitate multidisciplinary collaborations?

- Will the proposed network and network activities be valuable to early-stage investigators?
- Does the proposed program clearly outline a plan to identify and recruit NIH pain grant awardees (NIH-funded early-stage investigators and NIH-funded mentors) to participate in the network?
- IsAre the proposed amount and mode of communication to NIH early-stage investigators appropriate?
- Will the proposed communication plan ensure participation and buy-in from a diverse group of NIH early-stage investigators representing the whole continuum of pain research?
- Is there a proposed method to survey the community about their educational and collaborative needs? Is the plan appropriate?
- Will the proposed networking activities help prepare early-stage pain researchers for successful, impactful careers regardless of their home institution?
- Is there a proposed plan to facilitate communication/collaboration between researchers across the pain research continuum, between early-stage investigators and mentors, and among early-stage investigators?

Education/Training Component

- Does the application propose a useful and helpful course (or courses) for the pain community?
- Is there a plan to engage the community to determine what is needed to fulfill the educational goals of this program?
- Is there a plan for fostering leadership skills and opportunities for all early-stage investigators?
- Is there a plan to evaluate and measure educational activities?
- Does the proposalapplication include courses on scientific leadership, mentoring, how to serve on review panels, and grant writing (i.e., courses preparing early-stage investigators for an impactful and successful academic research career)?

Annual Meeting

- Does the program discuss how the program will disseminate information about the meeting to potential attendees?
- Is there a well-considered plan for inclusion of an appropriate number and type of attendees at this annual meeting, to include not only the K12 scholars but all NIH-supported pain researchers?
- Is there a plan about how to distribute funds to early-career researchers?

Program Evaluation

- Is there a clear and objective standard for evaluating the K12 program

Data Sharing

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.php?id=11151); (2) Sharing Model Organisms (https://grants.nih.gov/grants/policy/model_organism/); and (3) Genomic Data Sharing Plan (GDS) (https://osp.od.nih.gov/scientific-sharing/policies).

Governing Board

- Is the proposed constitution of the governing board appropriate?
- Is there a strong plan to recruit the governing board?
- Is the role of pain patients on the board defined?
- Is there a plan to maintain patient representation for the duration of the award?
- Is there a strong plan to include junior pain scientists -- who could provide diverse insights and helpful advice to the program design -- who have launched successful research programs, with appropriate attention to diversity, including gender, socioeconomic background, training, geographic location, disability, and race/ethnicity?

Protections for Human Subjects

Generally not applicable.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable.

Vertebrate Animals

Generally not applicable.

Biohazards

Not applicable

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

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

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Not Applicable

Resource Sharing Plans

Not Applicable.

Authentication of Key Biological and/or Chemical Resources:

Not applicable

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by NIH program staff convened by NINDS using the stated review criteria.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall assessment score.

Appeals (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm)of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

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

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159), including of note, but not limited to:

- Federalwide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

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

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity , sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- 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 (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html)and https://www.lep.gov (https://www.lep.gov/).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://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 (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 (https://grants.nih.gov/grants/policy/harassment.htm).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable.

3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (///grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)
PD/PI(s) mustsubmit annual progress reports to NIH. Progress reports should describe all relevant outcomes related to CCNPS activities over the years funded. This should include a summary describing the types of NIH grant awardees participating in the network, including their institutions and research specialties. Progress reports should describe how the CCNPS program has evolved in response to feedback and the results observed in previous years. Progress reports should describe efforts to evaluate the program, and any changes made to the program based on those evaluations. The reports also should describe in general terms the makeup of the governing board and any changes to this makeup.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (///grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (///grants.nih.gov/grants/guide/url_redirect.php?id=11171) for additional information on this reporting requirement.

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

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (///grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

[redacted]
National Institute of Neurological Disorders and Stroke
Email: [redacted]

[redacted]
National Institute of Neurological Disorders and Stroke
Email: [redacted]

[redacted]
National Institute of Dental & Craniofacial Research (NIDCR)
Phone: [redacted]
E-mail: [redacted]

David Thomas, Ph.D.
Office of Research on Women's Health
Phone: 301-435-1313
Email: david.thomas@nih.gov (mailto:david.thomas@nih.gov)

Peer Review Contact(s)

Not Applicable

Financial/Grants Management Contact(s)

Chief Grants Management Officer
National Institute of Neurological Disorders and Stroke (NINDS)
Email: ChiefGrantsManagementOfficer@ninds.nih.gov (mailto:ChiefGrantsManagementOfficer@ninds.nih.gov)

[redacted]
National Institute of Dental & Craniofacial Research (NIDCR)
Phone: [redacted]
E-mail: [redacted]

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 45 CFR Part 75 and 2 CFR Part 200.

