

Research Opportunity Announcement (ROA)

OTA-23-008

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

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 Native Research Resource Network (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-23-008
Related Notice	NOT-DA-23-022 OTA-23-007

<p>Research Opportunity Announcement (ROA) Purpose</p>	<p>As part of the NIH HEAL Initiative®, the N CREW Program 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-23-008) solicits applications from T/NASOs and Ally Organizations to form a Native Research Resource Network. The network will provide comprehensive training and resources to support T/NASOs in real-time as they lead research and data improvement projects. Components of the network will also provide coordination of resources, reporting, and cross-site activities. Applicants are strongly encouraged to read the related ROA (OTA-23-007), which solicits applications from T/NASOs for the planning, development, and piloting of research and/or data improvement projects. Native Research Resource Network members and T/NASOs will collaborate to meet program objectives.</p>
<p>Objective Review</p>	<p>NIH will engage a panel with appropriate expertise to evaluate applications. See the Objective Review section of this opportunity for further details.</p>
<p>Eligibility</p>	<p>See the Eligibility section of this opportunity for further details.</p>
<p>Funds Available and Anticipated Number of Awards</p>	<p>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 5 awards under this OTA-23-008 and 15 awards under the companion OTA-23-007. For this OTA-23-008 supporting the Native Research Resource Network, NIH intends to allocate approximately \$5.2 million/per year and anticipates annual budgets for awarded applications will range from \$500,000 to \$1,300,000.</p> <p>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).</p> <p>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.</p> <p>Awards pursuant to this funding opportunity are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.</p>
<p>Award Project Duration</p>	<p>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.</p>

<p>Application Submission Instructions</p>	<p>Applicants must submit applications via the NIH eRA ASSIST system by 5:00 PM local time on the due date (see Key Dates below).</p> <p>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-23-008 in the Opportunity Number field.</p> <p>Here are instructions for submitting applications via the NIH eRA ASSIST system. Technical assistance is available from the eRA Service Desk.</p> <p>On the eRA Commons home page, select the “Register Organization” link for more details.</p> <p>Submission and Contact Information. Applications should be submitted by the proposing entity’s Signing Official (SO) 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.</p> <p>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.</p>
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Key Dates

Post Date	June 23, 2023
Informational Webinar Dates (optional)	There will be a series of webinars. The first 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 5 PM 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

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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, resources, 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 by addressing HEAL related factors, also reflecting an openness to authentic collaboration with Native communities. HEAL related projects must include opioids, stimulants and/or pain and can also include related factors.

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-23-008) solicits applications from Tribes and Native American Serving Organizations (T/NASOs) and Ally Organizations to form a Native Research Resource Network. In Phase I, the Native Research Resource Network will provide comprehensive training and resources to support T/NASOs in real-time as they develop plans to lead research and data improvement projects. Components of the network will also provide coordination of resources, reporting, and cross-site activities. Organizations applying to this ROA should also carefully **read the related ROA, OTA-23-007**, which solicits applications from T/NASOs to engage in approximately 2 years of research planning, development, and other activities to provide a foundation from which all N CREW Program goals can be attained.

Phase II (not this ROA) is anticipated to begin in FY26 and will build on what is learned and achieved in Phase I. As such, the exact activities for Phase II are unknown at this time. Phase II will likely support implementation of research projects developed in Phase I. However, given the expected variation in initial research capacity of T/NASO Phase I recipients, Phase II might support additional pilot and development work, for example, for some T/NASOs. The Native Research Resource Network will continue to support the N CREW Program in Phase II, and Phase II activities will depend on T/NASO needs related to Phase II goals. 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.

Native Research Resource Network (This ROA)- Objectives

NIH seeks applications from T/NASOs and/or Ally Organizations to participate in a multi-component and agile Native Research Resource Network working responsively and collaboratively to:

- Develop and provide comprehensive, real-time resources and support to one or more T/NASO(s) as they enhance research capacity.
- Identify effective strategies and approaches for supporting T/NASOs as they develop, and conduct HEAL related research and/or data improvement projects.
- Identify and implement activities (including coordination across the N CREW Program) that will maximize investments and facilitate long-term sustainability of research and data gains made by T/NASOs
- Identify opportunities to scale effective strategies and foster similar gains across Native American communities.

