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# Native Collective Research Effort to Enhance Wellness (N CREW) Program: Addressing Overdose, Substance Use, Mental Health, and Pain

## Advancing Native Research Projects

# ***Note: Simplified Research Opportunity Announcement (ROA) Format***

- In alignment with HHS efforts to simplify and streamline research announcements, this ROA uses a slide format. The simpler ROA format is intended to:
  - Use plain, simple language
  - Remove unnecessary information
  - Make critical information easier to find
  - Improve navigation
  - Reduce the average time to apply

# 1. Review the Opportunity

## Advancing Native Research Projects – Tribes and Native Serving Organizations (T/NSOs)

### Phase II OTA-26-001

The Native Collective Research Effort to Enhance Wellness (N CREW) Program is part of the NIH Helping to End Addiction Long-term® (HEAL) Initiative, established to aggressively speed scientific solutions to the opioid public health emergency. Research led by Native communities is essential for enhancing culturally grounded, strengths-based, effective, and sustainable intervention strategies. Thus, N CREW aims to improve wellness for Native Americans by supporting community-driven research focused on reducing opioid/drug overdose through the study of substance use, pain, and related factors such as mental health. Using NIH’s Other Transactions Authority (OTA), N CREW supports innovative, flexible approaches that respond to the urgent, complex, and evolving needs, strengths, and priorities of research led by Tribes and Native Serving Organizations (T/NSOs).

This ROA (OTA-26-001) invites T/NSOs—including those without prior NIH funding—to lead community-prioritized research; **applicants are encouraged to also review companion ROA (OTA-26-002) on the Native Research Resource Partners (NRRPs).**

### Navigate to ROA Sections:

- Deadlines and Contact Information (5)
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# 1. Review the Opportunity

## Advancing Native Research Projects – Tribes and Native Serving Organizations (T/NSOs)

### Phase II OTA-26-001

<b>Eligible Applicants</b>	See the <a href="#">Eligibility section</a> of this opportunity for further details
<b>Type</b>	Other Transactions (OT2) Award, governed by <a href="#">42 U.S. Code § 282 (n)(1)(b)</a> - see link for definitions
<b>N Crew Overall Program Expected Funding (T/NSO and NRRP)</b>	<p>Up to \$217 million over five years for the entire N CREW program, but total program funds are subject to change.</p> <p>HEAL funding is designated specifically to support substance use and pain research, with separate allocations for each area. The funds expended will depend on NIH appropriations and the submission of a sufficient number of meritorious applications in each research area. In FY27, for the N CREW OVERALL Program costs (T/NSO, NRRP and any other activities), NIDA intends to commit up to \$18.4M in total costs for substance use research and capacity building, and NINDS intends to commit up to \$18.4M for pain-related research and capacity building. If fewer competitive applications are received in either research area, these planned commitments may be adjusted. Funding in future years will depend on annual appropriations.</p>
<b>Expected T/NSO Awards</b>	NIH intends to fund approximately 15-20 awards for this ROA to support T/NSOs
<b>Budget</b>	<b>No budget limit, recommended annual range:</b> \$250,000 – \$750,000 per year in direct costs. All costs must be well justified in accordance with the activity proposed.
<b>Application Due Date</b>	7/31/2026
<b>Earliest Start Date</b>	3/1/2027
<b>Performance Period</b>	Up to 5 years
<b>Related Notices</b>	OTA-26-002
<b>Participating Organization</b>	National Institutes of Health (NIH)
<b>Components of Participating Organization</b>	National Institute of Drug Abuse (NIDA), National Institute of Neurological Disorders and Stroke (NINDS), National Center for Advancing Translational Sciences (NCATS)

## 1. Review the Opportunity: Deadlines and Contact Information

KEY DATES	
Post Date	March 2, 2026
Informational Webinars Dates (optional)	There will be informational webinar(s). Webinar details, including the specific dates and registration links, will be posted online at: <a href="https://www.nih.gov/heal/research/ncrew">https://www.nih.gov/heal/research/ncrew</a>
Application Due Date	July 31, 2026 at 5:00pm in the applicant's local time zone
Anticipated Review	August, 2026
Anticipated Earliest Start Date	March 1, 2027

AGENCY CONTACTS	
Scientific/Research Contact	Kathy Etz <a href="mailto:NCREW@nih.gov">NCREW@nih.gov</a> National Institute on Drug Abuse (NIDA)
Financial/Agreements Officer Contact	Jennifer Cho <a href="mailto:NCREW@nih.gov">NCREW@nih.gov</a> National Center for Advancing Translational Sciences (NCATS)