[redacted]

National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

(https://www.usa.gov/)

NIH... Turning Discovery Into Health®

EXHIBIT B

Notice of NIH's Interest in Diversity

Notice Number: NOT-OD-20-031

Key Dates

Release Date: November 22, 2019

Related Announcements

NOT-OD-18-210 Ð Rescinded
NOT-MH-20-051

Issued by

National Institutes of Health (NIH)

Purpose

NIHÕs mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. To achieve this mission, NIH substantially invests in research to improve public health; it also devotes substantial resources to identify, develop, support and maintain the quality of its scientific resources, including human capital.

This diversity statement was informed by a literature review, the reports and deliberations of several internal NIH committees, as well as input from Institute and Center officials, program staff and external stakeholders.

Implementation Timeline

This notice is effective upon its release date and supersedes the prior Notice of Interest in Diversity (NOT-OD-18-210), and the current diversity language in existing funding opportunity announcements (FOAs).

Diversity Statement

Every facet of the United States scientific research enterpriseÑfrom basic laboratory research to clinical and translational research to policy formationÐrequires superior intellect, creativity and a wide range of skill sets and viewpoints. NIHÕs ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise

In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of

individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, such as:

A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27) and the report Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in NIH programs to enhance diversity. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm).

B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended. See NSF data at, https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf.

C. Individuals from disadvantaged backgrounds, defined as those who meet *two or more* of the following criteria:
   1. Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: https://nche.ed.gov/mckinney-vento/);
   2. Were or currently are in the foster care system, as defined by the Administration for Children and Families (Definition: https://www.acf.hhs.gov/cb/focus-areas/foster-care);
   3. Were eligible for the Federal Free and Reduced Lunch Program for two or more years (Definition: https://www.fns.usda.gov/school-meals/income-eligibility-guidelines);
   4. Have/had no parents or legal guardians who completed a bachelorÕs degree (see https://nces.ed.gov/pubs2018/2018009.pdf);
   5. Were or currently are eligible for Federal Pell grants (Definition: https://www2.ed.gov/programs/fpg/eligibility.html);
   6. Received support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) as a parent or child (Definition: https://www.fns.usda.gov/wic/wic-eligibility-requirements).
   7. Grew up in one of the following areas: a) a U.S. rural area, as designated by the Health Resources and Services Administration (HRSA) Rural Health Grants Eligibility Analyzer (https://data.hrsa.gov/tools/rural-health), *or* b) a Centers for Medicare and Medicaid Services-designated Low-Income and Health Professional Shortage Areas (qualifying zipcodes are included in the file). Only one of the two possibilities in #7 can be used as a criterion for the disadvantaged background definition.

      Students from low socioeconomic (SES) status backgrounds have been shown to obtain bachelorÕs and advanced degrees at significantly lower rates than students from middle and high SES groups (see https://nces.ed.gov/programs/coe/indicator_tva.asp), and are subsequently less likely to be represented in biomedical research. For background see Department of Education data at, https://nces.ed.gov/; https://nces.ed.gov/programs/coe/indicator_tva.asp; https://www2.ed.gov/rschstat/research/pubs/advancing-diversity-inclusion.pdf.

D. Literature shows that women from the above backgrounds (categories A, B, and C) face particular challenges at the graduate level and beyond in scientific fields. (See, e.g., From the NIH: A Systems Approach to Increasing the Diversity of Biomedical Research Workforce https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5008902/).

Women have been shown to be underrepresented in doctorate-granting research institutions at senior faculty levels in most biomedical-relevant disciplines, and may also be underrepresented at other faculty levels in some scientific disciplines (See data from the National Science Foundation National Center for Science and Engineering Statistics: Women, Minorities, and Persons with Disabilities in Science and Engineering, special report available

at https://www.nsf.gov/statistics/2017/nsf17310/, especially Table 9-23, describing science, engineering, and health doctorate holders employed in universities and 4-year colleges, by broad occupation, sex, years since doctorate, and faculty rank).