Given the significant diversity across T/NASOs' existing research capacity and expansion goals, no single organization is likely to meet the needs of all T/NASOs funded through N CREW. Partnership structures are also expected to require flexibility throughout Phase I as new needs emerge and the levels and types of resources needed change. For example, T/NASOs might need to change who they partner with, for how long they partner with each organization, and the degree to which they need to engage with each partner. Moreover, the N CREW program aims to develop a set of resources that are accessible and relevant to all T/NASOs across the nation, not just those funded through N CREW, requiring a broad range of expertise that no single organization can provide and that cannot be fully predicted in advance.

For this reason, NIH is using this flexible, agile funding mechanism (Other Transactions) to establish a Native Research Resource Network, which will allow for flexibility in modifying activities, partners or formal partnership structures over approximately the first 2 years of the N CREW Program. NIH anticipates the Native Research Resource Network will consist of about 5 organizations providing a wide range of expertise and resources, working in collaboration with one another, a diverse group of T/NASOs, and NIH.

NIH invites T/NASO and Ally Organizations to propose and describe **scientific, training, operational, coordination, institutional and other categories** of support that they can provide to advance N CREW Program goals. The Native Research Resource Network will collaborate with T/NASOs and NIH to co-create resources and co-develop and implement a variety of activities. Below are 4 broad categories of resources or activities that NIH anticipates will be needed by the Native Research Resource Network in Phase I. However, NIH **invites applicants to propose other resources or supports not covered below** because it recognizes that T/NASOs and Ally Organizations are best positioned to identify and anticipate innovative, effective approaches for enhancing research and data infrastructure and the conduct of research within Native American communities.

1. **Technical support, training, tools, or other resources** for T/NASOs that seek to build capacity for NIH-funded research and data improvement projects on HEAL related topics. Examples of expertise that may be needed are listed below, but the actual needs will be determined by T/NASOs:
 - Subject matter expertise related to overdose, substance use, pain management or other related factors such as mental health, wellbeing, etc.
 - Financial accounting systems
 - Tracking and reporting on activities

- Grant writing and monitoring
- Identification of research specific aims
- Assistance in identifying study designs
- Intervention research assistance
- Qualitative and quantitative research approaches
- Expertise in implementing research projects, e.g., Institutional Review Board review
- Assistance in producing reports (e.g., the Reflections Report required for T/NASO recipients)
- Data management and sharing tools and analytic expertise
- Data Safety and Monitoring Plans

2. ***Development and continual refinement of a coordination and reporting structure*** across all entities funded as part of the N CREW program, including T/NASOs working to develop and implement research and data improvement projects, members of the Native Research Resource Network, and other interested parties. This infrastructure is anticipated to:

- Coordinate and gather information across sites to ensure tracking of research outcomes, data improvements, interim reports, final reports, and other activities.
- Coordinate any NIH/HEAL reporting requests and work with the [HEAL Data Ecosystem](#) (where appropriate).
- Support dissemination of information learned across T/NASOs.
- Manage the coordination of comprehensive, real-time resources across T/NASOs.
- Develop and/or select and maintain collaboration infrastructure and technology to share materials, communicate updates or other information, etc.

The N CREW Program is seeking innovative applications for the development of a coordination structure that will allow T/NASOs some opportunity to specify how and with which organizations they would like to collaborate for all reporting, documentation, and other cross-site activities. NIH anticipates this coordination structure will include a subset of 2 or more organizations within the Native Research Resource Network working together (possibly partnered before applying or by NIH request), to increase the likelihood that the unique needs and partnering preferences of diverse T/NASOs can be met.

3. ***Meeting planning, technology, and related resources needed to establish, strengthen, and maintain partnerships*** in support of the N CREW Program goals. Given that partnerships are critical to the success of the N CREW Program, NIH anticipates dedicating funding to the development and implementation of innovative strategies for fostering and sustaining partnerships. Although final plans will be determined in collaboration with N CREW funded entities, NIH anticipates recipients will support:

- Approximately 4 teaming meetings or events (2 in-person and 2 virtual) to foster partnership building in the first year of funding; and
- Workgroups, special interest groups, governance meetings, and other cross-site meetings that will continue to enhance partnerships.

The member(s) of the Native Research Resource Network leading these partnership development efforts might be part of or work closely with the coordination and reporting structure described in #2 above.

