NIH HEAL INITIATIVE

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

Webinar | July 27, 2023

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LAND ACKNOWLEDGEMENT

We acknowledge that the NIH exists on the traditional lands of the Piscataway and Anacostan people, past, present and future. We honor the land itself and the Native people who belong to this land. We commit to our responsibility to take action, through listening, learning, and responding, to center Native American voices and communities in our work.

Webinar Housekeeping Items

- This webinar is being recorded.
  - The recording and materials will be made available to participants and published on the N CREW website 7-10 business days after the session.
- Please submit all questions in the Q&A box located in your control panel.
  - For most participants it should be located on the bottom of the screen.
- If you experience technical difficulties during this webinar, write a message in the Q&A box and we will assist.

Agenda

Topic
Overview of N CREW Program
Background
Goals and Structure
N CREW Research Opportunity Announcements (ROAs)
ROA OTA-23-007 Tribes and Native American Serving Organizations (T/NASOs)
ROA OTA-23-008 Native Research Resource Network (NRRN)
Other Transactions Authority (OTA) in Detail
Application Submission Process
Key Dates and Application Reminders
Application Review
Wrap Up
Questions and Answers

Overview of the Native Collective Research Effort to Enhance Wellness: Addressing Overdose, Substance Use, Mental Health and Pain Program
or *N CREW*

N CREW is part of the NIH HEAL Initiative

- The Helping to End Addiction Long-term® (HEAL) Initiative bolsters research across NIH to improve:
  - o Prevention and treatment for opioid misuse and addiction
  - o Pain management, including understanding and treating pain
- All funding for N CREW provided by HEAL.
- More information about the HEAL Initiative is available at: https://heal.nih.gov/.

Background: Tribal Consultations in 2018 and 2022 - Research Needed to Address the Opioid Crisis

Themes

- High priority to address overdose crisis including opioid/amphetamine use and pain
- Need to support Native organizations to lead research, requiring significant capacity building and infrastructure investment – "For us, by us"
- Need for more accurate and real-time data
- Need to specifically design and test interventions for/with Native populations
- Need for research and intervention to rely on Indigenous Knowledge, including incorporation of traditional healing practices, spirituality, holistic conceptions of health, and strength based solutions
- Definition of pain discussed throughout
  - Drugs as self-medication for pain (physical and psychological) and impact of SDOH

2022 Consultation report commits to new Program

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https://dpcpsi.nih.gov/thro/tribal-consultations/nih-heal-initiative

Driving Principle of N CREW: Community-Prioritized

Research prioritized by Native communities *is essential for enhancing culturally grounded, strengths-based, effective, and sustainable intervention strategies, ultimately promoting healthy equity.*

- Created in direct response to themes identified in Tribal Consultations

- Recognizes Tribes and Native American Serving Organizations (T/NASOs) are best positioned to identify and respond to community needs through culturally grounded knowledge that serves as the foundation for research and data strategies

- Will build and sustain highly collaborative partnerships between NIH, T/NASOs, and Ally Organizations established to respond to the opioid/drug public health emergency

- Is structured to offer culturally appropriate technical assistance, training, and resources to T/NASOs that are tailored to community strengths and support research capacity and data improvements

N CREW Program Goals

The N CREW Program supports T/NASOs to conduct locally prioritized research to address overdose, substance use, and pain, including related factors such as mental health and wellness.

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

2 — Enhance capacity within T/NASOs to conduct locally prioritized research, by developing and providing novel, accessible, culturally grounded technical assistance and training, resources, and tools.

3 — Improve access to and the quality of data on substance use, pain, and related health and wellbeing factors to maximize their potential use for use in local decision making.

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Key Definitions Across ROAs

- Tribes and Native American Serving Organizations are federally or state recognized Tribes or organizations with a core mission to serve and/or a track record in serving Native Americans and that are poised to reach this population.

- Native Americans (as defined for this Program) are American Indians, Alaska Natives, or Native Hawaiians.

