**HEAL Initiative: Native Collective Research Effort to Enhance Wellness (N CREW) Program -
Addressing Overdose, Substance Use, Mental Health, and Pain (OT2)**

Overview Information

Participating Organization	National Institutes of Health (NIH)
Components of Participating Organization	National Institute on Drug Abuse (NIDA)
	National Center for Advancing Translational Sciences (NCATS)
Other Interested NIH Institutes, Centers, or Offices	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
	National Cancer Institute (NCI)
	National Center for Complementary and Integrative Health (NCCIH)
	National Heart, Lung, and Blood Institute (NHLBI)
	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
	National Institute of Dental and Craniofacial Research (NIDCR)
	National Institute of Mental Health (NIMH)
	National Institute of Neurological Disorders and Stroke (NINDS)
	National Institute of Nursing Research (NINR)
	National Institute on Aging (NIA)
	National Institute on Alcohol Abuse and Alcoholism (NIAAA)
	National Institute on Minority Health and Health Disparities (NIMHD)
	Office of Research on Women's Health, National Institutes of Health (ORWH)
	Office of The Director, National Institutes of Health (OD)
	Tribal Health Research Office, National Institutes of Health (THRO)
Research Opportunity Announcement (ROA) Title	HEAL Initiative: Native Collective Research Effort to Enhance Wellness (N CREW) Program - Addressing Overdose, Substance Use, Mental Health, and Pain (OT2) (Subsequently referred to as N CREW)
Activity Code	**Other Transactions (OT2) Award mechanism**. This funding opportunity will use the Other Transactions Authority (OTA) governed by 42 U.S. Code § 282 (n)(1)(b). Other Transactions (OT) awards are not grants, cooperative agreements or contracts and use an OTA, provided by law. Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific governing agreement, which is negotiated with the recipient and may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing research landscape, performance and/or availability of funds.

Research Opportunity Announcement (ROA) Number	OTA-23-007
Related Notice	NOT-DA-23-022 OTA-23-008
Research Opportunity Announcement (ROA) Purpose	As part of the NIH HEAL Initiative®, N CREW seeks to promote wellness among Native Americans by advancing research addressing overdose, substance use, pain, and related factors such as mental health. N CREW will achieve its goals by supporting Tribes and Native American Serving Organizations (T/NASOs) to expand research capacity to lead locally prioritized research and improve the quality of HEAL related data. To launch the N CREW Program, **NIH is releasing two Research Opportunity Announcements (ROAs) for Phase 1 of the N CREW Program which will support approximately 2 years of development and planning activities.** This ROA (**OTA-23-007**) solicits applications for T/NASOs to lead the planning, development and piloting of research and data improvement projects. Applicants are strongly encouraged to review the companion ROA (**OTA-23-008**), which will support T/NASOs and Ally Organizations to provide comprehensive, real-time training and resources, and Program coordination to recipients of this current ROA. T/NASO's and the Native Research Resource Network will collaborate to meet program objectives.
Objective Review	NIH will engage a panel with appropriate expertise to evaluate applications. See the <u>Objective Review</u> section of this opportunity for further details.
Eligibility	See the <u>Eligibility</u> section of this opportunity for further details.
Funds Available and Anticipated Number of Awards	This is one of two ROAs being issued for Phase I of the N CREW Program. NIH intends to allocate up to $25 million across two years [Fiscal Year (FY) 24 and FY25] to fund approximately 20 awards – approximately 15 awards under OTA-23-007 and 5 awards under the companion ROA OTA-23-008. For this OTA-23-007 to support research and data projects, NIH intends to allocate up to $7.3 million/year and anticipates annual budgets for awarded applications will range from $200,000 to $550,000. There will be a Phase II of the N CREW Program (FY26-FY30 - Not covered under this ROA). The overall planned budget for all elements of the N CREW Program is approximately $268 million over a 7-year period (FY24-FY30). However, NIH HEAL procedures and OT mechanisms allow for significant flexibilities and adjustments, where necessary, to pursue catalytic and transformative initiatives. Award levels may change over time based on programmatic needs, funding availability, and recipient performance.

	Awards pursuant to this funding opportunity are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
Award Project Duration	Project duration for applications submitted in response to this Phase I ROA is expected to be approximately 1-2 years. Individual projects may be extended or curtailed based on programmatic objectives, performance, and available funds.
Application Submission Instructions	Applicants must submit applications via the NIH eRA ASSIST system by 5:00 PM local time on the due date (see Key Dates below).
	To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (See Submission Instructions), **which may take six (6) weeks or more to complete**. Applicants should therefore begin the registration process as soon as possible. Once the organization is registered, the individual(s) with the roles of Signing Official (SO) and Principal Investigator (PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process. (If an individual plans to serve in both roles, they will need two separate sets of credentials.) Complete applications must be submitted via ASSIST by the SO. Use OTA-23-007 in the Opportunity Number field.
	Here are instructions for submitting applications via the NIH eRA ASSIST system. Technical assistance is available from the eRA Service Desk.
	On the eRA Commons home page, select the "Register Organization" link for more details.
	Submission and Contact Information. Applications should be submitted by the proposing entity's Signing Official via NIH eRA Commons ASSIST no later than November 1, 2023 by 5 PM local time. If applicants are not registered in eRA or experience difficulty with submission, please contact NCREW@nih.gov for assistance. Inquiries can also be submitted to NCREW@nih.gov.
	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 guidance.