## 1. Review the Opportunity: Key Definitions

- **Milestones:** Objective, measurable events that indicate progress towards proposed specific aims.
- **Native Americans:** For the purposes of this ROA, Native Americans are defined as people who are members of Indigenous Tribes and communities, irrespective of where they live or reside, that have been recognized as having a special political and trust relationship with the United States, including those Tribes, bands or groups terminated since 1940 and those recognized now or in the future by the State in which they reside. This includes members or up to second generation descendants of federally recognized American Indian and Alaska Native Tribes (U.S. Constitution, Article I, Section 8, Clause 3; Cherokee Nation v. Georgia, 30 U.S. 1 (1831); Worcester v. Georgia, 31 U.S. 515 (1832); 25 U.S.C. § 5301(a)), and state recognized tribes and Urban Indians as described in the Indian Health Care Improvement Act (Public Law 94-437, 25 U.S.C. § 1601 et seq., as amended by Public Law 117-58, November 21, 2021)). Also included for the purposes of this ROA are Native Hawaiian communities as described in the Native Hawaiian Health Care Improvement Act (42 U.S.C. § 11701 et seq.).
- **N CREW Network:** This refers collectively to Tribes and Native-Serving Organizations (T/NSOs), the Native Research Resource Partners (NRRPs), and the National Institutes of Health (NIH), who collaborate to advance Native community-led research.

## 1. Review the Opportunity: Key Definitions continued

- **Other Transactions Authority (OTA):** A unique type of authority that allows an agency to enter a legal agreement (OT Agreement) with a recipient organization that is not a contract, grant, or cooperative agreement. Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific governing agreement, negotiated with the recipient, and may be expanded, modified, partnered, not supported, or later discontinued based on program needs, changing landscape, performance, and/or availability of funds. [Learn more about OTA.](#)
- **Principal Investigator(s):** The lead individual responsible for the scientific, technical, and budgetary aspects of an NIH funded project. The PI is responsible for overall conduct, reporting, compliance and the scientific integrity of the research.
- **Research Opportunity Announcement (ROA):** Used to solicit applications for programs using Other Transactions Authority.
- **Tribe or Native Serving Organization (T/NSO):** This refers to federally or state recognized Tribes or organizations with a core mission to serve Native Americans and a track record of meeting this mission.

## 1. Review the Opportunity: Other Transactions (OT2) Award Mechanism

This funding opportunity uses Other Transactions Authority (OTA), governed by 42 U.S. Code § 282(n)(1)(b). Each OT award has its own negotiated agreement and may be expanded, modified, partnered, or discontinued based on program needs, performance, and/or availability of funds.

This flexible mechanism is required to account for the significant variability across T/NSOs existing research capacity and priorities, allowing for:

- Real-time responsiveness to the distinct needs, resources, and research pathways of different T/NSOs
- Tailored ongoing engagement to community-driven research priorities
- Tailored milestones and activities as work evolves, including the ability to renegotiate activities and expectations over time
- Incorporation of Indigenous methodologies that may fall outside conventional NIH research frameworks
- Accommodation of Tribal governance and decision-making processes within the design and conduct of research

**By using OT authority to support T/NSOs, N CREW aims to leverage the flexibility needed to promote community-led research that is responsive to community needs in real-time.**

### NIH's HEAL<sup>®</sup> Initiative Goals

N CREW is part of the NIH HEAL Initiative<sup>®</sup>, which is an effort to speed scientific solutions to stem opioid misuse, addiction, and overdose by bolstering research to improve:

- Prevention and treatment for opioid misuse and addiction
- Management, treatment, and understanding of pain

More information about the NIH HEAL Initiative<sup>®</sup> is available at: <https://www.nih.gov/heal>.

### N CREW Program Goals

The initial three Program Goals were developed based on Tribal Consultations ([2018](#) and [2022](#)) and Native community input:

- Enhance capacity to conduct locally prioritized HEAL related research.
- Support T/NSOs to lead community prioritized research projects, including those elevating and integrating Indigenous Knowledge and culture.
- 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 research and to improve health outcomes.

A fourth goal was added in response to community input and working with sites in Phase I:

- Foster a collaborative network that advances Native community-led research and use of data by supporting the development of relationships and the provision and sharing of knowledge, tools, and resources.