Upon review of NSF data, and scientific discipline or field related data, NIH encourages institutions to consider women for faculty-level, diversity-targeted programs to address faculty recruitment, appointment, retention or advancement.

Inquiries

Please direct all inquiries to:

Division of Biomedical Research Workforce
Office of Extramural Research
Website: https://researchtraining.nih.gov
Email: NIHTrain@mail.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.

EXHIBIT C

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Notice of Award
FAIN# [redacted]
Federal Award Date
09-28-2022

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]
Grants Management Officer
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[redacted]

10. Program Official Contact Information
[redacted]
Health Science Policy Analyst
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[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
Extramural Research Programs in the Neurosciences and Neurological Disorders

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-28-2022 – **End Date** 08-31-2025	
20. Total Amount of Federal Funds Obligated by this Action	$6,882,205
20 a. Direct Cost Amount	$6,257,349
20 b. Indirect Cost Amount	$624,856
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$6,882,205
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$6,882,205
26. Project Period Start Date 09-28-2022 – **End Date** 08-31-2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$6,882,205

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

RESOURCE-RELATED RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

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 $6,882,205 (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 National Institute Of Neurological Disorders And Stroke 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
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

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

Salaries and Wages	$516,300
Fringe Benefits	$165,216
Personnel Costs (Subtotal)	$681,516
Consultant Services	$358,254
Equipment	$8,791
Materials & Supplies	$509,214
Travel	$335,505
Other	$879,641
Publication Costs	$505,428
ADP/Computer Services	$355,176
Equipment or Facility Rental/User Fees	$52,500
Participant Subsistence	$483,459
Participant Travel	$2,087,865
Federal Direct Costs	$6,257,349
Federal F&A Costs	$624,856
Approved Budget	$6,882,205
Total Amount of Federal Funds Authorized (Federal Share)	$6,882,205
TOTAL FEDERAL AWARD AMOUNT	$6,882,205
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$6,882,205

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$6,882,205	$6,882,205

Fiscal Information:

Payment System Identifier: [redacted]
Document Number: [redacted]
PMS Account Type: [redacted])
Fiscal Year: 2022

IC	CAN	2022
DA	[redacted]	$5,142,623
NS	[redacted]	$1,739,582

NIH Administrative Data:
PCC: [redacted] / **OC:** [redacted] / **Released:** [redacted] 09-27-2022
Award Processed: 09/28/2022 12:09:12 AM

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.
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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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

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) [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/.

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 eRA Commons (Commons) 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 Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). 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 or quarterly federal cash transaction reporting. 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. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

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 strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

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 should 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.

National Institute On Drug Abuse (NIDA)
National Institute Of Neurological Disorders And Stroke (NINDS)

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 – NS 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.

This award has been converted to a multi-year funded award, with 3 years of funding provided in the current fiscal year. The 4th and/or 5th years of support will be funded contingent upon an acceptable administrative progress review and receipt of the information below.

Effective December 22, 2010 (NOT-OD-11-010), NIH requires that all multi-year funded awards submit an annual progress report. The annual progress report is due each year on or before anniversary date 09/01 . Instructions on how to submit the report through the eRA Commons are posted at http://grants.nih.gov/grants/policy/myf.htm

This award is co-funded by the National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Drug Abuse. All publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this co-funded research are presented must include a formal acknowledgement of the NINDS/other funding entity support, citing the NINDS grant number as identified on this award document.

ADMINISTRATIVE CONTINUATION APPLICATION:

The Principal Investigator will submit an Administrative Continuation Application in order to request support for the final year of this project. A signed PHS 2590 face page, which will serve as the application package, is due 2 months prior to the anticipated start of the 4th year of support and should be sent by email from the Authorized Organizational Representative (AOR) to the Program Official and Grants Management Specialist identified below or in the eRA Commons. Note that the administrative review cannot be completed without the receipt of the RPPR documenting the 3rd year of progress. In order to prevent a lapse in funding, we strongly encourage you to submit the information above as well as the RPPR documenting the Y-03 year of progress 60 days prior to start of the budget period. We are unable to release additional funds until administrative review has been completed.

NINDS staff will review these documents administratively. If approved, a Notice of Award will be issued extending the project period for two additional years. If not approved for continued funding, a one-year no-cost extension will be permitted upon request.