Key Dates

Post Date	June 23, 2023
Informational Webinar Dates (optional)	There will be a series of webinars. The first one is scheduled for July 27, 2023 at 12:00pm EDT. Informational webinar details, including the specific dates and registration links, will be posted on the N CREW website: heal.nih.gov/ncrew.
Letter of Intent Due Date (optional)	September 1, 2023. A letter of intent is recommended but not required. An email with the LOI should be sent to NCREW@nih.gov, on or before the indicated date. The contact Principal Investigator and other relevant institutional officials should be copied on the correspondence.
Application Due Date	November 1, 2023 by 5pm local time. Applications must be submitted via NIH eRA Commons ASSIST. See Application Submission Instructions.
Anticipated Review	January 2024
Earliest Start Date	June 1, 2024

Agency Contacts

Potential applicants are encouraged to contact N CREW Program Staff to discuss the application process prior to submission.

Scientific/Research Contacts	Kathy Etz NCREW@nih.gov National Institute on Drug Abuse (NIDA)
Financial/Agreements Officer Contacts	Jennifer Cho NCREW@nih.gov National Center for Advancing Translational Science (NCATS)

Outline of this Opportunity

Key Definitions for This ROA

- Ally Organization: Organizations with the ability to document a track record of partnering successfully with Native American communities.

- Indigenous Knowledge: A body of observations, oral and written knowledge, innovations, practices, and beliefs developed by Tribes and Indigenous Peoples through interaction and experience with the environment.

- Milestones: Objective, measurable events that are indicative of project progress occurring as proposed in the application.

- Native American: American Indian, Alaska Native, or Native Hawaiian.

- Other Transactions Authority (OTA): A unique type of authority that allows an agency to enter a legal agreement with a recipient organization that is not a contract, grant, or cooperative agreement (Learn more about OTAs on the NIH website).

- Partnership: An association of two or more entities with a commitment to an ongoing relationship to work toward common goals as established.

- Research Capacity: Skills, knowledge, policies, processes, partnerships, review boards, technology, resource, or infrastructure needed to conduct research, including at a minimum: financial accounting systems, tracking and reporting on activities, research expertise, identification of research specific aims, study design expertise, expertise in implementing research plans, Institutional Review Board (IRB) review, and data management tools and expertise.

- Research Opportunity Announcement (ROA): Used to solicit applications for programs using Other Transactions Authority.

- Substance Use: Use, misuse of or addiction to opioids (e.g., synthetic opioids such as fentanyl; prescription pain relievers such as OxyContin ®, Vicodin ®, codeine, morphine, etc.; or heroin) or stimulants (e.g., methamphetamine or cocaine), including a focus on these substances alone or in combination with any other drugs or alcohol.

- Tribe or Native American Serving Organization (T/NASO): This refers to federally or state recognized Tribes and organizations with a core mission to serve and/or track record in serving Native Americans and that are poised to reach this population.

Description of the HEAL Native Collective Research Effort to Enhance Wellness (N CREW) Program

This study is part of the NIH's Helping to End Addiction Long-term® (HEAL) Initiative to speed scientific solutions to the national opioid public health crisis. The NIH HEAL Initiative® bolsters research across NIH to improve (1) prevention and treatment for opioid misuse and addiction, and (2) pain management. More information about the HEAL Initiative is available at: https://heal.nih.gov/. The Native Collective Research Effort to Enhance Wellness: Addressing Overdose, Substance Use, Mental Health, and Pain Program (subsequently referred to as N CREW) is a new program within the NIH HEAL Initiative®. N CREW was established to address health disparities and is responsive to the priorities shared by Tribal Leaders through Consultation to address the opioid public health emergency, including addressing opioid and stimulant use and pain.

The N CREW Program seeks to support T/NASOs to respond to the opioid/drug public health emergency, with strategies aimed at addressing overdose, substance use, and pain, and related factors such as mental health or wellbeing. Reflecting NIH's commitment to advancing Native science, the N CREW Program seeks to support T/NASOs to conduct community-led research and/or improve data while increasing research capacity. Research prioritized by Native communities is essential for enhancing culturally grounded, strengths-based, effective, and sustainable intervention strategies.

The N CREW Program focuses on three main goals that reflect priorities for addressing the opioid/drug overdose crisis identified in Tribal Consultations (in 2018 and 2022) and through community input:

1. Support T/NASOs to lead community prioritized research projects, including research elevating and integrating Indigenous Knowledge and culture.
2. Enhance capacity within T/NASOs to conduct locally prioritized HEAL related research, accomplished through the development and provision of novel, accessible, culturally grounded technical assistance and training, resources, and tools.
3. Improve access to and the quality of data on substance use, pain, and related health and wellbeing factors to maximize their potential for use in local decision-making.

The N CREW Program is designed as agile, flexible, and innovative to reflect the complexity and diversity across communities in responding to the opioid public health crisis, also reflecting an openness to authentic collaboration with Native communities.

The N CREW Program is planned as a **two-phased program** that is highly collaborative. To launch Phase I of the N CREW Program (approximately 2 years, FY24-FY25), **NIH is releasing two Research Opportunity Announcements (ROAs).** This ROA (**OTA-23-007**) solicits applications to support Tribes and Native American Serving Organizations to engage in the planning, development, piloting and/or implementation of research and/or data improvement projects. Organizations applying to this ROA should also carefully **read the related ROA, OTA-23-008**, which solicits applications to form a Native Research Resource Network, funded as part of N CREW, who will collaborate with recipients of this current ROA to meet program objectives. This includes comprehensive, real-time training and resources, and program coordination.