- Ally Organization are organizations with the ability to document a track record of partnering successfully with Native American communities

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	**ROA OTA 23-007** 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)	**ROA OTA 23-008** 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	

Foundational Component of N CREW: Collaboration

- T/NASOs, NRRN members, and NIH will collaborate to meet program objectives

- Both ROAs invite participation in cross-program activities including:
  - 4 Teaming Meetings (i.e., partnership development meetings) in the first year
    - 2 virtual, 2 in person
  - We also ask you to budget for
    - 2-3 ongoing special interest or cross-site workgroups
    - N CREW governance meetings (minimum once per month)

- N CREW award recipients will be invited to the annual HEAL Investigators meeting (in-person)

Potential Outcomes of N CREW

- Reduce overdose related health inequities through science based, culturally relevant, community embraced, and sustainable strategies

- Discover best way to enhance HEAL related research capacity within T/NASOs
  - Discover effective models of 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 and integration of Indigenous Knowledge in NIH research

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N CREW is Customized to Meet Program Goals Through the Use of Other Transactions Authority

- Application requirements designed to support needs of the Program
  - Described in ROAs
- Customized review strategy and process-Objective Review
  - Program-specific evaluation criteria
  - Non-traditional rating scale
  - Non-traditional reviewers (including NIH, other federal staff, and external experts)
- Projects may be altered in real-time in response to identified needs and discussions with NIH

Sierra, "Digital Landscape" NIDA Art Contest

ROA OTA-23-007
Tribes and Native American Serving Organizations (T/NASOs)
N CREW Research & Data Projects

T/NASO N CREW Research and Data Projects – *ROA OTA-23-007*

- Solicits Phase I applications from T/NASOs to:
  - Develop, plan or implement **research studies**
  - **Improve data** (e.g., access, quality, availability)
  - **Enhance capacity** to engage in research

- Projects **must explicitly** include a focus on overdose, substance use (including opioids or stimulants), **OR** pain management.
  - Supports inclusion of related factors (e.g., wellness, mental illness, alcohol use)

- What will **not** be funded:
  - Direct services in the absence of a research or research capacity component
  - Capacity building that is not focused on HEAL related research/data projects
  - Projects that do not include a focus on topics or outcomes related to the HEAL Initiative

Encouraged Activities and Priority Consideration
T/NASO N CREW Research and Data Projects – *ROA OTA-23-007*

Applicants are encouraged to
• Propose projects that generate knowledge to inform decisions and implement sustainable strategies to address overdose, substance use, or pain management • Consider a range of Indigenous and/or Western methodologies and approaches   • Includes those that rely on Indigenous Knowledge or lived experience of Indigenous researchers or practitioners

Priority consideration will be given to
• Applicants who document a commitment to advance their research capacity to participate in future NIH research • Meritorious applicants who have not previously applied for or received NIH funding

Expectations –
T/NASO N CREW Research and Data Projects – *ROA OTA-23-007*

- Expectations for award recipients include:
  - Consider scenarios (if any) where data sharing is appropriate – aligned w/Tribal policies, Native research approaches, and community preferences
  - Author a final reflections report to facilitate knowledge, information sharing, and research capacity building for addiction and pain management research in other Native American communities
    - Other formats will be considered with award recipients to best align with their community and communication preferences
- The ROA includes additional details about expectations for award recipients

Application Components –
T/NASO N CREW Research and Data Projects – *ROA OTA-23-007*

All applications will include multiple components:

Component	Description
1. Title Page (1 pg)	Proposal title & contact information for the applicant organization, signing official, principal investigator, multiple principal investigators, & key staff
2. Abstract (1 pg)	Short summary of the application
3. Specific Aims (3 pgs)	Discuss the broad overarching goals of the proposed project, detailing a high-level focus and description of: • Proposed work and **its significance for the community** and/or Native American populations • **Solutions that are novel or innovative** and **culturally appropriate** • How proposed activities and/or methods can **advance knowledge** to address drug overdose, substance abuse, or pain management and other related factors in the **local community**

