

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

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Phase II Research Opportunity Announcements (ROAs): General Questions

N CREW and The HEAL Initiative

1. Can you provide more information on HEAL Research Focus Areas?

The N CREW Program is part of the NIH's Helping to End Addiction Long-term®, or HEAL, Initiative, which is a congressionally mandated program that supports research to address the national opioid overdose crisis and improve pain management.

The HEAL Initiative emphasizes a whole-person approach, recognizing that substance use, mental health, and pain, and overall wellness are all interconnected. It also recognizes that health is shaped by both individual experiences and community factors. For N CREW, funded projects must include a focus on overdose, substance use, or pain management. Projects may also address related topics, such as mental health or wellness as long as it is community-prioritized, align with the goals of the HEAL Initiative, and fit within the broad goals of the N CREW program.

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. If HEAL program requires overdose, 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.

4. 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.

5. 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 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.

6. 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.

7. 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.

Preparing your application

8. 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.

9. 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.

10. We would like advice on the preferred biosketch format, especially with the new NIH requirement for all key personnel to use SciENCv format. If not required, can we use the SciENCvform? Also, are there any other formats or rules, including the formats related to NIH platforms, that we should be aware of as we prepare to submit an application?

While requirements may change in the future, NIH Other Transactions applications are not currently 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. However, if they choose to do so, applicants are allowed to use the new SciENCv forms. Whatever format you choose to use, please note that documents describing the experience of key personnel should be part of the flat file that that you will upload for submission, added in the appendix.

Further instructions on the submission process can be found on slide 17 in the 001 ROA and slide 19 in the 002 ROA. Other resources you might find helpful include a [webinar](#) of a live demonstration on how to submit your

application and this [eRA Commons user guide](#). If you encounter any challenges in submitting your application, please contact the eRA Commons helpdesk. You can also email ncrew@nih.gov so that we are aware. We recommend you submit your application a few days in advance of the application deadline to allow time to troubleshoot potential system issues.

11. What does ‘Other Support’ refer to?

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. This includes a list of all active and pending research resources, whether paid or unpaid. NIH uses this to ensure there is no scientific, budgetary, or commitment overlap across awards. Please provide an [Other Support form](#) for all Key Personnel listed in the application, including the PI/MPIs and any other staff proposed to play a considerable leadership or scientific role. View [NIH’s Other Support website](#) for more information.

12. The Current and Pending (Other) Support Form linked in the ROAs 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 ROAs.

13. 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.

14. In regards to biosketches, who is considered key personnel? Would consultants be required to submit a biosketch?

Key personnel will include the PI (or MPIs) and any other staff proposed to play a considerable leadership or scientific role. Applicants propose who to include as key personnel for the application submission. NIH and selected organizations will negotiate the final list of Key Personnel prior to award.

15. 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.

16. Can an MPI serve on more than one N CREW application, or is this considered a conflict of interest?

There is no restriction on serving as MPI, T/NSO, or partner on more than one N CREW application. If multiple projects are awarded, potential conflicts of interest or overlap between projects will be addressed during negotiations to clearly define roles and relationships. Scientific, budgetary, and effort overlap are not permitted on awarded applications.

17. Are there any stipulations for PIs? (for example, are there any required educational/professional qualifications that PIs must possess?)

There are no specific educational or professional qualifications required of the PI/MPIs. The application should include a biosketch for each PI that summarizes their expertise and work with Native communities or Tribes. As part of the management, staffing, and partnership section, you will include a description of how the staffing structure you've proposed will allow you to accomplish all planned activities. Note that reviewers will rate the likelihood of accomplishing proposed activities considering the proposed key personnel, staffing structure, partnerships, and /or plans to hire.

18. Are hyperlinks allowed in the ROA applications?

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

19. Are evaluations funded under these ROAs?

Because NIH is congressionally mandated to support scientific research, it rarely funds evaluation-only projects unless they include research questions such as investigating the mechanism of action, or the why and how behind an outcome. If your primary goal is program evaluation, you will find a much better fit with agencies dedicated to public service delivery and program evaluation, such as SAMHSA, CDC, and HRSA.

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

We anticipate that a resolution from each tribe will be required at the time of award. However, if the Consortium has a unique arrangement, we can consider that prior to award. If you have questions specific to your application, feel free to reach out to us at ncrew@nih.gov.

