

Native Collective Research Effort to Enhance Wellness (N CREW) Program - Questions and Answers (Q&A)

Phase II Research Opportunity Announcements (ROAs): General Questions

1. Can you share more about how the OTA application and awards process is different than grants, contracts and cooperative agreements?

An Other Transaction (OT) is a unique type of funding mechanism different from a contract, grant, or cooperative agreement. Generally, this awarding instrument is not subject to the FAR, nor grant regulations unless otherwise noted for certain provisions in the terms and conditions of award. It is, however, subject to the OT authority that governs the initiative as well as applicable legislative mandates. Using OT Authority allows N CREW to utilize a non-standard peer review referred to as objective review as well as a simplified application process using NIH ASSIST rather than the standard SF-424 grant application forms. OT Authority also allows NIH to provide substantial technical assistance throughout the award negotiation and implementation process. OT award budgets and activity are negotiated prior to each funding segment. Reporting is also different from standard NIH awards, and reporting requirements will be specified in the Terms and Condition of award. Through negotiation OT awards may be expanded, modified, partnered, not supported or later discontinued based on program needs, changing research landscape and/or availability of funds.

2. The N CREW Program seeks to promote wellness among Native communities 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 Serving Organizations that apply to conduct research or enhance data as part of the N CREW Program can define wellness based on community priorities.

3. Does cigarette smoking qualify as "Substance Use" under the HEAL program?

HEAL funding must target overdose. For this reason, N CREW projects must target substances related to overdose.

4. Are capacity building activities allowed in Phase II?

Yes! Capacity building and infrastructure activities are allowed in Phase II, under both option A that includes a planning and development period and option B that focuses on carrying out a research project. One of the goals of the N CREW Program is to *Enhance capacity to conduct locally prioritized HEAL related research*. We anticipate continued capacity building activities throughout Phase II. Please keep in mind that capacity building and other activities must be to support the proposed HEAL-related research project.

5. 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?

If your organization intends to only apply for Other Transaction Authority opportunities, then a UEI number is not required for initial registration. A UEI must be obtained prior to receiving an NIH award.

6. If Key Personnel change their place of employment while the application is under review but want to remain involved in the project, what impact, if any, would that have on the proposed project or candidacy to receive the award?

If the organizational affiliation of any of the MPIs or Signing Official change while the application is under review, please reach out to the N CREW program at ncrew@nih.gov as soon as possible. Changes in organizational affiliation among other Key Personnel should be disclosed at the start of negotiations. If changes are known at the time of application, this information should be included in the application with a statement on how the expertise would be provided once that individual's position changes. I.e., it should describe if the individual could remain actively involved in the project at their new place of employment and at what percent of effort or if changes need to be made.

7. If I accept a job at an Institution that is submitting an N CREW application but the job is to begin in August, can I list myself as a planned MPI at the new Institution or should we submit as if I will stay at my current institution?

The application on which you are serving as MPI at a partner site (i.e., not your current organization) should reflect your affiliated organization at the time of application. If the application is awarded, a written agreement between the primary applicant organization and each partner site is required confirming the arrangement prior to award. If you have moved institutions, and the application is considered for award, then changes in your organizational affiliation will be addressed during Just-In-Time and Negotiations with NIH.

8. Will names of the reviewers on the panel be disclosed?

Reviewers will be subject matter experts, including NIH Staff, federal employees, and/or external experts. The names of reviewers will not be disclosed.

9. Does N CREW require award recipients to share data?

Sites are encouraged to share data, first examining if and when data sharing may be appropriate for their communities. Applicants must provide a Data Management and Sharing Plan (DMSP) that outlines initial plans for how data will be managed and shared, with particular emphasis on potential restrictions or limitations related to Tribal policies or preferences. This Plan will be refined during the negotiations process but will be required prior to award.