HEAL SHARING REQUIREMENTS

1. Electronic copies of Publications will be deposited in PubMed Central with proper tagging of metadata to ensure online discoverability and accessibility within four weeks of acceptance by a journal.
2. Publications will be Published under the Creative Commons Attribution 4.0 Generic License (CC BY 4.0) or an equivalent license, or otherwise dedicated to the public domain (e.g., Creative Commons public domain tool, CC0).
3. Publications will be made publicly available immediately without any embargo period.
4. Underlying Primary Data for the Publications will be made broadly available through an appropriate data repository such as the HEAL central data repository.
5. To the extent feasible, Underlying Primary Data will be shared simultaneously with the Publication and made immediately accessible through release under the Creative Commons Attribution 4.0 Generic License (CC BY 4.0) or an equivalent license, or otherwise dedicated to the public domain (e.g., Creative Commons public domain tool, CC0).

ADDITIONAL TERMS AND CONDITIONS ON HEAL GRANTS

***in addition to* standard terms and conditions of awards, and standard IC terms, including standard clinical trials requirements outlined in the NIHGPS:**
https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.3_clinical_trials_registration_and_reporting_in_clinicaltrials.gov_requirement.htm

Data sharing requirements do not apply to SBIRs.

HEAL Data Sharing Requirements

NIH intends to maximize the impact of HEAL Initiative-supported projects through broad and rapid data sharing. All HEAL Initiative award recipients, regardless of the amount of direct costs requested for any one year, are required to comply with the HEAL Public Access and Data Sharing Policy, which also aligns with the **NIH Policy for Data Management and Sharing** (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html). HEAL award recipients must following all requirements and timelines developed through the HEAL Initiative Data Ecosystem, as described in HEAL's compliance guidance (https://heal.nih.gov/data/complying- heal-data-sharing-policy):

1. **Submit a Data Management and Sharing Plan as part of your application for HEAL funding; follow the plan as part of your award**
   - HEAL Initiative applicants, regardless of the amount of direct costs requested for any budget or project, must submit a data management and sharing plan (as part of their resource sharing plan) that outlines management and sharing of scientific data, accompanying metadata, other relevant data, and associated documentation. The plan should describe data types, file formats, submission timelines, and standards used in collecting or processing the data.
   - Data management and sharing plans should include the proposed repository where HEAL-generated data will be stored long-term.

Submission and curation costs may be included in budgets.

2. Upon award, finalize a data repository selection

- Data generated by HEAL Initiative-funded projects must be submitted to study- appropriate data repositories to ensure the data is accessible via the HEAL Initiative Data Ecosystem.
- Some repositories require use of specific data dictionaries or structured data elements, so knowing your repository's requirements up front can help reduce the burden of preparing data for submission.
- HEAL-funded awardees must follow requirements for selected repository

3. Within one year of award, register your study with the HEAL platform.

- This process will connect the Platform to information about your study and data, including metadata, and identify the selected repository.
- HEAL requests initial submission within one year of award, with annual updates, and to be updated in accordance with any release of study data.

4. Report data submission when HEAL-generated data are deposited in repositories

- At the completion of the study and/or when prepared to make the final data deposits in the repositor(ies) of choice, ensure your study registration is complete.
- The NIH HEAL Initiative expects submission of data used in publications to be submitted to repositories at the time of or prior to publication.

5. Report publications

Award recipients and their collaborators are required to acknowledge HEAL Initiative support by referencing in the acknowledgement sections of any relevant publication: "This research was supported by the National Institutes of Health through the NIH HEAL Initiative (https://heal.nih.gov/) under award number [include specific grant/contract/award number; with NIH grant number(s) in this format: R01GM987654]."

HEAL Initiative studies conducting clinical research or research involving human subjects must meet the following additional requirements:

- HEAL Initiative trials that are required to register in clinicaltrials.gov should reference support from and inclusion in the HEAL Initiative by including the standardized terms "the HEAL Initiative (https://heal.nih.gov/)" in the Study Description Section.
- All new HEAL clinical pain studies are required to submit their case-report forms/questionnaires to the HEAL Clinical Data Elements (CDE) Program. The program will create the CDE files containing standardized variable names, responses, coding, and other information. The program will also format the case-report forms in a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C § 794 (d)), which "require[s] Federal agencies to make their electronic and information technology accessible to people with disabilities." HEAL Initiative clinical studies that are using copyrighted questionaries are required to obtain licenses for use prior to initiating

data collection. Licenses must be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. For additional information, visit the HEAL CDE Program.