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Application Components (cont.) – T/NASO N CREW Research and Data Projects – *ROA OTA-23-007*

Component	Description
4. Planned Activities, Approaches, and Key Personnel (12 pgs)	• Describe **research/data-related activities and the identified needs** of the community, including: • Potential for advancing solutions for identified community needs • Potential for planned activities to yield long-term, sustainable benefits for T/NASO-led research • Strategies for building research capacity or data improvements, development and planning activities, and collaboration • Document the **experience of key personnel** supporting the planning and implementation of activities proposed. *(Include 3-page staff resumes)* • Provide a **management, staffing, and partnering plan** • Provide **draft milestones**, tasks to be completed to meet the milestones, description of how milestones will be completed, expected start and completion dates, and cost estimate

Other application components: 5. data management and sharing plan; 6. budget; 7. fiscal management plan; 8. T/NASO documentation, and; 9. letters of support as relevant

T/NASO Eligible Institutions – *ROA OTA-23-007*

- For the purposes of ROA OTA-23-007, a T/NASO is defined as federally or state recognized Tribes and/or organizations with core missions to serve and/or a track record in serving Native Americans and that are poised to reach this population.
    - If NASO, must document core mission and poised to reach this population.

- Examples: community organizations, local businesses, neighborhood authority or association, patient or consumer advocacy groups, regional/local and public healthcare systems, schools, law enforcement or criminal/juvenile justice agencies, or social service agencies.

- The following T/NASO entities located in the United States are eligible to apply under this ROA:
    - Non-profits [with and without 5019(c)(3) IRS Status]
    - For-profit Organizations
    - Governments
    - Non-federal Tribal governments and their respective departments of public health, commerce, labor, transportation, housing and recreation or other departments within a Tribe

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Eligible Institutions – *ROA OTA-23-007* (cont.): Academic, Healthcare and Research Organizations

- Academic research centers, academic or private healthcare organizations, and research organizations **are only** eligible if they meet **all** the following criteria:
  - Are a Tribe or organization with a core mission to serve Native Americans
  - Can document a track record of successfully meeting this mission
  - Are poised to reach this population
  - Can obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative, if appropriate, before the time of the award

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Eligible Institutions – *ROA OTA-23-007 (cont.): Business or Financial Management Companies*

- Business or Financial Management companies that manage finances for T/NASOs will need to:
  - Demonstrate a legally binding relationship with T/NASOs in financial matters
  - Be located in the U.S.
  - Obtain a Tribal Resolution, executive order, or letter of commitment from the Tribal authorized representative, if appropriate, before the time of the award

Additional Considerations of Eligibility – *ROA OTA-23-007*

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

- Foreign components **are** allowed if they maintain a legally documentable relationship to a U.S. Tribe

- 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

- Individuals not affiliated with an organization or who want to submit independent of their current organization are **not** eligible to apply

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Responsivity – *ROA OTA-23-007*

- 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 justification that clearly demonstrates a core mission to serve Native American populations and that they are poised to lead Native American community prioritized research work

Non-responsive applications will not be reviewed

Questions about responsivity? Email Ncrew@nih.gov

ROA OTA-23-008
N CREW Native Research Resource Network (NRRN)

N CREW NRRN - *ROA OTA-23-008 – Goals*

- Solicits applications from T/NASOs and/or Ally Organizations to participate in a Phase I (2 years) multi-component and agile NRRN working responsively and collaboratively to:

  - Develop and provide comprehensive, **real-time resources and support** to T/NASOs

  - **Identify effective strategies and approaches for supporting T/NASOs** as they develop and conduct HEAL related research and/or data improvement projects

  - Identify and implement activities to **maximize investments and facilitate long term sustainability** of research/data gains made by T/NASOs

- In Phase I the NRRN is structured to:

  - Provide a broad range of research support that cannot be fully predicted in advance