10. If HEAL program requires overdoes, substance use, and pain then how do we capitalize on the Indigenous need to emphasize resiliency factors rather than highlighting pathology? This award requires deficit, it seems, in order to qualify for Native wellness programming, could this be explained a bit further?

The N CREW Program is funded via HEAL funds, which are congressionally appropriated to address overdose, via the pathways of substance use or pain. While this focus is required by the funding source, N CREW recognizes the need to emphasize Native American resilience and strength in research projects. There are strength-based approaches that can be integrated into all aspects of the research process. These range from testing strengths-based healing interventions to measuring strength-based outcomes and other wellness factors, as just two examples.

11. Does NCREW have relations to pharmaceutical partners who might have study meds to treat chronic pain patients?

No, N CREW does not have relationships with pharmaceutical partners for access to study drugs.

12. Does the milestone-based budget include indirect costs?

Yes, please include direct AND indirect costs. If your organization does not have a Federally negotiated indirect cost rate, the de minimis rate of 10% may be requested.

13. Do all 5 years' budgets have to be the same?

No. Budgets requested should be based on the reasonable and justified needs for each budget period. It is possible for funding allocation and budget needs to not be the same each year.

14. Are the funds on a reimbursable basis?

In general, OT awards allow recipients to use a cost-reimbursement payment method. However, this will be negotiated prior to award.

15. Are all staff required to submit their bio sketches using the new SciENCv forms? If not required, can we use the SciENCv form?

While requirements may change in the future, NIH Other Transactions applications are currently not required to use NIH Common Forms. Specifically, applicants are NOT required to use the new SciENCv forms for biosketches. Applicants may use any format (e.g. resume, CV) to document the experience of key personnel, including experience working with the Native communities or Tribes. This information may be included in the appendix.

Applicants are allowed to use the new SciENCv forms, if they choose to do so.

16. The Current and Pending (Other) Support Form linked in the ROA has an expiration date of Jan 31, 2026. Should we use the expired form, or will there be an updated form?

Please use the form that is linked in the ROA.

17. Are we required to use the Common Forms for Biographical Sketch and Current and Pending (Other) Support?

Currently, common forms are not required for the N CREW Phase II applications. This may change in the future.

18. Is the Research Security Training required for all Key Personnel, and if so, when does it need to be complete?

Currently, the research security training is not required for the N CREW Phase II applicants. This may change in the future.

19. Is there guidance in the ROA about using hyperlinks, are they allowed?

Per [NOT-20-174](#), hyperlinks are not allowed in N CREW Phase II applications.

Phase II Research Opportunity Announcement (ROA): OTA-26-001 Advancing Native Research Projects

20. It sounds like the required milestone “N CREW Partnership and Collaboration” is additional, so there could be up to SIX total (up to five for project + one required on NCREW partnership and collaboration)?

Correct. The “required” milestone is additional to the (up to) five aims.

21. Can you provide more information on how applicants can "justify" that they are a Native Serving Organization?

Native Serving Organizations, or NSOs, must submit justification that demonstrates their core mission is to serve Native Americans. NSOs must also demonstrate a track record in meeting this mission. This could include documents such as the Organizational mission statement, financial documentation of partnerships, letters from Tribal authorized representative affirming past and/or future partnerships, or other documentation applicants deems appropriate in demonstrating their historical commitment to serving Native Americans.

22. Are academic institutions eligible to apply to this ROA (OTA-26-001)?

The applicant organization – not a center or unit within the organization – must meet the [eligibility](#) definition. Academic Institutions are only eligible if the academic institution (not the center or subcomponent of the organization) has a core mission to serve Native Americans and a track record of meeting this mission.

23. Are ROA OTA-26-001 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/NSOs as they enhance their research capacity and to lead research projects; thus, it is not expected applicants will have demonstrated expertise. But all applicants should have a plan.