- To the extent possible, HEAL awardees are expected to integrate broad data sharing consent language into their informed consent forms.

Additional details, resources, and tools to assist with data related activities can be found at https://www.healdatafair.org/.

All data collected as part of the NIH HEAL Initiative are so collected under a Certificate of Confidentiality and entitled to the protections thereof. Institutions who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative, in a manner that is
consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the institution's NIH funding, including NOT-OD-17-109 and 42 U.S.C. 241(d). Failure to adhere to this criterion may result in enforcement actions.

Declaration of Exceptional Circumstances (DECs)
This award is funded through the NIH HEAL Initiative (https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative). The requirements here include, but are not limited to, reporting requirements and data sharing are incorporated due to the need to respond to the national opioid public health crisis. As part of the response to this crisis, the NIH intends to maximize the availability of publications and the sharing of underlying data for NIH HEAL Initiative supported research projects. Award recipients are expected to cooperate and comply with all NIH data sharing including the aforementioned central data sharing platform requirements developed for this public health emergency during the project period.

Participation in Annual Investigator Meetings
The NIH HEAL Initiative will require a high level of coordination and sharing between investigators. It is expected that NIH HEAL Initiative awardees will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting, as well as other activities.

SPREADSHEET SUMMARY
AWARD NUMBER: [redacted]

INSTITUTION: [redacted]

Budget	Year 1
Salaries and Wages	$516,300
Fringe Benefits	$165,216
Personnel Costs (Subtotal)	$681,516

Consultant Services	$358,254
Equipment	$8,791
Materials & Supplies	$509,214
Travel	$335,505
Other	$879,641
Publication Costs	$505,428
ADP/Computer Services	$355,176
Equipment or Facility Rental/User Fees	$52,500
Participant Subsistence	$483,459
Participant Travel	$2,087,865
TOTAL FEDERAL DC	$6,257,349
TOTAL FEDERAL F&A	$624,856
TOTAL COST	$6,882,205

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	10%
F&A Cost Base 1	$1,881,544
F&A Costs 1	$188,154
F&A Cost Rate 2	10%
F&A Cost Base 2	$2,486,786
F&A Costs 2	$248,679
F&A Cost Rate 3	10%
F&A Cost Base 3	$1,880,228
F&A Costs 3	$188,023

EXHIBIT D

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Notice of Award
FAIN# [redacted]
Federal Award Date
08/26/2024

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]
Grants Management Specialist
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[redacted]

10. Program Official Contact Information
[redacted]
Health Science Policy Analyst
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[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
Drug Abuse and Addiction Research Programs

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2024 – **End Date** 08/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$158,940
20 a. Direct Cost Amount	$112,628
20 b. Indirect Cost Amount	$46,312
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$850,595
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$850,595
26. Project Period Start Date 09/28/2022 – **End Date** 08/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,732,800

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

RESOURCE-RELATED RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

SECTION I – AWARD DATA – [redacted]

Principal Investigator(s):
[redacted]

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of $158,940 (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 National Institute Of Neurological Disorders And Stroke 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
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

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

Salaries and Wages	$191,215
Fringe Benefits	$66,217
Personnel Costs (Subtotal)	$257,432
Consultant Services	$1,000
Materials & Supplies	$76,373
Travel	$5,521
Other	$17,747
Publication Costs	$22,718
ADP/Computer Services	$17,029
Equipment or Facility Rental/User Fees	$7,860
Participant Subsistence	$43,771
Participant Travel	$153,295
Federal Direct Costs	$602,746
Federal F&A Costs	$247,849
Approved Budget	$850,595
Total Amount of Federal Funds Authorized (Federal Share)	$850,595
TOTAL FEDERAL AWARD AMOUNT	$850,595
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$158,940

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (1) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
[redacted]	$850,595
[redacted]	$6,882,205
TOTAL	**$7,732,800**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$850,595	$7,732,800

Fiscal Information:
Payment System Identifier: [redacted]
Document Number:
PMS Account Type:
Fiscal Year: 2024

IC	CAN	2024
NS	[redacted]	$850,595

NIH Administrative Data:
PCC: [redacted] / **OC**: [redacted] / **Released**: 08/23/2024
Award Processed: 08/26/2024 12:05:15 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – [redacted] **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 – [redacted] **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).

Carry over of an unobligated balance into the next budget period requires 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) [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/.

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 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 – NS SPECIFIC AWARD CONDITIONS – [redacted] 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.