## 1. Review the Opportunity: HEAL Initiative® Research Focus Areas & Intersection with N CREW

- Because N CREW is part of the NIH HEAL Initiative®, proposed projects **must** focus on **overdose**, **substance use** (including opioids or stimulants), or **pain**.
  - See [HEAL strategic plans and research priorities](#) for more details on research areas.
- Projects **may also** address related factors that support positive health outcomes, such as: **well-being, mental health** and other community-identified factors.
- Within these topical areas, projects are expected to reflect community priorities and be driven by **applicant-identified needs and approaches**.
- While N CREW projects must focus on overdose, substance use, or pain, HEAL frames this work within an Indigenous and whole-person approach that recognizes community-specific risk and resilience factors including related issues (e.g., mental health, wellness, alcohol use, strength-based factors).
- Examples of HEAL focus-areas include:
  - Developing non-addictive pain treatments
  - Improving pain management
  - Improving opioid/drug addiction prevention and treatment
  - Addressing and preventing overdose
  - Enhancing recovery strategies

**N CREW affirms that Native communities hold the deepest knowledge of what will effectively prevent and reduce opioid and drug overdose and therefore expects applications to be grounded in community priorities, reflect local wisdom, incorporate factors communities identify as protective, and remain culturally centered throughout.**

**This ROA invites applications from T/NSOs for up to 5 years of funding** to plan and conduct research projects aligned with the [HEAL Initiative and N CREW Program Goals](#).

Applications may either include activities for planning and conducting the research project (**Option A**) or, when planning is not needed, include activities dedicated to solely conducting a research project (**Option B**).

### **This ROA Will Not Fund:**

- Activities focused exclusively on research capacity or data improvement projects **without a plan** to conduct a research project by year three of the award
- Direct services **in the absence of** a research or research capacity component
- Projects **without a focus on HEAL-related** topics or outcomes (<https://heal.nih.gov>)

# A

### **Planning & Research**

- Up to 2 years of planning activities for the research project
- At least 3 years of conducting the research project

# B

### **Research Only**

- All 5 years will be spent conducting the research project

# 1. Review the Opportunity: Planning and Research Example Activities

Research is a systematic investigation used to develop or contribute to generalizable knowledge by uncovering mechanisms, building on existing evidence, and advancing understanding to answer important questions that lead to new insights and practical solutions. There are many existing research traditions and methods, including Indigenous research methods. Applications may include various rigorous research methodologies that are appropriate to address their community prioritized research questions. Typically, projects **must** focus on HEAL-related research areas (i.e., overdose, substance use, or pain) and may also include related factors (e.g., well-being, mental health, alcohol use, etc.) to support positive health outcomes in Native communities.

## Potential Activity Examples include (but not limited to):

### Planning Examples (Option A)

- Planning or development of research
  - Identification of research questions via needs assessments, identification of community priorities, or other method
- Expanding research capacity and infrastructure
  - Hire research staff and establishing academic research partnerships
  - Establish community research advisory boards
  - Develop and conduct community or organization research training
  - Enhance technological capabilities to collect data or conduct research
- Research training for scholars working on proposed research
- Development, pilot and feasibility testing for proposed research, including testing interventions
- Development of a Native-led entity to conduct research in support of Tribal governance, health, and community priorities

**Note: Sites applying under Option A must demonstrate capacity to conduct a research project by Year 3**

### Research Examples (Options A&B)

- Identifying modifiable individual and/or community level factors impacting substance use or pain outcomes
  - Identifying factors that affect how Native communities access and use substance-use or pain-management interventions
  - Identifying unique risk or protective factors or relationships among these factors that can be targeted in intervention
- Testing interventions that address substance use or pain, which may include approaches important to Native Americans, for example:
  - Traditional healing and medicine
  - Spirituality
  - Strengths-based perspectives
  - Holistic conceptions of health
- Using enhanced data from the planning phase to address community prioritized research questions

## 1. Review the Opportunity: Collaboration & Partnership Requirements

N CREW promotes innovation and advances collective knowledge through sustained partnerships across the program. Success depends on active collaboration among participating individuals and organizations to achieve shared goals. Accordingly, all recipients are expected to engage consistently with partners across N CREW, including the NRRPs and NIH.

Applicants **should describe their willingness and be prepared** to collaborate and partner with other T/NSOs, the NRRPs, and NIH.

**As part of this, all applicants should factor in time and budget** for the following N CREW collaboration and partnership activities and deliverables (in addition to time and budget needed for the activities individualized to applicant's project needs):

- N CREW Network/Teaming Meetings (collaborative gatherings where N CREW recipients and NIH staff share updates, hold program relevant discussions, and plan next steps; two in person and up to two virtual meetings each year)
- Meeting and engaging with NIH staff, the NRRPs, and other awarded N CREW sites (several meetings per month)
- Participating in or leading trainings, Special Interest Groups, and other activities supported by the NRRPs
- Sharing project details with the NRRPs and NIH

# 1. Review the Opportunity: Data Management and Sharing, Reporting, & Other Federal Requirements

Applicants should also **factor in time and budget** for the following N CREW activities and deliverables:

## Data Management & Sharing Requirements

Sites are encouraged to share data, first examining if and when data sharing may be appropriate for their communities. See [NOT-OD-22-214: Supplemental Information for NIH DMS Policy - AI/AN Data](#)

- Applications should include a Data Management and Sharing (DMS) Plan outlining initial plans for how scientific data will be managed and shared, considering any potential restrictions or limitations including those related to Tribal policies or preferences.
- During negotiations and Phase II of the N CREW Program, funded recipients will refine this plan.
- A DMS Plan will be required prior to award.

