

# Native Collective Research Effort to Enhance Wellness (N CREW)

## Archived Phase I Questions and Answers

These questions relate to the expired [OTA-23-007](#) and [OTA-23-008](#) funding opportunities.

### N CREW Program

#### Program Background, Goals, and Structure

##### 1. How is the N CREW Program funded?

The N CREW Program is funded through NIH's Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®. This Initiative bolsters research across NIH to improve (1) prevention and treatment for opioid misuse and addiction, and (2) pain management, including understanding and treating pain. [Learn more about the HEAL Initiative.](#)

##### 2. What are the goals of N CREW?

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:

- Support T/NASOs to lead community prioritized research projects, including research elevating and integrating Indigenous Knowledge and culture.
- 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.
- 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.

##### 3. The work we are doing in our community aligns with the goals of the N CREW Program, but we are not sure about pursuing these current research opportunities. How can we share the work we are doing?

Currently there are two active research opportunity announcements: [OTA-23-007](#) and [OTA-23-008](#). Even if you are not sure about applying for either of the two active research opportunity announcements, please email us at [ncrew@nih.gov](mailto:ncrew@nih.gov) to let us know about your work! NIH is interested in learning about the different ways communities are addressing overdose, substance use, pain, and related factors.

##### 4. What are the NIH's desired outcomes and lessons learned across the N CREW Program?

N CREW embodies and recognizes that Tribes and Native American Serving Organizations (T/NASOs) are best positioned to identify and respond to community needs through culturally grounded knowledge and strategies. Therefore, we expect that the Program will lead to more sustainable community solutions stemming directly from the development of culturally-relevant research and data projects and increased capacity for research that is driven by Tribes and Native community priorities. NIH's desired outcomes for the

N CREW Program include the following and understand the outcomes and lessons learned will be community driven:

- Reduce overdose related health inequities through science based, culturally relevant, community embraced, and sustainable strategies
- Discover the best ways(s) to build/enhance HEAL® related research capacity within T/NASOs
  - Discover effective/innovative models of Tribal/Native research capacity and infrastructure including opportunities for Native scholars
- Data sharing and stewardship best practices
  - Partner to learn under what circumstances (if any) data sharing may be desired and supported
  - Potentially build Data Archive and support cross site collection of outcome data
- Advance application/integration of Indigenous Knowledge in NIH research

**5. N CREW is described on the website as “multi-component” and in the ROAs as a “two-phase” program. What does that mean?**

In short, N CREW is both multi-component in its structure and two-phase in terms of the timing of activities.

Let’s break that down:

***N CREW is multi-component in structure.***

Throughout the duration of the N CREW program, NIH will fund projects from two kinds of applications, each engaged in different kinds of activities. Specifically, NIH is currently inviting applications from:

1) Tribes and Native American Serving Organizations (T/NASO) who want to plan for or conduct research or data projects in their community.

And, separately

2) T/NASOs and Ally Organizations with demonstrated cultural expertise and experience to provide comprehensive training and resources to support T/NASOs awarded through the application type noted above.

NIH may also introduce other components of the N CREW Program to support achieving the broad N CREW Program goals.

***N CREW is two-phased in its timing of activities.***

Because the aim of the program is to build capacity of T/NASOs for engagement in research, NIH has designed the program in two phases.

Years 1 and 2 (FY24-FY25) constitute **Phase I**, otherwise known as the planning phase of the program. Phase I is currently open for applications. The two ROAs that are currently active (i.e., [OTA-23-007](#) and [OTA-23-008](#)) describe Phase I activities and N CREW Program goals.

Years 3 – 7 (anticipated FY26 start) constitute **Phase II** of the N CREW Program. This phase is intended to support the implementation of research, projects, and activities developed by participants in each component (i.e., application type) of Phase I. Although Phase II intends to build from the learning and achievements from Phase I, the receipt of an award in Phase I does not guarantee recipients’ continuation to Phase II. NIH will release more information about Phase II at a later date.

The following table summarizes the program components and timeline:

N CREW Program: Addressing Overdose, Substance Use, Mental Health, and Pain		Program Phases – Total \$~268 Million (FY24-FY30)	
		Phase I (FY24-FY25) Theme: Development and Planning \$~25 million	Phase II (~FY26-FY30) Theme: Implementation \$~240 million
Components	N CREW T/NASOs Research and Data Projects	<b>ROA OTA 23-007</b> Solicits applications from T/NASOs for planning, developing, piloting, and/or implementation of research and/or data improvement projects.	Phase II will build on Phase I and priorities, potential opportunities and associated activities to be announced at later date
	N CREW Native Research Resource Network (NRRN)	<b>ROA OTA 23-008</b> Solicits applications from T/NASOs and Ally Organizations to form a Native Research Resource Network (NRRN). NRRN will provide comprehensive training and resources, and program coordination.	
	Other Components	To be determined	

#### 6. How are ROAs OTA-23-007 and OTA-23-008 connected with one another?

- ROA OTA-23-007. This opportunity invites Tribes and Native American Serving Organizations (T/NASO) who want to engage in the planning, development, piloting and/or implementation of research and/or data improvement projects. As noted in this ROA, N CREW seeks to support T/NASOs to conduct community-led research and/or improve data while increasing research capacity.
- ROA OTA-23-008. T/NASOs and Ally Organizations awarded through the OTA-23-008 will form a Native Research Resource Network. The Native Research Resource Network will provide comprehensive training and resources to support T/NASOs awarded through OTA-23-007 in real-time as they develop plans to lead research and data improvement projects. Components of the Native Research Resource Network will also provide coordination of resources, reporting, and cross-site activities.

T/NASOs awarded through OTA-23-007 and Native Research Resource Network members awarded through OTA-23-008 will collaborate to meet program objectives. Note that final activities to be performed under OTA-23-008 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. NIH intends to fund approximately 20 awards – approximately 15 awards under OTA-23-007 and 5 awards under ROA OTA-23-008.