Phase II (not this ROA) is anticipated to begin in FY26 and will likely support the implementation of research and/or data improvement projects developed in Phase I. However, given the expected variation in initial research capacity and goals of T/NASO Phase I recipients, Phase II might support additional pilot and development work, for example, for some T/NASOs. Phase II projects will be individualized to applicants and will build on what is learned and achieved in Phase I. The receipt of an award in Phase I does not guarantee recipients' continuation to Phase II. It is anticipated that Phase II may be announced as open competition.

Advancing Research and Data (This ROA)- Objectives

NIH seeks applications from T/NASOs interested in building or enhancing their research capacity to generate knowledge and improve outcomes related to overdose, substance use, or pain. Applications may include related factors such as mental health and wellbeing. Strategies to do so will rely on community-driven activities and partnerships.

Projects responsive to this ROA may propose approximately two years of development or planning activities related to conducting research, improving data (e.g., access, quality, availability), and/or enhancing capacity to engage in HEAL related research. Projects must explicitly include a focus on overdose, substance use (including

opioids or stimulants), or pain management. They may also include related factors such as mental health or wellness, among others, to support positive health outcomes in Native American communities.

Within these broad parameters, the specific objectives, research questions, data improvements, and/or other related activities should be applicant-initiated. Projects may range, for example, from planning and development of research (e.g., needs assessments, research/data project planning, expanding research capacity) to pilot and feasibility assessments to conducting research. This includes technology (e.g., development, deployment, testing) needed to collect data or conduct research. It could also include research training and development for scholars working on the proposed research. All types of research, for example epidemiology, prevention, treatment, and services studies, as well as qualitative (including oral traditions) and quantitative data collection will be considered. Data availability and access are critical for research; therefore, projects that include a focus on data sovereignty and strategy development for improved data and knowledge sharing among T/NASOs, or possibly with others, are also responsive. Applicants are encouraged to propose research projects that will generate knowledge that can be used to inform decisions and implement sustainable strategies for addressing overdose, substance use, or pain management, and may include related outcomes.

Examples of relevant projects that were highlighted during Tribal Consultations include:

- Determining and addressing the modifiable individual or structural factors that will address health disparities in substance use and/or pain management outcomes.
- Considering the role of holistic conceptions of health, strength-based perspectives, traditional medicine, ceremony and spirituality (where research is desired and allowed) and other approaches important within Native American communities for addressing substance misuse or improving pain management, and addressing related factors including improving mental health.
- Increasing data relevance, accuracy, and timeliness to support local decision-making, and serve as a foundation for impactful research, and underpin the design of effective interventions.

Applicants are encouraged to consider a range of Indigenous and/or Western methodologies and approaches, including those that rely on Indigenous Knowledge or the lived experience of Indigenous researchers or practitioners, as applicable, or some combination thereof. Priority consideration will be given to applicants that can document a commitment to advance their research capacity to participate in future NIH research. The N CREW Program intends to build research capacity within T/NASOs. Therefore, for this ROA (OT-23-007), NIH will prioritize meritorious applicants who have not previously applied for or received NIH funding.

What will Not Be Funded:
- Direct services in the absence of a research or research capacity component.
- Capacity building that is not focused on HEAL related research/data projects (https://heal.nih.gov/).
- Projects that do not include a focus on topics or outcomes related to the HEAL Initiative.

Activities

Proposed activities are expected to be individualized and tailored to applicant needs and the objectives of their proposed project. However, there are two underlying sets of activities that intersect with this work that NIH considers instrumental for the success of the N CREW Program will be required if funded (1) Collaboration and Partnerships; and (2) Consideration of Data Management and Sharing (as appropriate - see below).

Collaboration and Partnerships. Success of the N CREW program relies on individuals and organizations partnering to achieve goals. NIH, T/NASOs, and Ally Organizations all have institutional knowledge that, when combined, facilitate innovation, and can more comprehensively meet the research related needs of T/NASOs

and the N CREW Program goals. Therefore, NIH considers the willingness to collaborate with other T/NASOs, Ally Organizations, and NIH a critical element of successful applications. While some applicants may apply with partners, other applicants may not have identified partners. All recipients will need to develop partnerships across the N CREW Program. Partnership development might require multiple strategies. As one strategy, all N CREW recipients should plan to participate in a series of at least 4 (2 in-person and 2 virtual) N CREW Teaming Meetings (i.e., partnership development meetings) to occur in the first year. These meetings will provide an opportunity to learn more about the activities of each recipient funded, develop and/or enhance partnerships to address capacity needs and advance research/data projects, and co-construct strategies to advance research in Native communities. The location of the meetings will be informed by the geographic location of recipients and NIH. Partner meetings for year 2 or beyond will be determined as N CREW Program and project needs emerge. Beyond these planned meetings, it is expected that all N CREW Program recipients will collaborate with essential partners across the N CREW Program in an interconnected manner. Budgets should reflect proposed collaboration and partnership plans, as applicable.