## HEAL Data Ecosystem

The NIH HEAL Initiative supports a **HEAL Data Ecosystem**, which aims to provide virtual open access to HEAL research data, findings, and publications to establish secure data access and computing infrastructure.

Recipients must, at a minimum, register their study/project, to include the title and a description, and should consider other ways they might engage with the ecosystem. Applicants can find more information on the HEAL data ecosystem here: <https://www.nih.gov/heal/heal-initiative-requirements/data-sharing-policy/about-heal-data-ecosystem>

## Reporting & Other Federal Requirements

The terms and conditions of award will address the reporting requirements; however, sites **must** prepare for the following reporting and regulatory requirements:

- **NIH:** Financial & progress reports, interim progress updates, closeout documents, and a Final Reflections Report\*
- To engage in **human subjects research**, recipients must:
  - Obtain [Federal Wide Assurance \(FWA\)](#) from the DHHS Office for Human Research Protections (OHRP; note FWA only required for non-exempt clinical research).
  - Comply with [45 CFR 46](#).
  - Provide the # of participants they plan to recruit - NIH will monitor progress made toward recruiting that number.
  - See NOT-[OD-22-001](#) for more information about NIH's implementation of the revised Common Rule provision regarding public health surveillance activities deemed not to be research.
  - [Exempt human subjects research](#) in NIH-supported studies involves low-risk activities that, while exempt from the full Common Rule IRB review, still require formal determination of exemption by an IRB, Human Subjects Education Training, and Inclusion Monitoring.
- Clinical trials must also comply with any relevant NIH and HHS regulations governing clinical trials. Refer to the [NIH Division of Human Subjects Research](#) website for NIH human subject policies and guidance, and to the [HHS Office for Human Research Protections](#) website for the Protection of Human Subjects regulations and related regulatory guidance.

\*At the conclusion of the project, recipients will submit a report reflecting on their experiences carrying out their research projects and overall participation in the N CREW Program network

# 1. Review the Opportunity: Eligibility

Tribes and Native Serving Organizations (T/NSOs) are eligible to apply, including those without previous NIH funding.

For the purposes of this ROA (OTA-26-001), a Tribe is any federally, state, or other recognized Tribe or Tribal government entity. An NSO is an organization with a core mission to serve Native Americans **and** a track record in meeting this mission. The following T/NSO entities that are located in the United States are eligible to apply under this ROA:

## Governments

- Tribal District Governments (with any Tribally required approvals)
- American Indian/Alaska Native Tribal Governments (Federally or other than Federally recognized)
- Departments of Tribal Governments, such as departments of public or behavioral health, commerce, labor, housing, etc. (within both Federally or Non-Federally recognized Tribal Governments)

## Non-Profit Organizations

- Non-profits with 501(c)(3) Status
- Non-profits without 501(c)(3) Status including, but not limited to:
  - Faith based or community-based organizations
  - Patient or consumer advocacy groups
  - Social service organizations
  - Healthcare systems & Providers (including FQHCs)
  - Schools
  - Law enforcement & criminal juvenile justice agencies
  - Neighborhood Associations

## For-Profit Organizations

- Small businesses
- For-Profit Organizations other than small businesses
- Business regularly employed by a T/NSO to provide fiscal management services

## Other Research Entities

- Academic Institutions, including academic research centers, academic healthcare organizations, private healthcare organizations, and other research organizations:
  - **Only eligible** if the academic institution (i.e., not the Center) has a core mission to serve Native Americans **and** a track record of meeting this mission
- Academic research entities that do not meet these eligibility specifications may be included in a T/NSO application as identified partners through MoU, contract, subaward, etc.

**Submit a justification for identifying as an NSO:** All NSOs (e.g., entities that fall within the shaded boxes) must demonstrate a core mission to serve Native Americans **and** a track record of meeting this mission, see “Justification for identifying as an NSO” section of this document (slide 23).

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 consultants are permitted.