24. Can an external researcher act as a PI or co-PI for the T/SNO? Will the T/SNO PI need to have a terminal degree?

Yes, an external researcher may act as a PI or multi-PI for the T/NSO application if there is confirmation of a written agreement between the T/NSO and external researcher. There is no requirement for the T/NSO PI to have a terminal degree, however all PIs must justify their expertise and ability to lead the proposed project.

25. To be listed as the PI on this ROA, is it acceptable that I am a consultant for the community organization while also holding an appointment at a research university? Would this be a subaward situation or am I to be a Multiple-PI? Is there some other configuration of PI that makes more sense?

An external researcher may act as a PI or multi-PI for a T/NSO application if there is a written agreement confirming the formal relationship between the T/NSO and external researcher or external researcher's organization. The T/NSO and MPI would decide the best partnership structure, for example whether the T/NSO would hire the PI/MPI as a consultant or through a subaward.

Note that NIH awards are made to the applicant organization (T/NSO), not the PI/MPI. The organization is responsible for research stewardship that the PI/MPI leads, even if the PI is not an employee, and must maintain a formal agreement with the PI. Also, the organization's Signing Official manages compliance, not the PI/MPI.

26. Can a nonprofit organization focused on providing resources, healing ceremonies, classes, sweat lodge, other educational self-help seminars be eligible to qualify to apply for ROA OTA-26-001?

Per the eligibility requirements for this ROA, Non-Profit Organizations with and without 501(c)(3) status are eligible to apply (see ROA slide 15). Please note that N CREW does not support services in the absence of a research project. If these resources and services are part of a research study, then they can be supported as part of that research. Please also note N CREW's focus on research capacity and infrastructure.

27. The ROA establishes an “earliest start date” of March 1, 2027. For those who have a Phase I award, if they are selected for a Phase II award, what date should they plan to begin Phase II? Can Phase I and II awards overlap?

Applicants that are current Phase I award recipients should plan your Phase II start date in accordance with the time at which you believe you will be ready to move from planning and development to implementing your research project, noting that it will be helpful to NIH for some organizations to begin in the Spring or early summer of 2027. All dates – start and end – are negotiable. If a Phase II award is made to your organization, these dates will be negotiated between you and NIH. You cannot overlap a Phase I and Phase II award.

28. What if we only want to do one research study, but don’t have a long-term goal of building research capacity and infrastructure for our organization?

One of the goals of N CREW is to increase research capacity and infrastructure. For this reason, N CREW may not be the best funding opportunity for your organization if you do not have a long-term goal to build out this capacity for more than one project.

29. How do I decide whether to apply under Option A or Option B?

When determining whether to apply under Option A or Option B, you should consider whether you had a Phase I award in addition to one primary factor – would you be ready, at the time of award, to implement a research project? In general, this means you are able to propose in your application your research question or questions, study population and sample, and a planned study design. Option B can still include some roll out or initial set up activities required to implement your specific research project. A few examples of these activities include a short pilot or feasibility test of the approach or study protocol, programming instruments, setting up and training research teams, purchasing of supplies or equipment, and administrative set up like preparing for reporting. However, overall, the research project should be planned and ready for implementation other than typical set up activities.

If you need time to finalize your research questions, identify your study sample, and/or plan your research design, Option A is likely a better fit for you. However, if you had a Phase I award, you will need to provide strong justification for why you are not applying under Option B. The planning and development activities should provide a clear pathway to implementation of a research project by Year 3.

Please note that capacity building is a component of both options and should not be a deciding factor in which option to pursue. If you would like to meet with N CREW program staff to discuss these two options, please email ncrew@nih.gov.

30. Can the research question/intervention be developed during the first 2 planning years phase?

If applying to Option A, yes this includes up to 2 years of planning and development and during that time the team can finalize the research questions or develop/tailor an intervention. However, note that sites applying under Option A must demonstrate capacity to conduct a research project by Year 3.