  - Be agile and allow for flexibility in modifying activities, partners, or formal partnership structures

N CREW NRRN - *ROA OTA-23-008 - Activities*

- Four broad categories of activities NIH anticipates will be needed:
  - Technical support, training, tools, or other resources
  - Development and continual refinement of a coordination and reporting structure
  - Meeting planning, technology, and related resources needed to establish, strengthen, and maintain partnerships
  - Activities to distill lessons learned, spur innovation, and accelerate progress in enhancing research capacity with N CREW funded T/NASO sites and broader Native American communities
- Applicants can apply to conduct activities in all categories, selected categories, or other categories they deem important
- NIH will prioritize applications with proposed activities that are likely to benefit greater numbers of T/NASOs

Example potential activities to support the N CREW Program in each category- *ROA OTA-23-008*

Technical Assistance Areas

- Tracking and reporting on activities
- Identifying study designs
- Intervention research
- Financial accounting systems
- Grant writing and monitoring

Partnership Development

- Development and implementation of innovative strategies for fostering and sustaining partnerships.
- Support teaming meetings, workgroups, governance meetings, other cross-site meetings

Coordination & Reporting

- 2 or more organizations from the NRRN will lead coordination
- Gather information & resources across sites
- Manage the coordination of comprehensive, real-time TA & resources
- Support dissemination of information learned

Spur Innovation & Accelerate Progress

- Identify, consolidate, and disseminate best or promising practices for developing and enhancing research capacity within T/NASOs; possibly develop a research readiness model
- Report on the different structures and strategies T/NASOs employ to carry out research.
- Develop an innovative program or process for training and mentoring research scholars.

What to include in the application-*ROA OTA-23-008*

Applications will include 8 components:

1. Title Page *(1 pg)*	• Application title & contact information for the applicant organization, signing official, principal investigator, multiple principal investigators, & key staff.
2. Abstract *(1 pg)*	• Short summary of the application.
3. Specific Aims *(3 pgs)*	• High level summary of the **scientific, training, operational, coordination, institutional and other strategies** proposed to support T/NASOs as they build research capacity and develop research projects. • 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.

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What to include in the application-*ROA OTA-23-008, continued:*

4. Planned activities, approaches, & key personnel (12 pgs)	• Describe the **proposed activities and approaches** for providing resources to and advancing T/NASO research and data improvement projects as well as enhancing research capacity for approximately 2 years. • Document the **experience of key personnel** supporting the planning and implementation of activities proposed. • *Include 3-page staff resumes – not included in the 12 pg limit* • Provide a **management, staffing, and partnering plan** • Provide **draft milestones**, tasks to be completed to meet the milestones, description of how milestones will be completed, expected start and completion dates, and cost estimates.

Other application components: 5. data management and sharing plan; 6. budget; 7. fiscal management plan; and 8. letters of support if applicable

Types of Eligible Institutions - *ROA 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.

- Eligible Entities:
  - Higher Education Institutions
  - Nonprofits Other Than Institutions of Higher Education
  - For-Profit Organizations
  - Local Governments
  - Other

Additional Considerations for Eligible Institutions – *ROA OTA-23-008*

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

- Foreign components **are** allowed if they maintain a legally documentable relationship to a U.S. Tribe

- 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

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Responsivity – *ROA OTA-23-008*

Applicants must be able to document strong Native American cultural expertise and experience working with Native populations

Applications that do not include this documentation will be considered non-responsive and <u>will not</u> be reviewed

Other Transactions Authority in Detail

Other Transactions Authority

- OTs allow the **nimble addition or subtraction** of expertise, tools, technologies, and partnerships to meet program needs

- OTs facilitate **engagement of nontraditional partners**

- Reporting requirements are **tailored for each award**

- Award **funding is different** (e.g., variable segment lengths, future commitments may be modified, terminated or extended by NIH)

- Collaborative involvement by the NIH in the technical direction and oversight of the research (e.g., participation in progress reviews and decisions on future efforts or direction)