Consideration of Data Management and Sharing. Accurate data are needed to comprehensively define the opioid/drug crisis, to understand related factors, and to identify prevention efforts and treatments that are most likely to lead to improved health outcomes. Sharing data generated from research can also spur additional discoveries and innovation, although data must also be managed to protect sensitive information. For Native American data, rapid advancements in data sharing must be balanced against historic and harmful misuse of data. Data sharing also must comport with policies and preferences of sovereign Tribal Nations. T/NASOs will be expected to collaborate across the N CREW Program to determine ways to manage sensitive data and consider under what scenarios (if any) such information might be shared while prioritizing Tribal policies, Native research approaches, and community preferences. If appropriate strategies are identified, the Program will seek to implement these strategies in collaboration with T/NASOs and Ally Organizations. Budgets should reflect proposed data management or sharing plans, as applicable.

Milestones

Applicants must submit a set of draft milestones. Milestones should be measurable and indicate progress and/or completion of each proposed task with timelines. At minimum, NIH anticipates applicants will include milestones addressing the following activities:

- Collaborate with partners across the N CREW Program on an ongoing basis.
- Actively participate in Teaming Meetings.
- Share activities that are undertaken with other N CREW Program recipients.
- Identify and complete activities that support the development of a research and/or data improvement project.
- Register their study with the HEAL platform within one year of award.

Applicants should include other milestones that align with the activities they propose for Phase I. The milestones submitted by the applicants will be evaluated, but final milestones will be negotiated in collaboration with NIH and based on the application and other N CREW Program resources and needs. Examples **may include**:

- Establish a local community assembly or advisory board to guide and advise on priorities and processes for conducting research or improving data.
- Plan and identify an internal process for partnerships and develop a structure to support collaboration to attain project goals.
- Develop a proposal for implementation of full research/data projects.
- Serve as a member of a governance structure (to be determined) that will support N CREW Program activities.

- Identify the resources needed to achieve project goals and engage in Technical Assistance.
- Conduct assessments of initial capacity and infrastructure for conducting research and refine research capacity goals.
- Develop and submit reports that describe research capacity assessments, goals and needed resources.
- Work with partners to identify Common Data Elements to be collected and shared across sites that conform to Tribal policies and preferences.
- Participate in activities to support developing data sharing best or promising practices that support advances in Native research and sharing data when allowed and desired.
- Share data collection instruments.
- Finalize a data sharing plan (note, all applicants must submit an initial data sharing and management plan in the application, but this may be refined over the course of the Program).
- Develop a proposal or plan for Phase II to sustain, expand, continue to more fully implement activities funded in Phase I.
- Participate in one or more trainings to learn or expand research skills.

Deliverables

Reflections Report. The N CREW Program seeks to establish or enhance research capacity for T/NASOs to promote research that is prioritized by Native communities. While some T/NASOs have their desired level of research capacity, many desire advancements to conduct research projects fully within their organizations. The capacity needed to conduct NIH supported research includes, at a minimum, financial accounting systems, tracking and reporting on activities, research expertise, identification of research specific aims, study design expertise, expertise in implementing research plans, Institutional Review Board (IRB) review, and data management tools and expertise, among other requirements.

To help facilitate knowledge, information sharing, and research capacity building for addiction and/or pain management research, recipients will be expected to submit a reflections report at the end of Phase I to serve as a blueprint for other organizations interested in enhancing their capacity to engage in research or improve data. NIH anticipates this deliverable will thoroughly capture the process and substance of the project, including partnerships, the lessons learned, challenges, and success of the project, and overall reflections. The format of this report may be written, although other formats will be considered with recipients to best align with their community and communication preferences.

Eligibility

The N CREW Program expects Tribes and Native American Serving Organizations (T/NASOs) to lead research efforts in collaboration with partners, as appropriate. For the purposes of this ROA (**OTA-23-007**), a T/NASO is defined as federally or state recognized Tribes and/or organizations with core missions to serve and/or a track record in serving Native Americans and that are poised to reach this population. These could include, for example, community organizations, local businesses, neighborhood authority or association, patient or consumer advocacy groups, regional/local and public healthcare systems, schools, law enforcement or criminal/juvenile justice agencies, or social service agencies.

The following T/NASO entities that are located in the United States are eligible to apply under this ROA:

Non-profits

- Non-profits with 501(c)(3) IRS Status
- Non-profits without 501(c)(3) IRS Status including but not limited to:
    - Faith-based or community-based organizations

- o Patient or consumer advocacy groups
- o Social service organizations o
- o Healthcare systems and providers (including Federally Qualified Health Centers)
- o Schools
- o Law enforcement and criminal/juvenile justice agencies
- o Neighborhood associations

For-Profit Organizations

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

Governments

- Tribal District Governments (with any Tribally required approvals as required by the Tribe)
- American Indian/Alaska Native Tribal Governments
- American Indian/Alaska Native Tribal Governments (Other than Federally Recognized)
- Business regularly employed by a T/NASO to provide fiscal management services.

Non-federal Tribal governments are eligible and their respective departments of public health, commerce, labor, transportation, housing and recreation or other departments within a Tribe.

Academic research centers, academic healthcare organizations, private healthcare organizations, and research organizations are eligible **only** if they are a Tribe or organization with a core mission to serve Native Americans, can document a track record of successfully meeting this mission, are poised to reach this population, and can obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative, if appropriate, before the time of award. Academic research centers that do not meet the above eligibility specifications may be identified partners in the application through an MoU, contract, subaward, etc.

If applying as a NASO, the applicant will need to document they have a core mission to serve Native Americans and are poised to lead community-prioritized research. See more information in the Developing Applications section.