REVISED AWARD: This award is being revised to increase the supplement award in the amount of $112,628 direct cost and $46,312 facilities and administrative costs. These funds may not be used for any other purpose without the prior written approval of the NINDS.

ADMINISTRATIVE SUPPLEMENT
This award provides an administrative supplement in the amount of $490,118 direct costs, and $201,537 facilities and administrative costs for the [redacted] initiative will closely cooperate with site Principal Investigators, mentors, trainees, evaluators, and established T32 programs to align and amplify training endeavors across the program. This approach will establish an integrated and supportive professional development network for the PAIN Cohort trainees, with the overarching goal of fostering their continued engagement and retention within the clinical pain research workforce. These funds may not be used for any other purpose without the prior written approval of the NINDS.

SPREADSHEET SUMMARY
AWARD NUMBER: [redacted] REVISED

INSTITUTION: [redacted]

Budget	Year 1
Salaries and Wages	$191,215
Fringe Benefits	$66,217
Personnel Costs (Subtotal)	$257,432
Consultant Services	$1,000
Materials & Supplies	$76,373
Travel	$5,521
Other	$17,747
Publication Costs	$22,718
ADP/Computer Services	$17,029
Equipment or Facility Rental/User Fees	$7,860
Participant Subsistence	$43,771
Participant Travel	$153,295
TOTAL FEDERAL DC	$602,746
TOTAL FEDERAL F&A	$247,849
TOTAL COST	$850,595

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	41.12%
F&A Cost Base 1	$602,746
F&A Costs 1	$247,849

EXHIBIT E

[redacted]

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:31 AM
To: [redacted]
Subject: Grant Termination Notification

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: NIH

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

[redacted]

Dear [redacted]:

Effective with the date of this letter, funding for Project Number [redacted] is hereby terminated pursuant to the Fiscal Year 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 9/28/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

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.[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. 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.

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 [redacted], Chief Grants Management Officer, NINDS
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[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 F

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Notice of Award
FAIN# [redacted]
Federal Award Date
03/24/2025

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]
Chief Grants Management Officer
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[redacted]

10. Program Official Contact Information
[redacted]
Health Science Policy Analyst
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[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
Extramural Research Programs in the Neurosciences and Neurological Disorders

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/28/2022 – **End Date** 03/21/2025	
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	$6,882,205
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$6,882,205
26. Project Period Start Date 09/28/2022 – **End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,732,800

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

RESOURCE-RELATED RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

SECTION I – AWARD DATA – [redacted] REVISED

Principal Investigator(s):
[redacted]

Award e-mailed to: [redacted]

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 [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 National Institute Of Neurological Disorders And Stroke 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
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

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

Salaries and Wages	$516,300

Fringe Benefits	$165,216
Personnel Costs (Subtotal)	$681,516
Consultant Services	$358,254
Equipment	$8,791
Materials & Supplies	$509,214
Travel	$335,505
Other	$879,641
Publication Costs	$505,428
ADP/Computer Services	$355,176
Equipment or Facility Rental/User Fees	$52,500
Participant Subsistence	$483,459
Participant Travel	$2,087,865
Federal Direct Costs	$6,257,349
Federal F&A Costs	$624,856
Approved Budget	$6,882,205
Total Amount of Federal Funds Authorized (Federal Share)	$6,882,205
TOTAL FEDERAL AWARD AMOUNT	$6,882,205
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (1) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
[redacted]	$6,882,205
[redacted]	$850,595
TOTAL	**$7,732,800**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$6,882,205	$7,732,800

Fiscal Information:
Payment System Identifier: [redacted]
Document Number:
PMS Account Type:)
Fiscal Year: 2022

IC	CAN	2022
DA	[redacted]	$5,142,623
NS	[redacted]	$1,739,582

NIH Administrative Data:
PCC: [redacted] / **OC**: [redacted] / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:06:02 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – [redacted] **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 – [redacted] **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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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

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) [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/.

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.

National Institute On Drug Abuse (NIDA) National Institute Of Neurological Disorders And Stroke (NINDS)

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 – NS SPECIFIC AWARD CONDITIONS – [redacted] 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 award related to DEI no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award 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, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. [redacted] 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 to avoid unilateral closeout.

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.