## 2. Get Ready to Apply

### Register your organization in eRA Commons

The Principal Investigator (PI) and Signing Official (SO) **must each be registered in eRA Commons before submitting an application**. Please start the registration process early (six weeks prior to the application deadline) to allow time to address any unforeseen challenges:

<https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era>

Steps to Register:

1. On eRA Commons home page (linked above) click *Register Organization*
  1. Select NIH Other Transaction Authority (OTA) Opportunities
  2. Complete registration form
  3. Submit registration request
2. Once the registration request is submitted, you **must verify your email within 8 days**, or the registration request will be cancelled. Check spam folder if you do not receive a request to verify email.
3. After email verification, NIH will review the registration request and follow-up with additional instructions.

Additional assistance on the registration process can be found here:

- [Initiating an OTA Application](#)
- [OTA Form Screen](#)

**Please note that**

1. For applications with Multiple PI's, the contact PI must be employed by or affiliated with the applicant organization.
2. It is strongly recommended that two different people hold the roles of PI and SO. However, if one person serves as both the PI and SO, they will need two sets of credentials (email address, username, password).
3. While the PI and SO must be registered, you are encouraged to also register other key personnel prior to application, though they can instead be registered prior to award.

### 3. Prepare your application - Overview

Applications must be submitted by the applicant's signing official (SO) using [NIH ASSIST](#). The SO's signature certifies that the applicant will provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of funds awarded.

**For best consideration, applications should be submitted on or before July 31, 2026** using the following formatting guidelines:

- Submit as text-recognizable, searchable (not scanned) PDF (Adobe) format.
- Minimum 11-point font with 1" margins, single-spaced
- Combine all sections and upload as one attachment with file name: TNSO\_PILastName\_OrgName.pdf
- Upload as a "flat file." To create a flat file, navigate to File > Print, select a "PDF" printer (e.g., "Adobe PDF"), click Print and name the file. This will "print to a PDF" and the file will be flattened.
- In addition to the single pdf submission, applicants will be required to enter the abstract and specific aims sections into specified fields within ASSIST.

#### Key Dates:

Register in eRA Commons

If possible, begin process by May 1

Submit Application

By July 31, 2026

#### Application Components (details on slides 18-23):

Component	Requirement
Title Page	Required, 1 page limit
Abstract	Required, 1 page limit
Specific Aims	Required, 3 page limit
Planned Activities & Approach	Required, 12 page limit
Anticipated Challenges	Required, 2 pages
Key Personnel	Required, No page limit
Multiple PI Plan	Required for applications with multiple PI's; No page limit
Data Management and Sharing Plan	Required, 2 page limit
Budget	Required, No page limit
Fiscal Management Information	Required, 1 page limit
Justification for identifying as a NSO	Required for NSOs, 2 page limit
Letters of Support	Recommended, no page limit or maximum

### 3. Prepare your application: Components

Section	Page Limit	Description
Title Page	1	The title page should include: Title; Applicant Organization; Organization address & contact information; Contact PI name and contact info (Commons ID, Email, Address, Phone) and name/contact of any MPIs or key personnel; Name and contact information of Applicant's Signing Official; Year 1 total cost (direct and indirect costs); and Total project cost (sum of direct and indirect costs per year) requested for the entire project period (up to five years).
Abstract	1	The abstract should include a short description of the project. There is no required format but recommend including: Background information about the need and rationale for the project; specific aims of project; project or study design and methods; several sentences about potential for the study to support positive health outcomes in Native community(ies); and how the study will address opioid/drug overdose, through research on substance use and/or pain and related factors.
Specific Aims	3	The Specific Aims section should expand on the abstract and (1) Describe the significance of the problem for the community and/or Native populations more broadly; (2) state the goals of the proposed work and how they align with N CREW/HEAL-program goals; (3) specify the key questions, gaps, and/or hypotheses the project will address, including identification of 3-5 specific aims, and; (4) briefly describe the overall approach/strategy that will be used to achieve the proposed aims.

### 3. Prepare your application: Components continued

The Planned Activities and Approach section is limited to 12 pages and should include the following subsections:

Subsection	Description
Planned Activities	<p>Describe the research planning (Option A) and/or research activities (Options A and B) and their potential to advance solutions to identified HEAL related needs of the community and yield long-term, sustainable benefits for Native communities or populations. Planned activities should be organized around each specific aim and <a href="#">milestone</a>.</p> <p><b>Option A (Planning &amp; Research):</b> Describe the planning activities, detailing (1) identified community needs; (2) how the proposed activities will lead to readiness for conducting the research project, and (3) the <a href="#">HEAL Initiative research focus area(s)</a> the project will address. Applicants <b>must</b> clearly articulate how their proposed planning activities will ensure they are fully prepared to conduct a research project by Year 3 or earlier, demonstrating that the planning activities are essential and sufficient to achieve readiness. Also describe what is currently known about the anticipated research project, including the research goals and anticipated research questions. The description of the proposed research activities should also include the rationale for the project, and as much information as is currently known describing the study population, methodology and project design, anticipated outcomes and scientific justification for selection of outcomes, data analysis plan, and plans for dissemination of findings to ensure sustainable benefits for Native communities or populations. Include rationale for how completed planning activities will refine these goals and activities.</p> <p><b>Option B (Research Only):</b> Describe the HEAL Initiative research focus area, community need and scientific rationale for the project, and the research goals. Also describe the research questions and research activities including the study population, methodology (including measures), study design, anticipated outcomes and scientific justification for selected outcomes, data analysis plan, plans for dissemination of findings, and plans to sustain research capacity, intervention implementation (if testing an intervention), or to ensure the research informs next steps. Please <a href="#">see slides describing the Objective Review Process</a> (slides 24-28) to understand what content will be required to evaluate your application.</p>
Milestones	<p>In addition to the required partnership &amp; collaboration milestone, identify up to 5 additional milestones (objective, measurable accomplishments that will indicate progress towards proposed specific aims). In addition to the list of milestones, you will submit a <a href="#">milestone-based budget plan</a> (not included in page limit; see slide 22).</p>
Management, Staffing, and Partnerships	<p>Describe plans for project administration, management, and staffing to ensure execution of the project, including any scientific partners (e.g., academic partners) crucial for success. Applications including partnerships should outline how partners will work together to accomplish activities in a partnership plan.</p>

### 3. Prepare your application: Components continued

Section	Page Limit	Description
Anticipated Challenges	2 pages	All applicants should provide a thoughtful description of potential challenges and strategies for addressing these challenges and any relevant prior experiences that inform their approach. Applicants are encouraged to describe how past projects, professional expertise, or collaborations have shaped their understanding of potential obstacles and solutions.
Senior/Key Personnel and Disclosure Requirements	N/A	<p>Document via <a href="#">Biosketches</a> (5 pages or less) the experience of key personnel, including experience working with Native communities or Tribes and subject matter expertise. Provide Biosketches for PIs and all key personnel. Biosketches should be submitted as an appendix within the application.</p> <p>In addition, as required by 42 U.S.C. § 6605, all senior/key personnel identified in an application must submit and certify information about current and pending research support via Other Support. <b>For a full list of the types of activities that should be disclosed in your Biosketch or Other Support form, please see the <a href="#">NIH Disclosure Table</a>.</b></p>
Multiple PI Plan	N/A	For applications with more than one PI, submit a leadership plan which also includes a Conflict Resolution Plan, specifying in detail how conflicts among PIs would be resolved, even if conflict is not anticipated.
Data Management & Sharing Plan	2 pages	Per NIH requirements, include a plan outlining how data will be managed (e.g. stored, protected) and shared. NIH encourages data sharing; however, there are justified exceptions to sharing data, including NIH recognition of Tribal Sovereignty in deciding if and how data will be shared ( <a href="#">NOT-OD-22-214</a> ).

### 3. Prepare your application: Milestone Based Budget

Section	Page Limit	Description
Budget	No Limit	<p><b>Two separate budget documents</b> should be included:</p> <p><b>(1)</b> An estimated milestone-based budget for the entire project period (up to 5 years), broken down by quarter to reflect work described in the milestone-based work plan (see details <a href="#">here</a>);</p> <p><b>(2)</b> A detailed and well-justified budget that includes all expected costs for year one of the award, such as:</p> <ul style="list-style-type: none"><li>• Personnel, equipment, travel, partners (sub-awards, contracting fees), and other direct costs</li><li>• Indirect (F&amp;A) costs</li><li>• Total cost (with direct costs included)</li></ul> <p>Budget estimates should account for the following:</p> <ul style="list-style-type: none"><li>• 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, up to 2 virtual).<ul style="list-style-type: none"><li>• Budget 3 days and 2 nights per in-person meeting. Location of meetings will be decided based on the geographic location of recipients and NIH, but assume one trip on the East Coast, and one on the West Coast.</li></ul></li><li>• Staff time for participation in cross-program workgroups and meetings, at a minimum expected to include the 4 Teaming Meetings, 2-3 ongoing special interest or cross-site workgroups, and N CREW governance meetings (minimum once per month).</li><li>• For manuscripts published in journals that are not immediately open access, applicants should include costs to pay for immediate open access.</li><li>• Travel costs for the PI(s) to attend annual HEAL Investigators meeting (if interested)</li></ul> <p><b>The proposed budget is subject to change through negotiation with NIH prior to award.</b></p>

### 3. Prepare your application: Milestone Based Budget

For each project year (up to five years), provide a milestone-based budget plan. This plan should estimate your costs by milestone and by quarter.