It is important to note that 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.

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 OTA-23-007. Partnership structures are also expected to require flexibility 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 from the NNRN, 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 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.

The use of Other Transactions Authority (OTA) allows the N CREW program to provide a broad range of research support to award recipients that cannot be fully predicted in advance, meaning that new ideas or needs that arise can be addressed quickly. Additionally, OTA allows the N CREW program and participants to quickly pivot. That is, there is agility and flexibility in the ability to modify activities, partners, or formal partnership structures in response to new or evolving needs. This flexibility allows N CREW to support the discovery and creation of the best infrastructure and capacity building strategies possible.

The use of Other Transactions Authority (OTA) offers the N CREW program the unique opportunity to develop a custom program to support attaining Program goals. OTA allows NIH to provide a broad range of research support to award recipients that cannot be fully predicted in advance, meaning that new ideas or needs that arise can be addressed quickly. Additionally, OTA allows the N CREW program and participants to quickly pivot. That is, there is agility and flexibility in the ability to modify activities, partners, or formal partnership structures in response to new or evolving needs. This flexibility allows N CREW to support the discovery and creation of the best infrastructure and capacity building strategies possible through, for example, testing novel research infrastructures, bringing in new partners, etc.

## Topical Areas of N CREW Research Projects

### 7. What kinds of research and data projects are anticipated to be funded under the N CREW Program?

Typically the project **must** include a focus on overdose, substance use (including opioids or stimulants), or pain management. Projects **may also** include related factors (e.g., well-being, mental health, alcohol misuse), to support positive health outcomes in Native American communities. Within these topical areas, the specific research and data projects are expected to be diverse since they are applicant-driven and based on their community's priorities but could broadly be classified into three areas: Projects to (1) plan for or conduct research; (2) to improve data (e.g., access, quality, availability), or: (3) to enhance capacity of your community/organization to engage in (NIH supported) research.

Projects may include, for example, planning and development of research (e.g., needs assessments, research/data project planning, expanding research capacity), pilot and feasibility assessments, and/or conducting research. This includes technology 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. Applications who are proposing a new way of implementing research will also be considered. The research may or may not involve human participants (e.g., administrative data analysis, artificial intelligence/machine learning approaches). Data availability and access are also 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, also align with the priorities of the N CREW Program.

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.

#### **8. Can you provide more detail about what are considered *HEAL related factors*?**

The N CREW Program 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. The HEAL Initiative emphasizes a whole-person approach in which individuals and communities are understood as unique, as are risk (e.g., alcohol use) and resilience (e.g., connection to culture) factors related to substance misuse and addiction, mental health, and pain. Further, risk and resilience are understood as intersecting with individual and community-level factors and circumstances. Please keep in mind that applications must include a focus on overdose, substance use (including opioids or stimulants), or pain management and may also include related factors (e.g., mental health, wellness, alcohol use). [Learn more about the HEAL Initiative.](#)

#### **9. The ROAs say that the N CREW Program seeks to promote wellness among Native Americans by advancing research addressing overdose, substance use, pain, and related factors. How is wellness defined?**

The N CREW Program does not specify a definition of wellness. Tribes and Native American Serving Organizations (T/NASOs) that apply to conduct research or enhance data as part of the N CREW Program can define wellness based on community priorities.

Note that wellness cannot be the only outcome measured. As we just talked about, the ROA states: 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.

## 10. What is research?

In the most general terms, research can be understood as a methodological approach used to answer a question; it is typically based on or meant to test or extend an existing theory or to create a new theory. The research question is important because it will drive the research project/process. The research approach should utilize methods that are well suited to answering the research question to obtain results that one can have confidence in. Additionally, the approach should be tracked from beginning to end, from the formation of the research question(s) through the reporting of results, to transparently document and demonstrate quality and reliability of the process and results.

The research process starts with an idea. This could be a local observation, or it could stem from previous research findings or frameworks. Taking this idea and turning it into a research question is the second step. From there, if you are testing or extending an existing theory, you would want to incorporate that into or let it guide your planning for the project. Then you design the research project, collect your data, analyze it, and report out your findings. If you are using research to create a new theory, you might move from your idea to your question, then move into designing your research project, data collection, data analysis and reporting of findings to ultimately lead up to being able to articulate your new theory.

There are many existing research traditions and methods – including Indigenous research methods – each with their own standards for rigor (i.e., parameters for judging quality and reliability of the research process and results). Research traditions and methods may also require the creation or refinement of standards for rigor. Further, the research processes may not always move forward in a linear fashion, meaning that sometimes steps in the process are revisited for a variety of reasons (e.g., researchers become aware of new information or theories during the process). All these factors support the use of a systematic process that is well-documented throughout the project. The NIH is committed to promoting rigorous and transparent research in all areas of science. 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/NASOs and the Native Research Resource Network will collaborate to meet program objectives.

It may be useful to see responses to two other questions listed in this Q&A: “[What kinds of research and data projects will be funded under the N CREW Program?](#)” and “[Once projects are funded through OTA-23-007, what support and resources will be available for planning and developing our research/data project?](#)”

## 11. What does it mean that the N CREW Program is a trans-NIH Program?

This means that many Institutes, Offices, and Centers within the National Institutes of Health are in support of ROAs [OTA-23-007](#) and [OTA-23-008](#).

Issuing Institutes and Centers include:

- [National Institute on Drug Abuse](#) oversees the program.



- [National Center for Advancing Translational Sciences](#) oversees the Other Transactions Financial Management and review.