4. **Activities to distill lessons learned, spur innovation, and accelerate progress** in enhancing research capacity within N CREW funded T/NASO sites as well as broadly for Native American communities. Below are some examples of what might be of interest, but these activities will be decided and developed in collaboration with all N CREW funded entities during Phase I:
- Track and consolidate challenges and successes, and report on the different structures and strategies T/NASOs employ to carry out research.
 - Identify, consolidate, and disseminate best or promising practices for developing and enhancing research capacity within T/NASOs, drawing on lessons learned across funded T/NASO sites; possibly developing a research readiness model or other model that can be broadly shared with Native American communities.
 - Support the identification by T/NASOs of culturally relevant common data elements (data that all recipients agree to collect at their site) that are meaningful both locally and across sites; possibly using tools like NIMHD [PhenX Social Determinants of Health \(SDOH\) Assessments Collection](#).
 - Working with State Public Health departments, the Indian Health Service, or other organizations to support access to or improve available data.
 - Develop a system, approach or tool to identify and partner research scholars with T/NASOs.
 - Develop an innovative program or process for training and mentoring research scholars.
 - Create a team responsible for assessing opportunities for and supporting the integration of Indigenous and Western science, where appropriate.
 - Work with T/NASOs and/or across the program to plan for scalability and sustainability in research capacity gains, the conduct of research, and for any intervention that is developed and tested through the N CREW Program.

Applicants are invited to apply to conduct activities in all 4 of these categories, selected categories, or other categories they deem important to addressing T/NASO research and data needs. NIH will prioritize applications with proposed activities that are likely to benefit greater numbers of T/NASOs. All organizations selected to participate in the Native Research Resource Network must be able to document strong Native American cultural expertise.

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 expects applicants will include milestones addressing the following activities:

- Collaborate with partners across the N CREW Program on an ongoing basis.
- Actively participate in the N CREW Teaming Meetings (i.e., partnership development meetings).
- Share information on activities that are undertaken by Native Research Resource Network recipients with NIH and other N CREW Program recipients.
- With T/NASOs, co-create a process to collaborate to develop research resources and/or engage in other proposed activities.
- Support efforts to coordinate across the N CREW Program by maintaining regular communication with NIH and the resource providers selected to coordinate the Program, anticipated to include participation in routine (e.g., weekly or bi-weekly, to be negotiated) meetings and submission of reports on activities, as needed.
- Register their project with the HEAL platform within one year of award.

Applicants should include other milestones that align with the resources and activities proposed to be provided within Phase I. The milestones submitted by applicants will serve as examples through which applications can be evaluated, but final activities to be performed will be determined by the needs identified in the T/NASO research applications (via ROA OT-23-007) and in real-time over the life of the N CREW Program, in collaboration with NIH. As such, tasks and milestones are expected to be updated during negotiations prior to award, and on an as needed basis throughout Phase I.

Eligibility

The T/NASOs and Ally Organizations funded under this ROA are expected to be diverse in their mission and entity type, but all must document significant experience working with T/NASOs.

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

The following entities are eligible to apply under this ROA:

Higher Education Institutions

- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)
- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)

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
- American Indian/Native American Tribal Governments (Federally Recognized)
- American Indian/Native American Tribal Governments (Other than Federally Recognized)

Other

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

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](#). Complete applications must be submitted 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. The SO 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. Applicants should begin the registration process early as the entire process can take up to 6 weeks to complete. 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 NRRN_PILastName_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, include (8) 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 one page)

Provide a short summary of the application.

3. Specific Aims (Limited to 3 pages)

The specific aims should summarize, at a high level, the scientific, training, operational, coordination, institutional and other strategies proposed to support T/NASOs as they build research capacity and develop research projects over approximately 2 years. Describe why the proposed work is likely to yield benefits for Native communities. Describe how the proposed strategies are innovative and will advance strategies for partnering and providing research training and resources.

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 activities and approaches for providing resources to and advancing T/NASO research and data improvement projects as well

as enhancing research capacity for approximately 2 years. Activities might be proposed in one or more of the 4 broad areas described above or other categories of supports anticipated to be needed by T/NASOs. Describe the planned approach for partnering to provide these resources. Describe a strategy for developing innovative, responsive solutions as needs emerge in real-time. Discuss the potential for planned activities to yield long-term, sustainable benefits for T/NASO led research potentially beyond the sites that receiving funding as part of the N CREW Program.

If proposing to support coordination across recipients funded through the N CREW Program, describe the coordination strategy, and explain how the strategy might work if T/NASOs are working with different entities within a coordination team (a decentralized coordination strategy). Describe how that strategy is innovative and allows T/NASOs flexibility and authority in how they engage in activities led by the coordination team.