T/NASOs are eligible to apply to this ROA (**OTA-23-007**) and the companion ROA (**OTA-23-008**).

If applying as a business or Financial Management company, the applicant will need to demonstrate a legally binding relationship with the T/NASOs in financial matters, meet other eligibility criteria, and obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative before the time of award.

Non-domestic (non-U.S.) Entities (Foreign applicants) are **not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are **not** eligible to apply. Foreign components are allowed if they maintain a legally documentable relationship to a US Tribe.

Applicant organizations may **not** submit more than one application. Individuals not affiliated with an organization, or who want to submit an application independent of their current organization, may not apply.

Applicants may use a Multiple Principal Investigator (MPI) model which allows the applicant to utilize a collaborative approach of having more than one individual lead the project. If an MPI model is selected the applicant will need to select one individual to serve as the main contact for the application and provide an MPI Plan. The MPI Plan should include the individual roles and responsibilities as well as a plan for communication/collaboration and how conflicts will be resolved between the parties.

Developing Applications

Letter of Intent (LOI)

LOIs are strongly encouraged, but not required. Submitting an LOI will help NIH prepare for providing technical assistance and plan for a timely review of applications. LOIs are not binding and will not be considered in the objective review. NIH recommends that applicants limit the LOI to 2 or fewer pages. Please include the following information:

- Legal name and, if applicable, the legal name(s) of partners.

- Name and contact information (including email and phone number) for the Principal Investigator who will serve as the application contact, any Multiple Principal Investigators, and other key persons.

- Describe any technical assistance that might be needed to apply to this ROA.

- Brief description of the activities that will be proposed in the application.

Letters of Intent should be submitted to NCREW@nih.gov no later than September 1, 2023.

Application Format

Applications will be accepted only from organizations listed in the Eligibility section of this announcement.

Applications must be prepared and submitted using NIH's ASSIST by the recipient Signing Official (SO). The organization must be registered in eRA Commons with one person designated as the Principal Investigator (PI) and one person designated as the SO. If an individual plans to serve in both roles, they will need two separate sets of credentials. Applicants should begin the registration process early as the entire process can take up to 6 weeks to complete. The SO's signature certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded for the performance of the OT award-supported project or activities resulting from the application. It is preferred, but not required, that all key personnel also be registered in eRA Commons prior to submitting an application.

Applications should be submitted on or before the "application due date" shown under the "Key Dates" section of this announcement in text-recognizable PDF (Adobe) format, use 11-point font with 1" margins and be single-spaced. The sections of the application **should be combined and uploaded as one attachment,** titled TNASO_PI_Last Name_ Org Name.pdf. In addition to the single pdf submission, applicants will be required to enter the abstract and specific aims sections into specified fields within ASSIST.

All applications should include the following sections: (1) title page; (2) abstract; (3) specific aims; (4) planned activities and approach, including a discussion of key personnel experience, a management/staffing plan, and milestones; (5) data sharing plan; (6) budget; and (7) fiscal management information. If applicable, applications should also include the following sections: (8) justification for identifying as a Native American Serving Organization, and (9) letters of support.

1. **Title Page (Limited to 1 page)**

The title page should include all the following information:

    A. Application title
    B. The Applicant Organization:
        a. Legal name and, if applicable, the legal name of all partners
        b. Entity address and contact information

C. Name and contact information (including email and phone number) for the Principal Investigator who will serve as the application contact (with NIH Commons Account information), any Multiple Principal Investigators, and other key persons

D. The name and contact information (including email and phone number) for the Applicant's Signing Official, the person authorized to negotiate and bind the Applicant as a signatory to the Other Transactions agreement

E. Total cost requested

2. Abstract (Limited to 1 page)

Provide a short summary of the application.

3. Specific Aims (Limited to 3 pages)

The specific aims should discuss the broad overarching goals of the proposed project, detailing a high-level focus of the proposed work and its significance for the community and/or Native American populations. It should include a discussion of solutions or approaches that are novel or innovative for the community and culturally appropriate, also addressing how the proposed activities and/or methods can advance knowledge to address drug overdose, substance use, or pain management and other related factors such as mental health in the local communities.

4. Planned Activities, Approach, and Key Personnel (Limited to 12 pages)

This section should include the following:

A. ***Planned Activities and Approach***: Describe the proposed research/data-related activities and the identified needs of the community, including how the activities have the potential for advancing solutions to the identified needs in the community. Also discuss the potential for planned activities to yield long-term, sustainable benefits for T/NASO-led research. The strategies for building research capacity or data improvements, development and planning activities, and collaboration should also be explained.

B. ***Key Personnel Experience***: document the experience of key personnel supporting the planning and implementation of activities proposed. The Principal Investigator and/or key personnel must document previous successful partnerships with American Indian/Alaska Native/Native Hawaiian (AI/AN/NH) communities or Tribes, an understanding of AI/AN/NH research preferences, and an understanding of Tribal sovereignty.

   o ***Include key staff resumes***: Include a 3-page or less resume for the Principal Investigator(s) and each person who will be assigned to manage performance, supervise work for tasks, or will otherwise be a main contributor to the proposed work. Note: Resumes **do not count** toward the 12-page limit for this section and should be submitted as an appendix within application pdf.

   o ***Multiple Principal Investigators***: More than one individual may be named as Principal Investigator in the application. One individual must be identified as the contact Principal Investigator. The contact Principal Investigator must be employed by or affiliated with the applicant organization. If a multiple Principal Investigator application is submitted a leadership plan that specifies how conflicts will be resolved is required.