The following Institutes, Centers, and Offices are participating:

- [National Institute of Mental Health](#)
- [National Institute of Neurological Disorders and Stroke](#)
- [National Institute on Alcohol Abuse and Alcoholism](#)
- [National Center for Complementary and Integrative Health](#)
- [National Institute of Arthritis and Musculoskeletal and Skin Diseases](#)
- [National Institute on Minority Health and Disparities](#)
- [National Institute of Dental and Craniofacial Research](#)
- [National Cancer Institute](#)
- [Office of Research on Women’s Health](#)
- [Tribal Health Research Office](#)
- [National Institute of Nursing Research](#)
- [National Institutes of Health Office of the Director](#)
- [National Heart, Lung, and Blood Institute](#)
- [National Institute on Aging \(NIA\)](#)
- [Eunice Kennedy Shriver National Institute of Child Health and Human Development](#)

## 12. Do participating Institutes and Centers have research focuses areas for the N CREW Program?

As the ROAs state, the N CREW Program will support research that is **community prioritized** to improve outcomes related to the opioid public health emergency, including research and data enhancements related to addiction and/or pain. Within these broad parameters, different NIH institutes each have a different focus. Some examples of what Institutes concentrate on are provided here, but these are examples and are not meant to be limiting.

For example, there are many NIH Institutes, Centers, and Offices focused on pain research and examples of topics of interest include:

- Understanding the biopsychosocial mechanisms of pain with a goal towards therapy development for complex human pain conditions with high unmet needs
- Developing safe, effective, pain therapies and pain management strategies
- Evaluating safety and effectiveness of pharmacological and non-pharmacological approaches, and models of care to improve acute and chronic pain management
- Addressing cross-cutting research areas across multiple ICOs (pain inequities in populations experiencing health disparities; diversity and inclusion in clinical studies; pain comorbidities and understudied pain conditions)
- Implementing and disseminating evidence-based integrated pain management models of care into clinical practice

As another example, the National Institute on Drug Abuse (NIDA) supports culturally appropriate etiology, prevention, treatment, implementation, and dissemination research focused on opioid or methamphetamine use, alone or in combination with other drugs, among Native adolescents and adults. Specific areas of interest include, but are not limited to:

- Research pertaining to increasing the availability of naloxone
- Intervening to improve the uptake of medication assisted treatment (MAT) to treat opioid use disorder (OUD) or to prevent OUD
- Etiologic or intervention research that addresses substance use (as related to opioid and stimulant overdose) and incorporates comorbid conditions, including alcohol use, suicidal ideation and other mental health conditions
- Research that includes trauma (current and historical), either as an etiological factor or considered in the intervention, including development, implementation, or analysis of trauma-informed interventions to address SUD

While specific areas of focus are not listed for other Institutes, you can find their mission by following the hyperlinks in the [previous question](#).

## Funding Information

### 13. How is the N CREW Program funded?

The N CREW Program is funded through NIH's Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®. This Initiative bolsters research across NIH to improve (1) prevention and treatment for opioid misuse and addiction, and (2) pain management. [Learn more about the HEAL Initiative](#).

### 14. What is Other Transactions Authority?

Other Transactions Authority (OTA) is 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. Policies and terms for individual OTs 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 ([Learn more about OTAs on the NIH website](#)).

### 15. What is different about Other Transactions Authority (OTA) for the N CREW Program?

OTA offers the N CREW program the unique opportunity to develop a custom program to support attaining Program goals. This includes supporting the development of individualized solutions in real time. It is a type of funding that allows N CREW to respond to the evolving and unique needs of the T/NASOs that participate in the program.

More specifically, OTA allows NIH to provide a broad range of research support to award recipients that cannot be fully predicted in advance, meaning that new ideas or needs that arise can be addressed quickly. Because N CREW will connect T/NASOs with partnering organizations to provide the needed support to build



T/NASOs research capacity, OTA is ideal for providing flexibility in the partnership selection, development and construct.

Additionally, OTA allows the N CREW program and participants to quickly pivot. That is, there is agility and flexibility in the ability to modify activities, partners, or formal partnership structures in response to new or evolving needs. This flexibility allows N CREW to support the discovery and creation of the best infrastructure and capacity building strategies possible through, for example, testing novel research infrastructures, bringing in new partners, etc.

## ROA OTA-23-007 – Tribes and Native American Service Organizations N CREW Research and Data Projects

### General Information about the Research Opportunity Announcement (OTA-23-007)

#### **16. Can single research projects, or one-off projects, be funded under ROA OTA-23-007?**

Yes. However, applicants should note that enhancing research capacity is one of the three primary goals of the N CREW Program and consider how a single project will work to enhance research capacity within the T/NASO.

#### **17. What kinds of research and data projects will not be funded under ROA OTA-23-007?**

- Direct services in the absence of a research or research capacity component.
- Capacity building that is not focused on HEAL related research/data projects ([HEAL Website](#)).
- Projects that do not include a focus on topics or outcomes related to the HEAL Initiative.

#### **18. Is the award for ROA 007 open to applications that identify a list of potential interventions to research in the proposal, with the idea that the actual intervention may be selected after the completion of a preliminary research/planning phase?**

Yes, this would be an acceptable approach.

#### **19. Would a pilot project be acceptable for this research opportunity announcement (ROA OTA-23-007)?**

Yes. Phase I supports planning and development activities. Pilot projects can be included in the planning and development work.

#### **20. ROA OTA-23-007 says 1 milestone will be to: "register study with the HEAL platform within 1 year of award." What does this entail?**

Registration will occur on the NIH HEAL Initiative's website: [heal.github.io/platform-documentation](https://heal.github.io/platform-documentation). This website provides more information about how to register your study and what type of information will be collected about your study. Registration involves submitting metadata (e.g., information about the type of study or study design, type of subject such as human participants or animals, variable information, etc.) that will allow your study to be findable within the HEAL platform. Program staff and the HEAL data ecosystem developers are flexible and can work one-on-one with Investigators to make sure their study and the expected data/outcomes are represented accurately in the Platform.