31. What if I am not ready for either Option A or Option B?

If you find that you are not positioned to apply for either Option A or Option B, there may be other N CREW opportunities in the future. If you would like to be added to a listserv to receive emailed updates about the N CREW program and funding opportunities, please email us at ncrew@nih.gov to be added to the list.

32. NIH Research funding often requires preliminary data to justify the project. For this ROA, what counts as preliminary data, and what is needed?

For this ROA, there is no requirement to have preliminary data to justify the project. The information required to justify a particular focus, direction, or project will vary depending on the proposed work and whether an applicant is applying under Option A or Option B. Preliminary data such as pilot work or

community needs assessments can be used as one way to justify the project. Preliminary data can be any type or amount of data that support the research focus and/or demonstrates the feasibility of a project. You might also demonstrate justification for the project through other documentation, such as Letters of Support or Tribal resolution/executive order/letter of commitment. A well-laid-out project plan and evidence of a strong team capable of executing the work is another way to help justify the project.

33. In the ROA, there are topics considered “must” and other topics that you indicate “may also” be included.” How are these two related? For example, would study of a resilience (wellness) factor related to substance use and pain be considered an appropriate project? Or would something more “central” to opioids/stimulants/pain be required?

“Must” topics are the primary focal topics for the awards and are required to be the focus of the project –overdose, substance use, or pain. Topics that “May also “be part of your research objectives but cannot be the primary focus of the work. “May also” topics must be related to the primary focal topics of substance use, overdose, or pain, and cannot treat them as standalone research foci. These “may also” topics can be supported through the award if connected to the “must” topics, though a purely theoretical connection is insufficient to justify support.

34. “Positive health outcomes” (ROA, Slide 12) that are important to the community and culture—sometimes differ from outcomes aligned with how NIH is organized and funded...or the way terms such as “recovery,” are defined may be different. Which outcomes should we prioritize, and how should we define them? If we include community-focused outcomes, what would that mean for the “scientific justification” (ROA, Slide 19) of those outcomes?

Due to requirements of the funding source, proposed projects must focus on overdose, substance use (including opioids or stimulants), and/or pain, in addition to other community-prioritized factors and health outcomes. Specific outcomes, both within and related to the required topic areas, and

how you define them should be driven by community input and priorities, as N CREW affirms that Native communities hold the deepest knowledge of what will effectively prevent and reduce opioid and drug overdose. The scientific justification can flow from the community-prioritization and can be documented in myriad ways, depending on preferences of the community, to include scientific literature, preliminary qualitative or quantitative work, and community knowledge.

35. Is a Tribal Resolution (TR) a required document for all tribal applicants, or is it only required under certain circumstances? If conditional, what specific situations or project characteristics would trigger the requirement for a Tribal Resolution?

A Tribal Resolution is not necessarily required for all tribal applicants. The tribe itself having a requirement for such a resolution for research on tribal lands is one situation that triggers this requirement. If the tribe lacks any specific policy, a tribal resolution may be required.

We understand that there is variation among Tribes in how they indicate approval for research. If the Tribe has established in its constitution the authority for the Executive (the Governor) to approve applications for funding opportunities via a *Tribal Authority Letter*, in lieu of a Tribal Resolution, then this would likely be sufficient for N CREW.

Please note that this letter is required at the *time of award*, not at the time of application, although it is helpful to include it with your application if possible. If we were to need any additional information prior to an award, we could seek it during negotiations after the review has taken place.

36. The ROA states there is no budget limit if the budget is well justified. While the recommended guidance is \$250-\$750k per year, it is also possible that some years might exceed this recommended amount. Is this ok?

Yes, exceeding the recommended annual cap of 750k is okay as long as it is well justified. Applicants should request the budget that is necessary for completing the proposed scientific aims. Please include a strong budget narrative. Per the ROA, all activities and associated costs will be negotiated prior to a potential award.

37. Can we pay for construction costs related to a research center? (i.e. are construction costs allowable if appropriately justified?)