- Neither a grant, cooperative agreement, nor a contract

Other Transactions Authority

Support or acquisition mechanism	Type of Funding	Research directed by	Responsive to changing priorities	Grant or procurement laws and regulations apply?	Governed by overarching federal *research* laws, regulations, policies	Review of Applications
Grant	Financial assistance mechanism to support research for the public good	Investigator	No	OMB Uniform Guidance & NIH Grants Policy and Statement	Yes	Peer review of broad criteria
Cooperative Agreement		Investigator with significant government involvement	Some		Yes	
Contract	Legally binding instrument to acquire good or services for the direct use or benefit of the Government	Government	Not really	Federal Acquisition Regulation (FAR)	Yes	Award based on stated evaluation factors
Other Transactions Authority	Legally binding instrument that may be used for a broad range of research and activities based on an OT Authority	Government / Investigator Collaboration	Yes	Federal laws and NIH policy applicable to all award instruments & Congressional authorizing language	Yes	Scientific Evaluation or Objective Review

Other Unique Aspects of Other Transactions Authority

- Supports development of individualized solutions in real time, flexibly responding to evolving, unique T/NASO needs
  - Provide a broad range of research support that cannot be fully predicted in advance
  - Facilitate T/NASOs ability to have some choice in partners, rather than pre-select
- Ability to quickly pivot
  - Be agile and allow for flexibility in modifying activities, partners, or formal partnership structures
  - Discover best infrastructure and capacity strategies
    - e.g., testing novel research infrastructures, bringing in new partners, etc.

Application Submission Process

How to Submit an Application

- Applications for Other Transactions are required to be submitted through the [Application Submission System & Interface for Submission Tracking (ASSIST)](#).

- Resource only for Other Transactions Authority (OTA) Users of ASSIST
  - This step-by-step instruction guide, together with the forms and information found in the research opportunity announcement (ROA), should be used to prepare and submit OT applications using ASSIST.
  - [Instruction Guide for OTA Submissions via ASSIST](#)

Prepare to Apply

- Prior to submission, the Principal Investigator and their organization must be registered in [eRA Commons.*](#) Please select the "[Register Organization](#)" link for more details.

- Required eRA Common Roles to Submit Application

Principal Investigator (PI) & **Signing Official (SO)**

- **It is desirable**, though not required, that other key personnel/whole applicant team are also registered in eRA Commons.

- If an application is awarded, additional registrations (e.g. [System Award Management](#)) will be required

- OT applications must be submitted through [NIH's ASSIST](#), Users can access ASSIST directly or through eRA Commons

- To complete the application, users must have access to a browser, a pdf generator, and Adobe Reader Software

*Note that registration in eRA Commons may take up to six (6) weeks of more to complete-please start early

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OTA Applications – Registration and Submission

- Specific instructions in ROAs: [ROA OTA-23-007](#) and [ROA OTA-23-008](#)

- Registration and application submission assistance are available from the [eRA Service Desk](#).