Please note that registration of your study does not mean submission of the actual data. Registering your study increases transparency for collaborators and others in the research community to reach the Principal Investigators directly if they know a dataset exists. Registration can be performed by the Principal Investigator or another member of the research team.

**21. Once projects are funded through OTA-23-007, what support and resources will be available for planning and developing our research/data project?**

Given the significant diversity across T/NASOs' existing research capacity and the individuated nature of community prioritized projects, the N CREW Program aims to develop supports that are comprehensive, accessible, relevant, flexible, and culturally responsive through the creation of the Native Research Resource Network (NRRN). This network can assist T/NASOs with creating or disseminating resources; identifying effective strategies and approaches to support research capacity building; identifying and/or implementing activities (including coordination) to help facilitate long-term change; finding opportunities to scale effective strategies to other communities; among many other examples. NRRN is designed to be flexible to allow for modifying supports, activities, partners, and formal partnerships structures throughout the funded project period to meet the real time needs of T/NASO awardees.

**22. Does a Phase I award guarantee transition to Phase II?**

No. The receipt of an award in Phase I does not guarantee recipients' continuation to Phase II.

**Eligibility for ROA OTA-23-007**

**23. Who is eligible for this research opportunity?**

T/NASOs are eligible to apply to ROA OTA-23-007. For the purposes of ROA OTA-23-007, T/NASOs are 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 or faith-based 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
  - Patient or consumer advocacy groups
  - Social service organizations
  - Healthcare systems and providers (including Federally Qualified Health Centers)
  - Schools
  - Law enforcement and criminal/juvenile justice agencies
  - 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 demonstrate 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.

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.

### **24. Who is *not* eligible for this research opportunity?**

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.

Individuals not affiliated with an organization, or who want to submit an application independent of their current organization, may not apply.

### **25. What are examples of Tribes/Native American Serving Organizations (NASOs)?**

For the purposes of OTA-23-007 (and OTA-23-008), Tribes/NASOs are defined as 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. In OTA-23-007, examples of NASOs are provided, including 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.

NASOs must provide justification that demonstrates a 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.

## **26. How do I determine if my organization is a Native American Serving Organization (NASO) and eligible to apply to ROA OTA-23-007?**

**Tribes:** All federally or state recognized Tribes are eligible to apply to OTA-23-007. 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.

### **Native American Serving Organizations (NASOs) that are not Tribes:**

To determine whether your organization is a NASO and eligible to apply to OTA-23-007:

- Consider what entity will be the applicant organization. **The applicant organization is the organization that is registered or will be registered in eRA Commons** for application submission.
- The applicant organization must meet all eligibility requirements specified in OTA-23-007 for their type of organization:
  - If the applicant organization is an **academic research center, academic healthcare organization, private healthcare organization, research organization**, your entity must meet **all** of the following criteria to be eligible to apply as a NASO:
    - be a Tribe or organization with a core mission to serve Native Americans,
    - document a track record of successfully meeting this mission,
    - are poised to reach Native Americans, and
    - can obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative, if appropriate, before the time of award.
  - If your entity is a **business or financial management company**, your entity will need to:
    - Demonstrate a legally binding relationship with T/NASOs in financial matters
    - Meet other eligibility criteria, i.e., located in the United States
    - Obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative, if appropriate, before the time of award.
- For **all other applicant organizations**, including non-profit organizations, for-profit organizations, and governments, etc., to apply as a NASO your entity must demonstrate:
  - A core mission to serve Native Americans OR a track record in serving Native Americans and
  - Are poised to reach Native Americans.

## **27. Can my Tribe/organization apply to this ROA (OTA-23-007) and ROA (OTA-23-008)?**

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

## **Review and Selection for ROA OTA-23-007**

### **28. Are ROA OTA-23-007 applicants encouraged to have experience managing federal awards?**

Applicants are not required to have experience managing federal awards. They are required to have the organizational capacity and fiscal experience and/or expertise available to manage a program greater than \$200,000. This expertise could be based on prior experience, partnerships (or planned partnerships) or a proposed plan to successfully manage the federal award. The purpose of the N CREW Program is to support T/NASOs as they enhance their capacity to do research; thus, it is not expected applicants will have demonstrated expertise. But all applicants should have a plan.

### **29. What should be included in our application ROA OTA-23-007?**

Applications for both ROAs require multiple sections (see below). In general, please keep in mind that the content of your application needs to thoroughly describe your project. The application should include everything the reviewer needs to know in order to understand and assess the project.

All ROA OTA-23-007 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.

Details about each of these sections, including page limits, are included in the ROA.

### **30. What are “Specific Aims”?**

Applications for ROA OTA-023-007 require that applications include a Specific Aims section (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.

### **31. What criteria will be used to determine what OTA-23-007 applications are non-responsive?**

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.

Applications that are non-responsive will not be reviewed.

### **32. How will applications be reviewed?**

Responsive applications to this ROA will be reviewed by subject matter experts using a process referred to as Objective Review. 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.

Each of the Objective Review Criteria listed below will be rated by reviewers using a rating scale of a) highly likely, b) moderately likely, or c) unlikely (for more details about each, see ROA OTA-23-007):

- Likelihood of contributing to advances in addressing substance use (including opioid and/or stimulants) and/or pain disparities for Native Americans
- Likelihood of accomplishing proposed activities
- Likelihood of forming effective collaborations and partnerships

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:

- 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.

### **33. How many total awards will be made for OTA 23-007?**

For OTA-23-007, NIH intends to fund approximately 15 awards. Annual budgets, per award, are anticipated to range from \$200,000 to \$500,000. Note that there is not a cap on the budget you may submit. Number and award levels are subject to change based on programmatic needs, funding ability, and recipient performance.