The HEAL program does not have construction appropriation authority. Therefore, awarded funds cannot be utilized for construction.

38. A threshold of \$200k is mentioned in relation to the need to complete an NIH Evaluation of Financial Management Systems Questionnaire. Does this mean managing 200K annually?

Almost all applicants will be required to submit a NIH Evaluation of Financial Management Systems Questionnaire if the application is being considered for award. The application instructions require applicants to describe their organizational capacity and fiscal experience with managing program costs over \$200k or provide a proposed plan for managing the award if funded. The \$200k is based on annual program funding greater than \$200k.

Phase II Research Opportunity Announcements (ROAs): OTA-26-002 Native Research Resource Partners

39. What are examples of Ally Organizations?

Ally Organizations are defined as organizations that can document a track record of partnering successfully with Native American communities. To be eligible for OTA-26-002, Applicants must demonstrate significant experience working with T/NSOs. Applicants do not need to be a federally or state recognized Tribe or a Native 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

40. Are there more specific examples of the NRRP Key Functions? For example, a clearer example of the difference between Key Function 1 and Key Function 5?

Broadly speaking, *Key Function 1: NRRP and N CREW Network Coordination Management* is focused more on operational/administrative functions that facilitate the network running smoothly (i.e., day-to-day operations). It also includes governance across the NRRP sites. *Key Function 5: N CREW Network Vision and Collaboration* is focused on activities related to strategic vision for the entire N CREW Program and network and relationship building functions (e.g., shaping where the network is going and helping everyone work together effectively). Governance across the entire N CREW Program is included here.

We understand the activities across one or more Key Functions might overlap. This is fine. However, applications should clearly delineate proposed activities and how they relate to a Key Function.

Please note that NIH has identified these as key functions that seem necessary for the N CREW Program to operate optimally. However, we are looking for the best ideas from the field on how to best support the N CREW Program. You can propose your ideas on how these key functions would optimally work together. You can also propose other key functions that would be helpful.

41. The ROA mentions those who receive awards might need to create an integrated workplan and this may vary from what was proposed in the application. What does this look like? Do you encourage partnership while writing the proposal?

If you are selected to negotiate for an NRRP award, you might be asked to do work that is different from what you proposed in your application or to integrate the work that you proposed with the work of other NRRP sites. We anticipate that work across the NRRP sites will overlap, and sites will need to partner, and this creates a need for an integrated workplan with other NRRP sites, indicating who is doing what and how the work intersects.

It will also be important to re-evaluate workplans overtime to be sure all emergent N CREW Program needs are met. The plans or activities proposed in applications will serve as examples through which applications can be evaluated. However, final activities will be based on needs identified in T/NSO research applications, what is proposed by other NRRPs, and in real-time over the course of Phase II. NIH anticipates this will require ongoing close collaboration, including at least one NRRP Meeting per year where NRRP sites will advance the NRRP strategic vision, review and update the Integrated Workplan, and conduct other relevant business (see slide 15 in the ROA). Integrated Workplans must be finalized within the first quarter of the award period.

Applicants are encouraged to identify partners that provide them with the strongest expertise needed to carry out proposed Key Functions. With mutual consent of the applicant and NIH, successful recipients may be asked to establish partnerships with other entities.

42. Will the NRRP be responsible for collecting or managing data?

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

- Coordinating and gathering information across T/NSOs and sites, possibly generating summary data
- Initiating data collection activities at the request of T/NSOs or NIH
- Providing data management and sharing support to T/NSOs
- Coordinating any NIH/HEAL reporting requests and working with the HEAL Data Ecosystem (where appropriate and with permission from T/NSO 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.
- Potentially supporting T/NSO research development projects, which are smaller scale projects designed as a pathway for T/NSOs to engage in community led research and to enhance foundational skills to do so. NRRP organizations engaging in these projects may be responsible for assisting with human subjects research oversight for their projects, including IRB and through use of NIH's Human Subjects System for human subjects research.