- Identify one high level, measurable milestone for each specific aim
  - You may include up to five milestones, depending on the number of aims.
  - These milestones should reflect major benchmarks toward completing each aim.
- Include an additional **required** milestone on **N CREW partnership and collaboration**.

#### Clarification on milestones vs. planned activities

- **Milestones** represent high-level indicators of progress toward your aims (e.g., test the efficacy of an intervention).
  - Note: Prior to award, recipients must adapt and submit a final Year 1 milestone and quarterly budget table, negotiated with and agreed upon by NIH staff.
- **Planned activities** provide a more detailed description of the work required to achieve each milestone, but they are not themselves milestones.
  - Applicants do not need to list Planned activities in the milestone table.

#### Milestone-Based Budget Table

Milestone	Year X: Estimated Costs per Award Quarter			
	Q1	Q2	Q3	Q4
Specific Aim 1-Related Milestone				
Specific Aim 2-Related Milestone				
<b>(Required)</b> N CREW Partnership & Collaboration: Complete and implement plans to 1) partner with other T/NSOs, NIH and NRRP, including scheduling and attending meetings and participating in governance meetings, 2) Share activity updates with the NRRP and NIH, including a list of planned activities to advance on milestones with a timeline indicating when these activities will occur broken down by quarter				

### 3. Prepare your application: Components continued

Section	Page Limit	Description
Fiscal Management Information	1 page	Describe the Applicant's organizational capacity and fiscal experience with managing program costs over \$200,000. If the applicant does not have prior experience managing program costs over \$200,000 they <b>must</b> submit a proposed plan for managing the award if funded (see the <a href="#">NIH Evaluation of Financial Management Systems Questionnaire</a> for guidance).
Justification for identifying as a NSO	2 pages	For NSOs only (not required for Federal or state recognized tribes): provide the NSO name and a justification that demonstrates their core mission to serve Native Americans <b>and</b> a track record in meeting this mission. May include documents such as: Organization mission statement articulating their core mission to serve Native Americans, financial documentation of partnership, Letter(s) from Tribal authorized representative affirming past and/or future partnership.
Letters of Support (Encouraged)	No Limit	<b>Note:</b> Applications involving Tribal government or proposing research on Tribal lands will need an executed Tribal resolution, executive order, or letter of commitment from the Tribal authorized representative sanctioning the project <u>at the time of the award</u> . Letters of support from identified partners, organizations, consultants, or community leaders should be included in the application as relevant.

## 4. Learn about Objective Review

**Responsive applications will be reviewed with a process called Objective Review, which may include the following:**

- Reviewed by subject matter experts, including NIH Staff, federal employees, and/or external experts
- Reviewers will use the [review criteria](#) (described on slides 25-28) to guide their assessment of applications
- Applicants **will not** receive written feedback on their application
  - If resources allow, NIH staff will meet by phone with applicants to discuss review if requested by the applicant
  - NIH will not accept an appeal of the objective review or funding decisions

**Applications that do not meet the intent of the ROA will be considered non-responsive and not be reviewed. This includes:**

- Activities are focused exclusively on research capacity or data improvements without a plan to conduct a research project by year three of the award
- Activities include direct services without a research or a research capacity component
- Research topics are not focused on [HEAL-related research areas](#) (See slide 10)
- NSOs do not include a justification demonstrating a core mission to serve Native Americans **and** a track record in meeting this mission

## 4. Learn about Objective Review – Review Criteria

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

**Criterion 1:** Likelihood of contributing to advances in addressing substance use and/or improving pain outcomes for Native Americans

**Criterion 2:** Likelihood of accomplishing proposed activities

**Criterion 3:** Likelihood of forming effective collaborations and partnerships

For each, reviewers will indicate a rating of:

(a) Highly likely, (b) Moderately likely, or (c) Unlikely

The following slides provide examples of questions reviewers should address to determine their rating for each criterion. Each question may apply to **Option A**, **Option B**, or **Both Options**.