## ROA OTA-23-008 The Native Research Resource Network

### General Information about the Research Opportunity Announcement (OTA-23-008)

#### **34. Will the NRRN be responsible for collecting or managing data?**

It is possible the NRRN members will collect and/or manage data but this will be developed in real time as the Program is built out. T/NASO sites will advise on what is allowable and activities will be developed within the acceptable parameters. NRRN example activities around data collection and management include:

- Coordinating and gathering information across T/NASOs and sites, possibly generating summary data
- Initiating data collection activities at the request of T/NASOs or NIH
- Providing data management and sharing support to T/NASOs
- Coordinating any NIH/HEAL reporting requests and working with the HEAL Data Ecosystem (where appropriate and with permission from T/NASO sites)
- Supporting dissemination of information learned throughout the program
- Managing the coordination of comprehensive, real-time resources
- Developing and/or selecting and maintaining collaborative infrastructure and technology to share materials, communicate updates or other information, etc.

#### **35. Do the resources created by the Native Research Resource Network need to be Tribe specific?**

No. Resources created by the NRRN do not need to be Tribe specific. NIH will prioritize resources with the broadest utility – including resources generalizable to multiple Tribes or resources developed or designated for one Tribe but adapted for others. NIH expects all Tribe specific resources to be developed in partnership with the Tribe.

#### **36. Does a Phase I award guarantee transition to Phase II?**

No. The receipt of an award in Phase I does not guarantee recipients' continuation to Phase II.

### Eligibility for ROA OTA-23-008

#### **37. Who is eligible for this research opportunity?**

T/NASOs and Ally Organizations are eligible for OTA-23-008. 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

### **38. Who is *not* eligible for this research opportunity?**

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.

Individuals not affiliated with an organization, or who want to submit an application independent of their current organization, may not apply.

### **39. Can my Tribe/organization submit more than one application for this ROA (OTA-23-008)?**

No. Applicant organizations may **not** submit more than one application.

#### **40. What are examples of Ally Organizations for ROA OTA-23-008?**

For ROA OTA-23-008, Ally Organizations are defined as organizations that can document a track record of partnering successfully with Native American communities. To be eligible for OTA-23-008, Applicants must demonstrate significant experience working with T/NASOs. Applicants do not need to be a federally or state recognized Tribe or a Native American Serving Organization.

Examples of Ally Organizations include:

- A research technical assistance organization that is not affiliated with a federally or state recognized Tribe or organization but has experience contracting with Tribes or researchers for the purpose of coordinating data collection, analysis and reporting on projects focused on Native American populations or communities.
- A faith-based or community-based organization that is not affiliated with a federally or state recognized Tribe or organization that serves a significant number (in terms of their total community/clients) of Native Americans.
- A Center within a University with deep experience working authentically with Tribes and Native communities.

### **Review and Selection for ROA OTA-23-008**

#### **41. What should be included in our application for ROA OTA-23-008?**

Applications require multiple sections (see below). In general, please keep in mind that the content of your application needs to thoroughly describe your project. The application should include everything the reviewer needs to know in order to understand and assess the project.

All ROA OTA-23-008 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.

Details about each of these sections, including page limits, are included in the ROA.

#### **42. What are “Specific Aims”?**

Applications for ROA OTA-23-008 require that applications include a Specific Aims section (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.

#### **43. What criteria will be used to determine what OTA-23-008 applications are non-responsive?**

Applicants will be considered non-responsive if they do not document strong Native American cultural expertise and experience working with Native populations.

Applications that are non-responsive will not be reviewed.

#### **44. How will applications be reviewed?**

Responsive applications to this ROA will be reviewed by subject matter experts using a process referred to as Objective Review. 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.

Each of the Objective Review Criteria listed below will be rated by reviewers using a rating scale of a) highly likely, b) moderately likely, or c) unlikely (for more details about each, see ROA OTA-23-008):

- Likelihood of meeting N CREW Program needs
- Likelihood of contributing to 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?
- Likelihood of forming effective collaborations and partnerships

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 and 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.

#### **45. How many total awards will be made for OTA-23-008?**

For OTA-23-008, NIH intends to fund approximately 5 awards. Annual budgets, per award, are anticipated to range from \$500,000 to \$1,300,000. Note that there is no annual budget limit, the budget must reflect the needs of the proposed activities. The number and award levels are subject to change based on programmatic needs, funding ability, and recipient performance.

#### **46. Are ROA OTA-23-008 applicants encouraged to have experience managing federal awards?**

Applicants are not required to have experience managing federal awards. They are required to describe their organizational capacity and fiscal experience and/or expertise available, particularly with managing program costs over \$200,000.

## Common Questions for ROA OTA-23-007 and ROA OTA-23-008

### General Questions for ROAs OTA-23-007 and OTA 23-008

#### **47. If a project for either ROA includes multiple tribes delivered under the auspices of a Tribal Consortium, do we need a resolution from each Tribal Nation or will a resolution from the Consortium Board suffice?**

A resolution from each tribe will be required at the time of award.

#### **48. Projects that include multiple PIs must submit an “MPI Plan” (also called a “leadership plan”). Does the MPI plan require its own section of the proposal or is it part of another section (and if so, which section), and does it count toward the page limit of that section and/or the application?**

For the purposes of this program, the MPI Plan and Leadership Plan are the same document and does not count toward any page limit for the application. The MPI leadership plan can either be submitted as an appendix within the single pdf application document or as a pdf attachment in ASSIST in the Leadership Plan field denoted after selecting Add Additional PD/PI.

### Application Budget for ROAs OTA-23-007 and OTA-23-008

#### **49. Who should attend the Teaming Meetings and how many days should we budget for this annual meeting?**

Applicants should budget for a Principal Investigator and at least one other team member (or as many are anticipated as needed) to attend the Teaming Meetings. Applicants may choose different individuals and partners, but budgeting for at least two attendees for up to three days (two nights) would be a reasonable estimate (per year).