C. ***Management, Staffing, and Partnering Plan***: Describe how the applicant will provide the necessary project administration, organization, and staff to ensure successful execution of the proposed project, including demonstrating a readiness to partner or collaborate. Applicants applying with partners should

include a partnership plan that outlines how the partners will work together to accomplish the proposed activities.

D. **Milestones:** Applicants should include draft milestones (that can be measured), tasks to be completed to meet the milestone with of a description of how they will be completed, expected start and completion dates for each milestone, and estimated cost to complete each milestone. For an example, see the Questions and Answers posted on the [N CREW Website](#).

5. Data Management and Sharing Plan

NIH requires researchers to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan. Applications should include a Data Sharing Plan outlining initial plans for how scientific data and accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations including those related to Tribal policies or preferences. (See also [Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data](#)).

During negotiations and Phase I of the N CREW Program, funded recipients will refine this plan. Upon NIH approval of a Plan, NIH expects researchers and institutions to implement data management and sharing practices as they have described. Costs associated with data management and data sharing may be allowable under the budget for the proposed project.

Phase I projects will be subject to the [NIH Data Management and Sharing Policy](#), which requires that recipients submit a plan to manage and share data. Justified exceptions to sharing data are allowed, as noted in the Policy.

The NIH HEAL Initiative® also supports a [HEAL Data Ecosystem](#), which aims to provide virtual open access to HEAL research data, findings, and publications as well as to establish a secure data access and computing environment. In Phase I, all recipients should consider this ecosystem and how they might engage with it.

6. Budget (No page limit)
Proposed budgets must provide a realistic and well-justified cost proposal for performing the proposed work over a period of up to 2 years. Budgets for individual awards are expected to vary, depending on the proposed activities and resources. NIH *anticipates* annual total budgets will range from $200,000 to $550,000 depending on the proposed activities and resources, but there is no annual budget limit. The budget must reflect the needs of the proposed work.

Provide the overall expected cost for each of the following categories:

- Personnel
  - Budgets must adhere to latest NIH salary limitation notice (See [NOT-OD-23-056](#), Guidance on Salary Limitation for Grants and Cooperative Agreements)
- Equipment
- Travel
- Partners such as Subawards/subcontracts/consultants
  - Partners need to provide details of cost breakdown
- Other direct costs
- F&A (indirect) costs – if an applicant has an approved facilities and administrative costs rate agreement with the federal government, the approved rate should be reflected in the budget request. If the

applicant does not have an approved facilities and administrative costs rate agreement, they may propose a rate for NIH review and consideration.
- Total cost (with indirect costs included)

Budget estimates should account for the following:

- Travel costs for a PI and at least one other team member (or as many are anticipated as needed) to attend the 4 Teaming Meetings (2 in-person, 2 virtual) in the first year of the project. The location of the in-person meetings will be decided based on the geographic location of recipients and NIH.
- Staff time for participation in cross-program workgroups and meetings, at a minimum expected to include the 4 Teaming Meetings, 2-3 ongoing special interest or cross-site workgroups, and N CREW governance meetings (minimum once per month).
- For manuscripts published in journals that are not immediately open access, applicants should include costs to pay for immediate open access.
- There is a high level of coordination and sharing among NIH Health Initiative award recipients. To facilitate collaboration, N CREW award recipients will be invited to attend an annual HEAL Investigators meeting. Applicants interested in attending this meeting should budget for annual in-person travel for their Principal Investigators.

7. Fiscal Management Information (Recommended less than 1 page)
Describe the Applicant's organizational capacity and fiscal experience with managing program costs over $200,000, and/or proposed plan for managing the award if funded.

8. Tribe or Native American Serving Organization Documentation (Recommended 2 pages or less)
The applicant must provide the name of the Tribe(s) or the name of the Native American Serving Organization and, if not a Tribe, a justification that demonstrates their core mission to serve Native Americans and that they are poised to lead Native American community prioritized research work. For example, this may be by submitting a copy of their organization's mission statement articulating their core mission to serve Native Americans, information about its track record of partnering with Native American communities and individuals, and/or through means they deem appropriate of demonstrating their historical commitment to serving Native Americans. If the T/NASO regularly employs a Financial Management company that regularly serves to legally bind the T/NASO in financial matters, that company may be the applicant organization if they meet other eligibility criteria described in the Eligibility Section and can obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative before the time of award.

9. Letters of Support (No page limit)
Letters of support (including Tribal resolutions, and/or executive orders) from identified partners, organizations, etc. should be included in the application as relevant. As each situation will be unique, applicants should carefully evaluate what letters of support will be most helpful for evaluating their application. For example, if a T/NASO is partnering with other T/NASOs, they should provide letters of support with a description of how they will work together.

For applications involving Tribal governments or proposing research on Tribal lands, an executed Tribal resolution, executive order, or letter of commitment from the Tribal authorized representative sanctioning the project will be required at the time of award.