- Should anyone have technical assistance questions about their registration or application, please reach out to the eRA Service Desk by submitting a [web ticket](#) or calling them at:
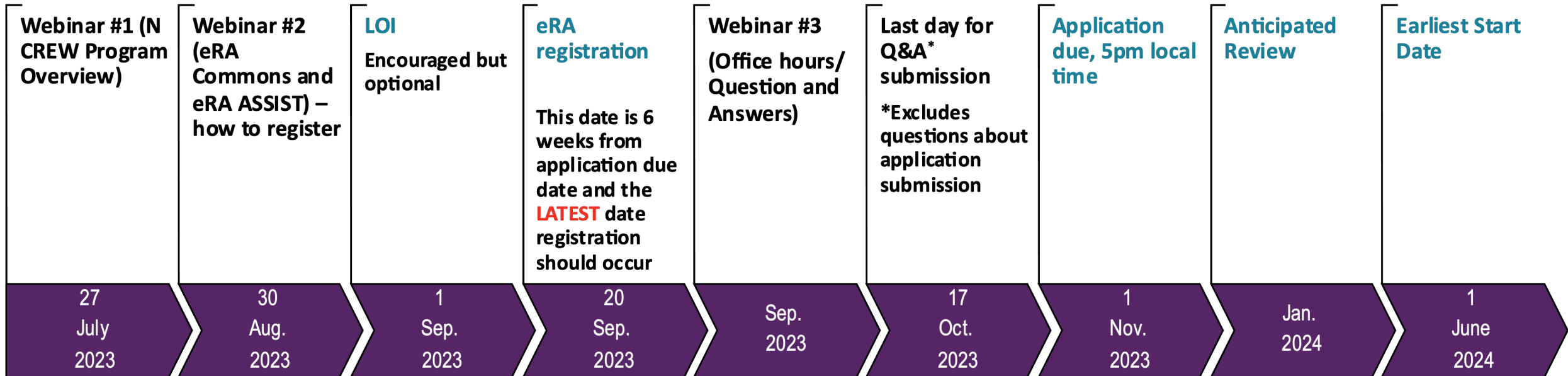
  Toll-free: 1-866-504-9552 (Press 1 for eRA Commons or ASSIST)
  Phone: 301-402-7469 (Press 1 for eRA Commons or ASSIST)

- Should anyone reach out to the Service Desk, please indicate that you are requesting assistance for an Other Transactions application for OTA-23-007 or OTA-23-008, so it is clear from the beginning of the request.

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Key Dates and Application Reminders

Key Dates for
OTA-23-007 OTA-23-008

Webinar #1 (N CREW Program Overview)	Webinar #2 (eRA Commons and eRA ASSIST) – how to register	LOI Encouraged but optional	eRA registration This date is 6 weeks from application due date and the **LATEST** date registration should occur	Webinar #3 (Office hours/ Question and Answers)	Last day for Q&A* submission *Excludes questions about application submission	Application due, 5pm local time	Anticipated Review	Earliest Start Date
27 July 2023	30 Aug. 2023	1 Sep. 2023	20 Sep. 2023	Sep. 2023	17 Oct. 2023	1 Nov. 2023	Jan. 2024	1 June 2024

(Optional) Letter of Intent

- Letter of Intent (LOI) Deadline: **September 1, 2023**
  - Submit to NCREW@nih.gov
- LOIs are encouraged to:
  - Help NIH prepare for providing technical assistance (TA)
  - Plan for a timely review of applications
- LOIs should include (in 2 or fewer pages)
  - Legal name of applicant and partners
  - Contact information of Principal Investigator(s) and other key persons
  - Description of TA that might be needed to apply for OTA-23-007 or OTA-23-008
  - Brief description of activities that will be proposed in the application

LOIs are not binding and will not be considered in the objective review

Data Management & Sharing Plan

- In accordance with [NIH Data and Management Sharing Policy](#), describe how the proposed data generated from the project will be managed and shared.

- Justified exceptions to sharing data are allowed, as noted in the Policy.
  - See also [Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data](#).

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

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Application Reminders – Both ROAs

- Applicant organizations may **not** submit more than one application per ROA.

- Organizations **may** participate as a partner on more than one application per ROA

Application Budget Reminders OTA 23-007

- Proposed budgets must provide a realistic and well-justified cost proposal for performing the proposed work over a period of **up to 2 years**. Budgets for individual awards are expected to vary, depending on the proposed activities and resources. NIH anticipates annual total budgets will range from **$200,000 to $550,000** depending on the proposed activities and resources, **but there is no annual budget limit. The budget must reflect the needs of the proposed work.**
- Provide the overall expected cost for each of the following categories:
  - Personnel
    - Budgets must adhere to latest NIH salary limitation notice (See NOT-OD-23-056, Guidance on Salary Limitation for Grants and Cooperative Agreements)
- Equipment
- Travel
- Partners such as Subawards/subcontracts/consultants
  - **Partners need to provide details of cost breakdown**
- Other direct costs –(Including e.g. the request of funds toward Data management and Sharing in the budget and budget justification sections)
- F&A (indirect) costs – if an applicant has an approved facilities and administrative costs rate agreement with the federal government, the approved rate should be reflected in the budget request. If the applicant does not have an approved facilities and administrative costs rate agreement, they may propose a rate for NIH review and consideration.
- Total cost (with indirect costs included)