#### **50. Are indirect costs (or F&A/Facilities and Administrative) required?**

No. Indirect costs or F&A (Facilities and Administrative) are not required for this opportunity. Any indirect costs are included in the total budget and in the total award amount.

#### **51. Can you provide guidance on indirect costs?**

Applicants with an indirect/F&A (Facilities and Administrative) cost rate agreement with the Federal Government should include that amount in the total budget and in the total award amount.

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.

**52. Which federally negotiated indirect cost (F&A) rate should a university-based research partner for our project use in calculating their budget? Should it be the approved “research,” “Other sponsored programs,” or some other rate?**

The N CREW Program is a research and data capacity building project. Applicants and partners should follow their internal organizational policies to determine which type of rate should be applied. If a partner has an approved facilities and administrative costs rate agreement with the federal government, the approved rate should be reflected in the budget request. If a partner does not have an approved facilities and administrative costs rate agreement, they may negotiate a rate with the applicant organization that will be subject to NIH review.

**53. Is the anticipated budget range based on direct or total costs?**

The anticipated budget range is meant to be a gauge for the level of funding that NIH may provide for the applicable ROAs. The final award will be based on pre-award negotiations and the final dollar amount may be more or less than the range provided. Applicants should provide a reasonable budget request based on the activity described in the application.

**Review and Selection of Applications Submitted for ROAs OTA-23-007 and OTA-23-008**

**54. When will my application be reviewed and by whom?**

We anticipate the review of responsive applications will begin in January 2024. Applications will be reviewed by subject matter experts using a process referred to as Objective Review. The subject matter experts will include NIH and other federal staff, and external expertise as needed.

**55. How will awards be selected for funding?**

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

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.

**56. Will applicants receive written feedback on their applications for ROAs OTA-23-007 and OTA-23-008?**

No. Applicants will not receive written feedback on their application. However, if resources allow, NIH may provide feedback in a post review discussion call if requested by the applicant.

**57. Can I appeal the outcome of the objective review?**

No. Appeals of the objective review will not be accepted for applications submitted in response to this funding opportunity.

**Award Activities and Administration (OTA-23-007 and OTA-23-008)**

**58. What are milestones?**

A milestone is a finding or set of findings that signal the achievement of a specific aim in your research plan or project that can be objectively measured. An example of a poorly defined milestone is *"collaborate with partners"* whereas a well-defined milestone would be *"Attend 4 Teaming Meetings with other N CREW Program recipients within the first 12 months of the project"*

**59. Where can I find a sample milestone document?**

See below for a sample milestone chart. You may use this format, or any format of your choosing, in developing proposed milestones.

Milestone	Task(s)	Start Date (months after award)	Due Date (months after award)	Milestone Definition	Payment
1. Develop a Research Agenda	1.1. Develop a planning committee to meet bi-weekly	0	3	Milestone name/description: <ul style="list-style-type: none"> <li>Determine committee members</li> <li>Meet bi-weekly</li> </ul>	\$7,000
1. Develop a Research Agenda	1.2. Create an initial draft research agenda	15	17	Milestone name/description: <ul style="list-style-type: none"> <li>Determine format of agenda</li> <li>Create timeline for drafting agenda</li> </ul>	\$2,000
1. Develop a Research Agenda	1.3. Share research agenda with the community for input	17	21	Milestone name/description: <ul style="list-style-type: none"> <li>Schedule community meetings to present agenda and collect feedback</li> <li>Revise research agenda based on community input</li> </ul>	\$4,000

**60. Are there meetings I am required to attend?**

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
- 2-3 ongoing special interest or cross-site workgroups
- 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

In addition, we expect that T/NASOs and the NRRN will actively participate in regular N CREW meetings and engage in regular meetings with partnering T/NASOs throughout the duration of the program.

### **61. What are HEAL PI Meetings?**

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. This annual two-day meeting brings together HEAL-funded researchers across the career spectrum, federal officials, community partners, and others who are taking on pain and opioid crises from all angles, studying a broad range of topics. Applicants interested in attending this annual meeting should budget accordingly for their Principal Investigators.

### **62. Do I need to submit progress reports?**

Yes. 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.

### **63. What are the data sharing requirements?**

NIH updated its [Data Management and Sharing Policy](#) (DMS Policy), effective January 25, 2023. It reinforces NIH's longstanding commitment to making the results and outputs of NIH-funded research available to the public through effective and efficient data management and data sharing practices. Under the DMS Policy, NIH requires researchers to prospectively plan for how scientific data will be preserved and shared. Thus a data sharing and management plan will be required before the time of award. NIH also honors Tribal Sovereignty, and so justified exceptions to the DMS Policy requirements are allowed, as noted in the policy. A data sharing plan should provide a justification for exemptions to the DMS Policy. Please also review supplemental material to the DSM Policy for Tribes ([Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data](#)) for additional detail.

**64. Since the N CREW Program is funded through HEAL, will research or data projects on pain management require the normally required Common Data Elements (CDEs)?**

The NIH HEAL Initiative® supports a [HEAL Data Ecosystem](#), which aims to accelerate sharing HEAL-generated data and results among the broad community of researchers, health care providers, community leaders, policy makers, and other HEAL stakeholders who can benefit from learning the results of initiative research. Core HEAL-defined CDEs can be found in the [HEAL CDE repository](#). The supplemental CDEs will be added soon, in the meantime they can be accessed by contacting [heal\\_cde@hsc.utah.edu](mailto:heal_cde@hsc.utah.edu).

The N CREW Program, in partnership with T/NASOs, may develop common data elements that are appropriate and meaningful for Tribes and Native American Serving Organizations. While not required, we encourage applicants to consider and use the HEAL-defined CDEs for pain projects and as relevant for addiction projects. The final project requirements for all research and data projects, including clinical pain research studies, will be negotiated prior to an award.