ADDITIONAL TERMS AND CONDITIONS ON HEAL GRANTS

***in addition to* standard terms and conditions of awards, and standard IC terms, including standard clinical trials requirements outlined in the NIHGPS:**
https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.3_clinical_trials_registration_and_reporting_in_clinicaltrials.gov_requirement.htm

Data sharing requirements do not apply to SBIRs.

HEAL Data Sharing Requirements

NIH intends to maximize the impact of HEAL Initiative-supported projects through broad and rapid data sharing. All HEAL Initiative award recipients, regardless of the amount of direct costs requested for any one year, are required to comply with the HEAL Public Access and Data Sharing Policy, which also aligns with the **NIH Policy for Data Management and Sharing** (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html). HEAL award recipients must following all requirements and timelines developed through the HEAL Initiative Data Ecosystem, as described in HEAL's compliance guidance (https://heal.nih.gov/data/complying- heal-data-sharing-policy):

1. Submit a Data Management and Sharing Plan as part of your

application for HEAL funding; follow the plan as part of your award

- HEAL Initiative applicants, regardless of the amount of direct costs requested for any budget or project, must submit a data management and sharing plan (as part of their resource sharing plan) that outlines management and sharing of scientific data, accompanying metadata, other relevant data, and associated documentation. The plan should describe data types, file formats, submission timelines, and standards used in collecting or processing the data.
- Data management and sharing plans should include the proposed repository where HEAL-generated data will be stored long-term. Submission and curation costs may be included in budgets.

2. Upon award, finalize a data repository selection

- Data generated by HEAL Initiative-funded projects must be submitted to study- appropriate data repositories to ensure the data is accessible via the HEAL Initiative Data Ecosystem.
- Some repositories require use of specific data dictionaries or structured data elements, so knowing your repository's requirements up front can help reduce the burden of preparing data for submission.
- HEAL-funded awardees must follow requirements for selected repository

3. Within one year of award, register your study with the HEAL platform.

- This process will connect the Platform to information about your study and data, including metadata, and identify the selected repository.
- HEAL requests initial submission within one year of award, with annual updates, and to be updated in accordance with any release of study data.

4. Report data submission when HEAL-generated data are deposited in repositories

- At the completion of the study and/or when prepared to make the final data deposits in the repositor(ies) of choice, ensure your study registration is complete.
- The NIH HEAL Initiative expects submission of data used in publications to be submitted to repositories at the time of or prior to publication.

5. Report publications

Award recipients and their collaborators are required to acknowledge HEAL Initiative support by referencing in the acknowledgement sections of any relevant publication:
"This research was supported by the National Institutes of Health through the NIH HEAL Initiative (https://heal.nih.gov/) under award number [include specific grant/contract/award number; with NIH grant number(s) in this format: R01GM987654]."

HEAL Initiative studies conducting clinical research or research involving

human subjects must meet the following additional requirements:

- HEAL Initiative trials that are required to register in clinicaltrials.gov should reference support from and inclusion in the HEAL Initiative by including the standardized terms “the HEAL Initiative (https://heal.nih.gov/)” in the Study Description Section.
- All new HEAL clinical pain studies are required to submit their case-report forms/questionnaires to the HEAL Clinical Data Elements (CDE) Program. The program will create the CDE files containing standardized variable names, responses, coding, and other information. The program will also format the case-report forms in a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C § 794 (d)), which
  “require[s] Federal agencies to make their electronic and information technology accessible to people with disabilities.” HEAL Initiative clinical studies that are using copyrighted questionaries are required to obtain licenses for use prior to initiating data collection. Licenses must be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. For additional information, visit the HEAL CDE Program.
- To the extent possible, HEAL awardees are expected to integrate broad data sharing consent language into their informed consent forms.

Additional details, resources, and tools to assist with data related activities can be found at https://www.healdatafair.org/.

All data collected as part of the NIH HEAL Initiative are so collected under a Certificate of Confidentiality and entitled to the protections thereof. Institutions who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative, in a manner that is consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the institution’s NIH funding, including NOT-OD-17-109 and 42 U.S.C. 241(d). Failure to adhere to this criterion may result in enforcement actions.

Declaration of Exceptional Circumstances (DECs)
This award is funded through the NIH HEAL Initiative (https://www.nih.gov/research- training/medical-research-initiatives/heal-initiative). The requirements here include, but are not limited to, reporting requirements and data sharing are incorporated due to the need to respond to the national opioid public health crisis. As part of the response to this crisis, the NIH intends to maximize the availability of publications and the sharing of underlying data for NIH HEAL Initiative supported research projects. Award recipients are expected to cooperate and comply with all NIH data sharing including the aforementioned central data sharing platform requirements developed for this public health emergency during the project period.