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Application Budget Reminders OTA 23-008

- Proposed budgets must provide a realistic and well-justified cost proposal for performing the proposed work over a period of **up to 2 years**. Budgets for individual awards are expected to vary, depending on the proposed activities and resources. NIH anticipates annual total budgets will range from **$500,000 to $1,300,000** depending on the proposed activities and resources, but there is no annual budget limit. **The budget must reflect the needs of the proposed work.** Higher budgets are likely to be allocated to T/NASO or Ally Organizations proposing to support the cross-site coordination infrastructure and/or cross-site research and data acceleration activities.
- Provide the overall expected cost for each of the following categories:
  - Personnel
    - Budgets must adhere to latest NIH salary limitation notice (See NOT-OD-23-056, Guidance on Salary Limitation for Grants and Cooperative Agreements)
- Equipment
- Travel
- Partners such as Subawards/subcontracts/consultants
  - **Partners need to provide details of cost breakdown**
- Other direct costs (Including e.g. the request of funds toward Data management and Sharing in the budget and budget justification sections)
- F&A (indirect) costs – if an applicant has an approved facilities and administrative costs rate agreement with the federal government, the approved rate should be reflected in the budget request. If the applicant does not have an approved facilities and administrative costs rate agreement, they may propose a rate for NIH review and consideration.
- Total cost (with indirect costs included)

Application Review

Objective Review – *Both ROAs*

- Responsive applications will be reviewed by subject matter experts via an Objective Review process.

- The subject matter experts will include NIH staff, other federal staff, and external expertise as needed.

- The Objective Review process will use review criteria taken directly from the ROAs to guide assessment of the applications and the discussions between those experts and NIH N CREW program staff.

Objective Review – *Both ROAs*

With the review criteria in mind, the assessment of potential Overall Impact will be rated as:

- **high** potential impact
- **medium** potential impact
- **Low** potential impact

Objective Review – *Both ROAs*

Importantly, for both ROAs the 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 Criteria: *ROA OTA-23-007 Addressing Overdose, Substance Use, Mental Health, and Pain*

1. **Likelihood of contributing to advances in addressing substance use (including opioid and/or stimulants) and/or pain disparities for Native Americans:**
   - Are the proposed activities likely to (1) enhance research capacity and/or data improvements or (2) prepare for T/NASO-led research and data projects on opioid/drug use and/or pain, and related outcomes as applicable (e.g., mental health, wellbeing)?
   - Are the proposed approach(es), activities, and/or resources, contributing in innovative and unique ways to addressing community needs?
   - How likely will the proposed activities foster the development and long-term success of T/NASO led research that supports strategies to impact opioid/drug and/or pain related outcomes and increase wellness in Native American communities broadly?

Review Criteria: *ROA OTA-23-007 Addressing Overdose, Substance Use, Mental Health, and Pain*

2. **Likelihood of accomplishing proposed activities:**
   - Are the proposed milestones feasible and/or appropriate to complete the proposed work?
   - Are the proposed key personnel, staffing structure, partnerships, and/or plans to hire additional personnel and form new partnerships, appropriate for achieving the proposed activities?

Review Criteria: *ROA OTA-23-007 Addressing Overdose, Substance Use, Mental Health, and Pain*

3. **Likelihood of forming effective collaborations and partnerships:**
   - Does the applicant demonstrate a readiness to engage and collaborate with partners as appropriate [e.g., other T/NASOs, Native Research Resource Network members (see OTA-23-008), and NIH]?
   - Will proposed activities be carried out in a way that promotes relationships of mutual trust and respect among recipients of the N CREW Program?