**65. What are study requirements for projects involving Human Participants?**

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), and comply with [45 CFR 46](#), and, as applicable, any relevant [FDA regulations](#) (e.g., 21 CFR 11, 50, 54, 56, 312, and 812) 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.

## Submission Information and Process (OTA-23-007 and OTA-23-008)

### General Questions and Key Dates for OTA-23-007 and OTA-23-008

**66. Can you provide an example of how to name the application file?**

The file naming convention consists of three parts. If you are applying for ROA OTA-23-007, the first part of the file name should be TNASO. If applying for ROA OTA-23-008, the first part of the file name should be NRRN. Then for both ROAs us the underscore PI Last Name followed by underscore Applicant Organization.

Example if applying to 007: TNASO\_Johnson\_InnovateEnterprises

Example if applying to 008: NRRN\_Johnson\_InnovateEnterprises

## 67. Are there instructions for resume format?

There are no specific instructions for resume formatting, although some baseline formatting suggestions in terms of margins and fonts are provided in the ROAs. You may consider a condensed version of the NIH biosketch if you wish, or any other format of your choosing. Your resume will be sufficient as long as it includes the relevant information to support your application, is legible, and is within the 3-page limit as specified in the ROAs.

## 68. What are the key dates in the timeline for the planning of our application?

- **Research Opportunity Announcements Released:** June 21, 2023
- **Applicants Register in eRA Commons:** As soon as possible\*
- **Webinar #1 Overview of the N CREW Program:** July 27, 2023
- **Webinar #2 Instructions for Using eRA Commons and ASSIST:** August 30, 2023
- **Letter of Intent Due (Optional):** September 1, 2023
- **Webinar #3 Questions and Answers:** October 3, 2023
- **Application Submission Due:** November 1, 2023
- **Review:** January and February 2024
- **Earliest Award Start Date:** June 1, 2024

\*Note that all applicants must be [registered in eRA Commons](#) before submitting their application using [ASSIST](#), which may take between 2-3 weeks or more to complete. Applicants should therefore begin the registration process as soon as possible. Please contact [NCREW@nih.gov](mailto:NCREW@nih.gov) if there are issues, after contacting the [eRA Service Desk](#).

## 69. When may I submit my application?

Once the Applicant Organization is registered in eRA Commons, applications can be submitted at any time. All applications must be received by November 1, 2023 by 5:00 pm (based on local time of the applicant organization). We highly encourage all applicants to start the process of submitting early to allow time for any system issues to be resolved prior to the deadline.

## 70. What happens if I miss the application deadline for either OTA-23-007 or OTA-23-008?

If you become concerned, prior to the application deadline, that you may not be able to submit your application on time, please email [NCREW@nih.gov](mailto:NCREW@nih.gov) to inform us of your concerns.

If you encounter issues that cause you to miss the application deadline, contact the N CREW Team at [NCREW@nih.gov](mailto:NCREW@nih.gov) as soon as possible. In your correspondence, please outline what issues you encountered.

## 71. How do I submit my application?

Applications are submitted via the [NIH eRA ASSIST](#) system. [Here are instructions for submitting applications via the NIH eRA ASSIST system](#). Technical assistance is available from the [eRA Service Desk](#). Please also see the [eRA Commons and ASSIST Questions and Answers](#) for additional information on the application submission

process. If you have issues submitting that cannot be resolved after discussion with the Service desk, please notify [ncrew@nih.gov](mailto:ncrew@nih.gov).

## **72. Who may I contact if I have questions about my application?**

For technical questions about the NIH eRA ASSIST system, please contact the [eRA Service Desk](#). Questions about the N CREW Program and Research Opportunity Announcements can be emailed to [NCREW@nih.gov](mailto:NCREW@nih.gov). If you would like, you may also email [NCREW@nih.gov](mailto:NCREW@nih.gov) to schedule a meeting with N CREW Staff. Please note that the NIH N CREW team can discuss questions about responsiveness to the ROAs, eligibility, and the process of applying. NIH staff cannot comment on research ideas or concepts shared in a Letter of Intent and cannot answer questions related to specific content of the application.

## **Letter of Intent (LOI) Submission**

### **73. Is a letter of intent (LOI) required to apply for the research opportunities?**

A letter of intent is 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. Letters of Intent should be submitted to [NCREW@nih.gov](mailto:NCREW@nih.gov) no later than September 1, 2023.

### **74. What should be included in the LOI?**

NIH recommends including the following information in no more than two pages, single-spaced:

- 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

### **75. Should I include any budget information in the LOI?**

No. Budget information for the proposed project should not be included in the LOI. Budget information is required for the application due on November 1, 2023.

### **76. Should I include letters of support with my LOI?**

No. Letters of support should not be included with your LOI. Letters of Support could be submitted with the application due on November 1, 2023.

### **77. What if I have questions during the LOI preparation?**

If you have additional questions about the LOI, please email [NCREW@nih.gov](mailto:NCREW@nih.gov). NIH can address questions about responsiveness to the ROAs, eligibility, and the process of applying. NIH staff cannot comment on research ideas or concepts shared in the Letter of Intent and cannot answer questions related to specific content of the application.

## **78. If we submit a Letter of Intent, will we receive feedback before the official submission?**

NIH encourages applicants to submit a Letter of Intent to help NIH plan for timely review of applications and better align Technical Assistance webinars with any needs identified. The Letter of Intent is not an application submission but rather a notification of intent to apply. Prior to application submission, NIH can address questions about responsiveness to the ROAs, eligibility, and the process of applying. NIH staff cannot comment on research ideas or concepts shared in the Letter of Intent and cannot directly answer questions related to specific content of the application.

## **eRA Commons and ASSIST**

### **79. My organization will not have a Unique Entity Identifier (UEI) in time for submitting our full application. Can we still register our organization in eRA Commons?**

Yes. To register your organization in eRA Commons you will not need a UEI. However, a UEI must be obtained prior to receiving an NIH award.