Human Subjects Protections

For research involving human participants, NIH has specific requirements for research staff, and policies regarding research conduct, safety monitoring, and reporting of information about research progress. If funded, all human subjects research must be approved by an Institutional Review Board (IRB) and be conducted under a Federal Wide Assurance (FWA). Before engaging in any human subjects research, recipients must obtain Federal Wide Assurance (FWA) from the DHHS Office for Human Research Protections (OHRP) (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html), and comply with 45 CFR 46 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html), and, as applicable, any relevant FDA regulations (e.g., 21 CFR 11, 50, 54, 56, 312, and 812) (https://www.fda.gov/medical-devices/medical-device-databases/code-federal-regulations-title-21-food-and-drugs) governing the protection of human subjects and the conduct, management, and oversight of clinical trials. Working with an IRB to gain approval may be included as an Activity in Phase I.

Recipients will need to provide to the NIH Agreement Officer/Specialist (the NIH staff person who is authorized to award Other Transactions) evidence of an active FWA prior to the commencement of any human subject research activities contemplated under this Agreement. Further, recipients must comply with all applicable laws and regulations relating to the privacy and confidentiality of human subjects.

In addition, for research involving human participants, recipients will be required to provide the number of participants they plan to recruit, and NIH will monitor progress made towards recruiting that number.

Objective Review

Applications to this ROA will be reviewed using a process referred to as Objective Review.

Non-Responsive Applications

Applicants will be considered non-responsive if:

- Activities include direct services in the absence of a research or research capacity component
- Research topics are not HEAL-related
- NASOs do not include a justification that clearly demonstrates a core mission to serve Native American populations and that they are poised to lead Native American community prioritized research work.

Non-responsive applications will not be reviewed.

Review Process

Responsive applications will be reviewed by subject matter experts via an objective review process. The subject matter experts will include NIH and other federal staff, and external expertise as needed. The Objective Review process will use review criteria (described below) to guide the subject matter reviewers on the assessment of applications, the preparation of written evaluation summaries, and the discussions between those experts and NIH program staff.

Applicants will not receive written feedback on their application based on the objective review. However, if resources allow, NIH may provide feedback in a post review discussion call if requested by the applicant. NIH will not accept an appeal of the objective review or funding decision outcomes.

Review Criteria

Individual subject matter experts will review and assess each application taking into account the following:

For each of the following criteria, reviewers will indicate a rating of a) highly likely, b) moderately likely, or c) unlikely:

1. ***Likelihood of contributing to advances in addressing substance use (including opioid and/or stimulants) and/or pain disparities for Native Americans***
   - Are the proposed activities likely to (1) enhance research capacity and/or data improvements or (2) prepare for T/NASO-led research and data projects on opioid/drug use and/or pain, and related outcomes as applicable (e.g., mental health, wellbeing)?
   - Are the proposed approach(es), activities, and/or resources, contributing in innovative and unique ways to addressing community needs?
   - How likely will the proposed activities foster the development and long-term success of T/NASO-led research that supports strategies to impact opioid/drug and/or pain related outcomes and increase wellness in Native American communities broadly?
2. ***Likelihood of accomplishing proposed activities***
   - Are the proposed milestones feasible and/or appropriate to complete the proposed work?
   - Are the proposed key personnel, staffing structure, partnerships, and/or plans to hire additional personnel and form new partnerships, appropriate for achieving the proposed activities?
3. ***Likelihood of forming effective collaborations and partnerships***
   - Does the applicant demonstrate a readiness to engage and collaborate with partners as appropriate [e.g., other T/NASOs, Native Research Resource Network members (see OTA-23-008), and NIH]?
   - Will proposed activities be carried out in a way that promotes relationships of mutual trust and respect among recipients of the N CREW Program?

Assessment of Overall Impact: Reviewers will provide an assessment of whether the overall proposed activities are likely to have a high, medium, or low potential impact on advancing research/data or research capacity building to address overdose, substance use, and/or pain management, also possibly including related factors such as mental health and wellness within Native American communities.

Additionally, reviewers will be asked to identify key aspects of applications that merit additional interest:

1. **Components:** Laudable activities within applications that independently have potential to significantly advance the N CREW Program goals.
2. **Areas for Improvement:** How applications or independent activities proposed might be improved.

Review outcomes are likely to include recommendations that could facilitate dialogue or site visits between applicants and federal staff, leading to modifications of the milestones submitted to NIH. Components of the applications may be accepted into the final plan in whole, in part, or may be omitted. The modified tasks and milestones, as shaped by the objective review process, will serve as a framework for the final negotiated terms for the resulting awards.

Negotiations

Based on the objective review, NIH will select a subset of applicants and/or subsections of applications to negotiate award terms. Final funding decisions will be based on the outcome of the objective review and negotiations between the selected recipients and NIH. Agreements for all awards will be negotiated via video conference, site visit, and/or teleconferences.

NIH reserves the right to:
- Accept applications in their entirety or to select only portions of applications for award.

- Fund projects by combining applications as part of a reorganized, consolidated consortium operating under an article of collaboration, teaming arrangement, or other means acceptable to NIH.
- Remove applicants from award consideration should the parties fail to reach a finalized, fully executed agreement, or the applicant fails to provide requested additional information in a timely manner.

If a limited number of responsive applications are received and/or there are significant gaps in the research areas proposed, NIH may determine a need to invite additional organizations to submit an application for consideration after the posted due date. Invited applications will undergo an internal review process based on the criteria specified above.

Financial and Risk Assessment

As is standard for OT programs, all applicants will be subject to financial analysis and risk assessment conducted by NIH staff.