Review Criteria: *ROA OTA-23-007 Addressing Overdose, Substance Use, Mental Health, and Pain*

Assessment of Overall Impact ROA OTA-23-007:

- Are the overall proposed activities likely to advance 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.

Review Criteria: *ROA OTA-23-008 Native Research Resource Network*

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

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Review Criteria: *ROA OTA-23-008 Native Research Resource Network*

2. **Likelihood of contributing research and/or data expertise to support T/NASOs to make advances in addressing substance use (including opioids and/or stimulants) and/or pain disparities:**

   o Is there sufficient evidence that the applicant will be able to provide and/or contribute to the development of research and/or data subject matter expertise and resources?

   o Does the applicant document prior experience collaborating with Native American communities to conduct research?

Review Criteria: *ROA OTA-23-008* *Native Research Resource Network*

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

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Review Criteria: *ROA OTA-23-008 Native Research Resource Network*

Assessment of Overall Impact ROA OTA-23-008:

- o Are the overall proposed activities likely to advance T/NASO led research/data to address overdose, substance use, and/or pain management, also possibly including related factors such as mental health or wellness within Native American communities?

Wrap Up

Wrap Up: N CREW Program Highlights

- Responsive to Tribal Consultations

- Rooted in tribal sovereignty

  - Projects are community-prioritized

- Designed to provide novel, accessible, culturally grounded training, resources, and tools to build research capacity in community

  - Advance application and integration of Indigenous Knowledge in NIH research

- Supports community prioritized research and and enhancements in data

- Leverages OTA to facilitate the N CREW Program and participants quickly pivoting in response to lessons learned and new or evolving needs

N CREW Program has Trans-NIH Support

Issuing Institutes and Centers

- <u>National Institute on Drug Abuse</u>
  - Program

- <u>National Center for Advancing Translational Sciences</u>
  - Other Transactions Financial Management and Review

Participating Institutes, Centers, and Offices

- <u>National Institute of Mental Health</u>
- <u>National Institute of Neurological Disorders and Stroke</u>
- <u>National Institute on Alcohol Abuse and Alcoholism</u>
- <u>National Center for Complementary and Integrative Health</u>
- <u>National Institute of Arthritis and Musculoskeletal and Skin Diseases</u>
- <u>National Institute on Minority Health and Disparities</u>
- <u>National Institute of Dental and Craniofacial Research</u>
- <u>National Cancer Institute</u>
- <u>Office of Research on Women's Health</u>
- <u>Tribal Health Research Office</u>
- <u>National Institute of Nursing Research</u>
- <u>National Institutes of Health Office of the Director</u>
- <u>National Heart, Lunch, and Blood Institute</u>
- <u>*Eunice Kennedy Shriver* National Institute of Child Health and Human Development</u>

Upcoming Technical Assistance

Webinar on eRA Commons and ASSIST – Aug 30th at 1:30 EDT

- NIH staff will walk through:
  - How to register organizations in eRA Commons
  - A hypothetical application submission in ASSIST
- Highlight common error messages and how to address them
- Answer questions

Webinars for Office Hours/Questions and Answers - TBD

- Please email ncrew@nih.gov with your questions and answers
- Sign up information forthcoming

Questions and Answers

- Questions and Answers are updated weekly on the NCREW website

Kathy Etz

Barbara Oudekerk

Jaclyn Smith

Angela Walden

Carly Marshall

NIH N CREW Team Contact Us!
NCREW@NIH.GOV
Plus many other staff - not pictured

Nakia Brown

Jennifer Cho

NIH HEAL INITIATIVE

Questions and Answers

Email:
ncrew@nih.gov

Website:
heal.nih.gov/ncrew

Thank you!

NIDA, NCATS, HEAL and NIH are grateful for your time and attention. We look forward to learning from and partnering with you. Please consider applying!!!

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