### **80. Is there another way, other than ASSIST, to submit my application?**

No. Applicants must submit applications via the [NIH eRA ASSIST](#) system. [Here are instructions for submitting applications via the NIH eRA ASSIST system](#). Technical assistance is available from the [eRA Service Desk](#).

### **81. If I need help with eRA or ASSIST, what do I do?**

Call or email the eRA Commons Service Desk. In your correspondence, be sure to clearly identify you are an Other Transactions Authority (OTA) applicant for OTA-23-007 or OTA-23-008, depending on which Research Opportunity Announcement you are applying to. Hours of operation are Monday - Friday, 7 a.m. to 8 p.m. Eastern time, except Federal holidays. Note that the Service Desk's busiest hours are between 10 a.m. ET and 3 p.m. ET.

- *Toll-free:* 866-504-9552 (Press 1 for eRA Commons or ASSIST)
- *Phone:* 301-402-7469 (Press 1 for eRA Commons or ASSIST)
- *TTY:* 301-451-5939
- *Web:* <http://grants.nih.gov/support/> (preferred method of contact)
- *Email:* [s2ssupport@mail.nih.gov](mailto:s2ssupport@mail.nih.gov) (for system-to-system support)

If you need immediate help (i.e., you are within two days of a deadline or in the event of a security emergency), call the Service Desk.

You can also download this [step-by-step instruction guide](#) for registering your organization in eRA Commons and submitting an application in ASSIST.



**82. When I register in eRA Commons, what type of opportunity should I select? There are many options.**

When OTA applicants submit their eRA Commons registration, they should select [*NIH Other Transaction Authority (OTA) Opportunities*]. There are two other options, but only select *NIH Other Transaction Authority (OTA) Opportunities*].

**83. I registered as my organization’s Signing Official on our eRA Commons registration and want to know what happens next?**

Once the registration is submitted and approved by eRA, the Signing Official (SO) will receive an email to verify before the registration is completed and any account information is sent out. So please check for that email. Registrants should follow the [process for eRA Commons registration](#) to help ensure a successful Commons registration.

**84. Do all of the key personnel (i.e., Co-Investigator, Senior/Key Personnel, Other Significant Contributor, Collaborator, Consultant, Sub-Awardee, etc.) listed on our application need an eRA Commons ID to submit our application?**

No. For submission, at a minimum, there must be the Signing Official (SO), with signature authority for the organization, and there must be at least one person with the role of Principal Investigator (PI) with the organization. The application must be submitted by the individual with Signing Official credentials. However, please note that it will be helpful to the NIH if all key personnel are registered in eRA Commons.

**85. Can one individual serve in both the Signing Official (SO) role and the Principal Investigator role (PI) role in eRA Commons?**

It is strongly recommended that the SO and the PI and contacts are different people. If this is not possible, the individual serving in both roles will need both the Signing Official role (admin) and a separate username and password for the Principal Investigator (science) role in eRA Commons. *The email address used to register both roles can be the same.*

**86. What is the difference between the Signing Official (SO) and Principal Investigator (PI) Roles in eRA Commons?**

The Signing Official:

- Holds authority to legally bind your organization and assume responsibility.
- Registers the organization and maintains profile data.
- Accesses information for all applications, including status and award information.
- Should an application be awarded, the signing official will be defined as the business official in the Other Transactions (OT) agreement. This individual must be authorized to act for the organization and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to the OT.

The Principal Investigator:

- Holds eRA Common's role as the designated Program Director/Principal Investigator (PD/PI) of an application.
- Accesses information for on application and award information.
- Has the ability to maintain person profile information; check application status; review assembled application image used for performing post-submission administrative functions.
- Should an application be awarded, the PD/PI directs the project or activity being supported by the OT and is accountable, along with any other PD/PI listed on the OT award, to the organization for the proper conduct of the project or activity.
- There can be multiple PD/PIs. If this is the case, then all of them should be registered and have the PD/PI role in eRA.

**87. Our current Signing Official (SO) is no longer with the Organization. What is the process for updating our SO in eRA Commons?**

If your SO is no longer with your organization and you have no other individuals listed currently as SO, please contact the [eRA Service Desk](#) for assistance.

**88. Are applicants allowed to have a fiscal sponsor or fiscal agent arrangement?**

Yes, an applicant is allowed to have a fiscal sponsor/fiscal agent arrangement. However, prior to making an award, NIH will require supporting documentation from the applicant. Specifically, a copy of the agreement between the applicant and the fiscal sponsor/fiscal agent would need to be submitted. In addition, the fiscal sponsor would need to obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative before the time of award. NIH will conduct a financial capability review to ensure that the applicant, working with the fiscal sponsor/fiscal agent, is able to meet all the requirements for proper fiscal stewardship of the award.

**89. Can fiscal sponsors and fiscal agents serve in the Signing Official role in eRA commons for a community organization?**

Yes, the fiscal sponsor/fiscal agent can serve as the Signing Official in eRA commons for the community organization if they can obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative before the time of award.

**90. The application must be uploaded to eRA Commons ASSIST as a "flattened" PDF. What does that mean and how do I do it?**

A PDF that has fillable fields, electronic signatures, text boxes or images inserted, becomes layered with each of these elements representing a layer. Flattening a PDF merges these separate elements into one flat layer. There are a number of methods to flatten a PDF, the easiest of which is to print it as a PDF.

To do this, go to File>Print, select the printer option from the menu that has says PDF, such as "Adobe PDF". Depending on the software available to you, the specific option may vary but should contain "PDF". Click the Print button and name the file. This will "print to a PDF" and the file will be flattened.

**91. Is a cover letter required for ROAs OTA-23-007 or OTA-23-008 applications?**

A cover letter is not required. If ASSIST requires a cover letter attachment to submit your application, you can upload a copy of the Title Page.

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