Participation in Annual Investigator Meetings
The NIH HEAL Initiative will require a high level of coordination and sharing between investigators. It is expected that NIH HEAL Initiative awardees will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings, including an annual

HEAL Investigators Meeting, as well as other activities.

SPREADSHEET SUMMARY
AWARD NUMBER: [redacted] REVISED

INSTITUTION: [redacted].

Budget	Year 1
Salaries and Wages	$516,300
Fringe Benefits	$165,216
Personnel Costs (Subtotal)	$681,516
Consultant Services	$358,254
Equipment	$8,791
Materials & Supplies	$509,214
Travel	$335,505
Other	$879,641
Publication Costs	$505,428
ADP/Computer Services	$355,176
Equipment or Facility Rental/User Fees	$52,500
Participant Subsistence	$483,459
Participant Travel	$2,087,865
TOTAL FEDERAL DC	$6,257,349
TOTAL FEDERAL F&A	$624,856
TOTAL COST	$6,882,205

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	10%
F&A Cost Base 1	$1,881,544
F&A Costs 1	$188,154
F&A Cost Rate 2	10%
F&A Cost Base 2	$2,486,786
F&A Costs 2	$248,679
F&A Cost Rate 3	10%
F&A Cost Base 3	$1,880,228
F&A Costs 3	$188,023

EXHIBIT G

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Notice of Award
FAIN# [redacted]
Federal Award Date
03/24/2025

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]
Chief Grants Management Officer
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[redacted]

10. Program Official Contact Information
[redacted]
Health Science Policy Analyst
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
[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
Drug Abuse and Addiction Research Programs

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2024 – **End Date** 03/21/2025	
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	$850,595
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$850,595
26. Project Period Start Date 09/28/2022 – **End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,732,800

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

RESOURCE-RELATED RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

SECTION I – AWARD DATA – [redacted] REVISED

Principal Investigator(s):
[redacted]

Award e-mailed to: [redacted]

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 [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 National Institute Of Neurological Disorders And Stroke 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
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Additional information follows

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

Salaries and Wages	$191,215

Fringe Benefits	$66,217
Personnel Costs (Subtotal)	$257,432
Consultant Services	$1,000
Materials & Supplies	$76,373
Travel	$5,521
Other	$17,747
Publication Costs	$22,718
ADP/Computer Services	$17,029
Equipment or Facility Rental/User Fees	$7,860
Participant Subsistence	$43,771
Participant Travel	$153,295
Federal Direct Costs	$602,746
Federal F&A Costs	$247,849
Approved Budget	$850,595
Total Amount of Federal Funds Authorized (Federal Share)	$850,595
TOTAL FEDERAL AWARD AMOUNT	$850,595
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (1) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
[redacted]	$850,595
[redacted]	$6,882,205
TOTAL	**$7,732,800**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$850,595	$7,732,800

Fiscal Information:
Payment System Identifier: [redacted]
Document Number:
PMS Account Type:
Fiscal Year: 2024

IC	CAN	2024
NS	[redacted]	$850,595

NIH Administrative Data:
PCC: [redacted] / **OC**: [redacted] / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:19:43 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – [redacted] **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 – [redacted] **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).

Carry over of an unobligated balance into the next budget period requires 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) [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/.

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 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 – NS SPECIFIC AWARD CONDITIONS – [redacted] 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 award related to DEI no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award 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, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. [redacted]. 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 to avoid unilateral closeout.

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.

SPREADSHEET SUMMARY
AWARD NUMBER: [redacted] REVISED

INSTITUTION: [redacted].

Budget	Year 1
Salaries and Wages	$191,215
Fringe Benefits	$66,217
Personnel Costs (Subtotal)	$257,432
Consultant Services	$1,000
Materials & Supplies	$76,373
Travel	$5,521
Other	$17,747
Publication Costs	$22,718
ADP/Computer Services	$17,029
Equipment or Facility Rental/User Fees	$7,860
Participant Subsistence	$43,771
Participant Travel	$153,295
TOTAL FEDERAL DC	$602,746
TOTAL FEDERAL F&A	$247,849
TOTAL COST	$850,595

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	41.12%
F&A Cost Base 1	$602,746
F&A Costs 1	$247,849