## 4. Learn about Objective Review – Review Criterion 1

### Criterion 1: Likelihood of contributing to advances in addressing substance use and/or pain outcomes for Native Americans

Application Type	Questions to guide assessment for review criterion 1
<b>Option A</b> (Planning before Research)	Are the proposed planning activities likely to enhance research capacity in substance use and/or pain research?
<b>Option A</b> (Planning before Research)	Are the proposed activities likely to increase capacity to conduct the proposed research project?
<b>Both Option A and B</b>	Will the proposed project contribute to new insights or advance knowledge in meaningful ways that support addressing community needs?
<b>Option B</b> (Research Only)	How likely are the proposed research activities to lead to strategies that impact opioid/drug and/or pain related outcomes and increase wellness in Native communities?
<b>Option B</b> (Research Only)	How likely is the approach to provide answers to the research questions?

## 4. Learn about Objective Review – Review Criteria 2 & 3

### Criterion 2: Likelihood of accomplishing proposed activities

Application Type	Questions to guide assessment for review criterion 2
<b>Option A</b> (Planning before Research)	How likely are the proposed key personnel, staffing structure, partnerships, and/or plans to hire personnel and form new partnerships to support the achievement of the proposed activities?
<b>Both Option A and B</b>	Are the activities and timeline proposed within each milestone feasible and appropriate to complete the proposed work?
<b>Option B</b> (Research Only)	How likely is the existing capacity (such as key personnel, partnerships, environment, data or research infrastructure) combined with any new personnel (e.g., consultants, co-PI's, etc.) to support conducting the proposed research?

### Criterion 3: Likelihood of forming effective collaborations and partnerships

Application Type	Questions to guide assessment for review criterion 3
<b>Both Option A and B</b>	Does the applicant demonstrate a readiness and willingness to engage and collaborate with partners as appropriate [e.g. other T/NSOs, Native Research Resource Partners, and NIH]?
<b>Both Option A and B</b>	Will proposed activities be carried out in a way that promotes relationships of mutual trust and respect among recipients of the N CREW Program?

### Overall Impact

Reviewers will assess whether the proposed activities are likely to overall have a **high, medium** or **low** potential impact on advancing research to address:

- Overdose, substance use, and/or pain in Native American Communities
- May also assess impact on related factors, such as mental health and wellness

### Components

Reviewers will identify laudable proposed activities within applications that independently have the potential to achieve N CREW Program goals

### Areas for Improvement

Reviewers will identify how applications or independent proposed activities might be improved

## 5. Post Submission Procedures – Next Steps After Review

### **After review:**

- NIH may contact applicants, request additional information, and/or conduct site visits.
- Sites may be asked to modify milestones, budgets, include/exclude certain application components, or add partnerships.

### **Final award decisions will consider:**

- Reviewer ratings and comments (e.g., overall impact, components, areas for improvement)
- Programmatic needs
- Available budget
- Negotiations
- Timely submission of any needed information

**If a limited number of responsive applications are received and/or there are significant gaps in the research areas proposed, NIH may 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.**

## 5. Post Submission Procedures – Post Review Activities

Applicants may be contacted after review to provide more information and/or arrange site visits to discuss the following activities:

- **Negotiations: Other Transaction Awards require negotiations on project parameters prior to award.** NIH will select a subset of applicants with whom to negotiate award terms. **NIH maintains the right to:**
  - Award applications as proposed, or negotiate awards to modify milestones, budgets, or include/exclude certain components. This could include new components not proposed.
  - Combine or reorganize applications as part of a consolidated consortium operating under an article of collaboration, teaming arrangement, or other agreed upon 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.
  - Consider prior approval requests to incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award; always at the recipient's own risk.
- **Financial Risk Assessment:** All applicants will be subject to financial analysis and risk assessment conducted by NIH staff. Any identified risks or financial concerns must be addressed in a timely manner during the negotiation for an Other Transactions Award to be made. Applicants are encouraged to investigate their audit status and clear any outstanding audit reports.
- **Special Award Terms:** The full terms and conditions for each Other Transactions (OT) award under this ROA will be negotiated individually and included in the OT Agreement between NIH and the recipient. The OT mechanism permits substantial ongoing involvement by NIH Staff (including Program staff) and enables NIH to adjust projects in real time to align with overall N CREW Program goals.
- **Addition of Partners:** With mutual consent of the applicant and NIH, successful recipients may be asked to establish partnerships with entities identified to provide the support necessary to complete the proposed project (e.g., **academic research partners**). If initially submitted partnerships are not sufficient to meet program goals, NIH will actively engage with potential applicants to discuss identifying and introducing potential partners with all partnerships subject to final NIH approval.
- **Payment:** NIH OT recipients receive payments through the [Payment Management Services \(PMS\)](#) operated by the DHHS Program Support Center.
- **Reporting:** The terms and conditions of an award will specify required reports, including ongoing financial and progress reports and other reports as required throughout the project period, and, at the end of the award period, a final federal financial report, final progress report, and final invention statement.