Special Award Terms

The complete terms and conditions of each Other Transactions award issued under this ROA are subject to negotiation and will be contained in the OT Agreement entered between NIH and the recipient. This Special Award Terms section is provided for informational purposes only to provide prospective applicants with an understanding of key expectations and terms that may differ from traditional NIH award mechanisms (e.g., cooperative agreements/grants or procurement contracts). All terms and conditions of award will flow down to any partners (e.g., subrecipients, collaborators) participating in the OT award.

The funding mechanism of this ROA is Other Transactions Authority (OTA). The use of OTA will support NIH taking a flexible approach to negotiate award terms and conditions. The OTA award mechanism allows significant ongoing involvement from NIH Program Staff and allows NIH to alter the course of projects in real-time to meet overarching N CREW Program goals. This may mean an awarded activity could be expanded, modified, or discontinued based on Program needs, achievement of agreed-upon activities, or availability of funds. During the funding period, performance will be reviewed on an ongoing basis with course corrections taking place where necessary. As a result, NIH reserves the right to fund projects in increments and/or continue or discontinue work at the end of each phase.

NIH expects publications resulting from the NIH HEAL Initiative funded studies to be immediately available to the public upon publication. Recipients should plan to coordinate with journals in advance to pay for immediate open access. Prior to publication, award recipients are encouraged to alert their Other Transactions Program Official and Agreement Specialist of upcoming manuscripts to ensure coordination of communication and outreach efforts.

Potential Addition of Partners for Award
With mutual consent of the applicant and NIH, successful proposers might be asked to develop partnerships with entities identified and approved by NIH. This might be the case if NIH determines during objective review that a T/NASO does not have sufficient capacity to conduct their proposed project, that T/NASO may be asked to partner with another T/NASO to provide the support needed to begin work on the applicant's project.

Post Review Submission of Milestones and Timeline
NIH will review and approve the proposed milestone-based work plan agreed upon during negotiations for inclusion in the OT Agreement. Those selected for funding will:

- Produce and submit a written final plan with self-identified milestones and a timeline to be agreed upon with NIH staff (may be informed by negotiations); and
- Achieve milestones as defined in a binding, written agreement to be developed and agreed upon by NIH and the recipient.

Payment

The OT award will use the Payment Management System (PMS) operated by the DHHS Program Support Center. Payments by PMS may be made by one of several payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis as specified in the terms of the Agreement. Generally, payments align with achievement of milestones and a payment schedule will be negotiated prior to issuance of the award to minimize the amount of time elapsing between the transfer of funds from the Federal Government and disbursement by the recipient. NIH and/or applicants may negotiate non-milestone-based payment structures for part or all of the award period.

Reporting

The terms and conditions of award will address this requirement as appropriate based upon the final negotiated and agreed upon budget.

1. Financial and Progress Reports:
   - Recipients will be asked to provide regular progress reports to the OT Program Official and Agreements Officer. The frequency and types of technical and financial reports (e.g., Federal Financial Reports) required will be specified in the Agreement document, and will include, at minimum, financial status reports that will establish the burn rate for the project and a bi-annual progress report.
   - A final Federal Financial report is required for all Other Transactions Awards. A final reflections report that summarizes the project and tasks will be required at the end of the Agreement period.

     The reports shall be prepared and submitted in accordance with the terms and conditions requirements. Failure to submit a required report may deem an applicant ineligible for Phase II support.

2. i-Edison: Agreement terms and conditions will contain a requirement for patent reports and notifications to be submitted electronically through the i-Edison Federal patent reporting system at https://www.nist.gov/iedison.

Questions and Answers

Responses to Questions about this ROA will be posted here: : heal.nih.gov/ncrew.

Submission and Contact Information

Letters of Intent should be submitted to NCREW@nih.gov no later than September 1, 2023.

For best consideration, applications should be submitted in ASSIST **Wednesday, November 1, 2023**, **by 5 PM local time**.

Financial and administrative questions should be addressed to Jennifer Cho, NCATS Agreements Officer, by email at NCREW@nih.gov.

Technical questions regarding ROA should be addressed to NIDA program official Dr. Kathy Etz by emailing NCREW@nih.gov.

eRA Registration

NCATS (the NIH Institute that will administer awards) uses the eRA Commons system to administer OT awards. Therefore, prior to submitting your application via eRA ASSIST, it is essential that your organization, Principal Investigator (PI), and Signing Official are registered at eRA Commons. It is desirable, though not required, that other key personnel are also registered at eRA Commons. Please plan to complete the registration process early to avoid application submission problems. To register, please follow the instructions via this website: https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era.

1. Complete the online Institution Registration Form and click Submit.

2. The NIH database will send you an email with the link to confirm your email address.

3. Once your email address is verified, NIH will review your request and let you know of the result via email.

4. If your request is denied, you will get an email notifying you of the reason.

5. If your request is approved, you will get an email with your Commons User ID and temporary password.

6. Log into Commons with the temporary password and the system will prompt you to change temporary password to a permanent one. Your Signing Official will be prompted to electronically sign your registration request. (Please review your registration information carefully.)

7. Once your Signing Official has electronically signed the request, your organization will be active in Commons, and you may create and maintain additional accounts for your institution staff.

Once you have established an eRA account, the next step in the process is to formally submit your application in ASSIST, which is a component of the eRA system.

Please note that in order to receive an award, you **may** need to register for one or more of the following if you haven't done so already:

System for Award Management (SAM)

Unique Entity ID (UEI) created in SAM.gov

Employer Identification Number (EIN)