- B. **Key Personnel Experience:** Document the experience of key personnel supporting the planning and implementation of activities proposed. Applicants must document they have significant experience in partnering with T/NASOs on research/data projects, demonstrating understanding of Tribal sovereignty and principles of American Indian, Alaska Native, and Native Hawaiian research.
- **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.
 - **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 quality control, compliance with expectations, and simultaneous management of multiple tasks. Organizations applying with other organizations should include a partnership plan. Also describe the applicant approach to making prompt, responsive staffing adjustments when needed. In addition, applicants must document willingness to and planned staffing structures that allow for partnering across the N CREW Program, including with a diverse group of T/NASOs, other members of the Native Research Resource Network, and NIH.
- D. **Milestones:** Applicants should include draft milestones (that can be measured), tasks to be completed to meet the milestones with of a description of how they will be completed and expected start and completion dates for each milestone. In addition, provide an estimate of how much each milestone will cost to complete. For an example, see the Questions and Answers posted on the [N CREW Website](#).

5. Data Management and Sharing Plan

Although members of the Native Research Resource Network will be providing resources to T/NASOs, it is possible members will generate data by consolidating information across sites, initiating data-generation activities at the request of T/NASOs or NIH, and/or providing data management and sharing support to T/NASOs.

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. Applications should include a Data Management and Sharing Plan outlining initial plans for how scientific data and any 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 during 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 described. Costs associated with data management and data sharing may be allowable under the budget for the proposed project.

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. NIH *anticipates* total annual budgets will range from \$500,000 to \$1,300,000 depending on the range of resources and activities proposed, but there is no annual budget limit. The budget must reflect the needs of the proposed activities. Higher budgets are likely to be allocated to T/NASO or Ally Organizations proposing to support the cross-site coordination infrastructure and/or cross-site research and data acceleration activities.

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 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 of one per month). Native Research Resource Network members selected to conduct cross-site coordination will also engage in routine (e.g., weekly or bi-weekly, to be negotiated) meetings with NIH.
- Funding for promptly hiring new consultants, partnering with new entities, or bringing on new team members based on emerging needs.
- 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, and/or expertise available, particularly with managing program costs of over \$200,000.

8. Letters of Support (No page limit)

Letters of support (including Tribal resolutions and/or executive orders as appropriate) 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 applications involving Tribal governments or proposing research being conducted on Tribal lands, an executed Tribal resolution, executive order, or letter of commitment from the Tribal authorized representative sanctioning the project will be required prior to 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-subject/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.

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

Applications will be considered non-responsive if they do not document strong Native American cultural expertise and experience working with Native populations. 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 the 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 three following criteria, reviewers will indicate a rating of a) highly likely, b) moderately likely, or c) unlikely:

1. ***Likelihood of meeting N CREW Program needs***

- Are the proposed activities and planned approach(es) likely to meet the needs of T/NASOs as they enhance research capacity and develop research projects?
- Are there robust, flexible efforts or strategies to understand T/NASO needs and meet these needs in real-time as projects progress?
- Is the applicant likely to use approaches that are culturally grounded and responsive to T/NASO preferences?
- Is there a clear commitment to advancing T/NASO-led research?
- How likely is it that the proposed key personnel, staffing structure, partnerships, and/or plans to hire additional personnel and form new partnerships, will contribute to the success of the proposed activities?

2. ***Likelihood of contributing research and/or data expertise to support T/NASOs to make advances in addressing substance use (including opioids and/or stimulants) and/or pain disparities?***
 - Is there sufficient evidence that the applicant will be able to provide and/or contribute to the development of research and/or data subject matter expertise and resources?
 - Does the applicant document prior experience collaborating with Native American communities to conduct research?

3. ***Likelihood of forming effective collaborations and partnerships***
 - How strong is the commitment to collaboration and development of partnerships?
 - Is there sufficient prior experience or planned activities to ensure effective collaboration and development of partnerships with T/NASOs, other Native Research Resource Network members, and NIH?
 - Consider whether the proposed activities will be carried out in a way that promotes relationships of mutual trust and respect.

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 T/NASO led research/data to address overdose, substance use, and/or pain management, also possibly including related factors such as mental health or wellness within Native American communities.

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

- **Components:** Laudable activities within applications that independently have potential to significantly advance the N CREW Program goals.
- **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 applications 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

With mutual consent of the applicant and NIH, successful proposers might be asked to enter into partnerships with entities identified and approved by NIH.

Post Review Submission of Milestones and Timeline

NIH will review and approve the proposed milestones 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 a 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 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 emailing 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 \(EIN\)](#)