21. How would you like the letters of support to appear in the proposal? For Phase I, we simply attached a single LOS at the end of the application. Should we do the same for the multiple letters we'll have for the Phase II application, or upload one separate file of combined letters?

Letters of Support should be included at the end of the one flat file uploaded to eRA Assist in accord with the instructions in the ROA. In addition to the single pdf submission, applicants will be required to enter the abstract and specific aims sections into specified fields within ASSIST.

22. Are there considerations we should be thinking about related to any language or wording in our submissions? Any additional comments around the review process?

Applicants should focus their application on the 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. Applicants should

refrain from incorporating language that is unclear or unrelated to the scientific concepts and should specify objective and measurable aspects for reducing opioid/drug overdose.

23. How does the application needs to plan for sharing data collected and is there a Data Coordinated Center already in place to manage and assist?

Applicants are required to submit a Data Management and Sharing Plan and 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 (NOT-OD-22-214). However, HEAL supports a Data Ecosystem, and recipients must, at a minimum, register their study/project, to include the title and a description of the study - not the actual study data - and should consider other ways they might engage with the ecosystem. There is not currently a Data Coordinated Center.

If a recipient would like assistance considering data sharing benefits and challenges, the NRRP can provide support to recipients. We anticipate this an ongoing conversation across N CREW Phase II.

24. NIH recently released a new format for the data management and sharing plan attachment effect for NIH applications 5/26/26. Should we use that or the old version for this submission?

We recommend you use the updated version "2026 Pilot DMS Plan format page" linked here: [Data Management and Sharing Plan Format Page | Grants & Funding](#). The new version was designed to minimize applicant burden.

25. Are applicants required to prepare and submit the NIH Human Subjects Table? What if all our participants will be recruited from Tribal/Native groups and communities and it is not appropriate to include persons from different races and ethnicities?

For the application, you do not need to submit the full Human Subjects table. You should include whatever information you have available at the time of submission. The focus of N CREW is to fund Tribes and Native American Serving Organizations (T/NSOs) to address opioid/drug overdose, substance use, pain, and related factors such as mental health.

Prior to award if your project is selected for funding and involves active, non-exempt human subjects research from the outset, you will need to complete the Human Subjects Table using the designated OMB categories. If you anticipate conducting research involving human subjects but cannot describe the study at the time of application (i.e., [your study is a delayed onset human subject study](#)), complete the [Delayed Onset Study Record](#), listing the title of the study and the justification for the omission of the human subjects study information. Multiple delayed onset studies may be uploaded in a single record/justification attachment /(clinical trial or not).

26. Is the full Human Subjects Table required if all of our participants will be recruited from Tribal/Native groups and communities?

For the application, you do not need to submit the full Human Subjects table. You should include whatever information you have available at the time of submission. The focus of N CREW is to fund Tribes and Native American Serving Organizations (T/NSOs) to address opioid/drug overdose, substance use, pain, and related factors such as mental health.

Prior to award if your project is selected for funding and involves active, non-exempt human subjects research from the outset, you will need to complete the Human Subjects Table using the designated OMB categories. If you anticipate conducting research involving human subjects but cannot describe the study at the time of application (i.e., your study is a delayed onset human subject study), complete the Delayed Onset Study Record, listing the title of the study and the justification for the omission of the human subjects study information. Multiple delayed onset studies may be uploaded in a single record/justification attachment /(clinical trial or not).

27. Do we need to submit an organizational chart with the application?

There is no requirement to submit an organizational chart as part of your N CREW application.

28. Is it possible for the same organization to submit two applications under the same lead PI?

It is allowable for one organization to submit two applications, if there is no scientific overlap across the applications. If there are any similarities/overlap in the proposed work, they cannot be submitted as two separate proposals. An individual PI is limited to a maximum of six NIH applications per calendar year (per NOT-OD-25-132).

While submitting two applications is allowed, note that it is uncommon for NIH to provide two OT awards to the same organization under a specific Research Opportunity Announcement. If two applications are submitted and both are selected for negotiations and possible funding, NIH maintains the right to combine or reorganize applications as part of a consolidated consortium operating under an article of collaboration, teaming arrangement, or other agreed upon means prior to award.

29. Do all of the MOUs need to be finalized and signed as part of the application, or can they be executed after the funding announcement is made? If we include letters of support as appendices with our application, would that be sufficient at this stage?

There is no requirement to submit signed MOUs as part of the application. NIH will select a subset of applicants with whom to negotiate, and during this negotiation period NIH may request MOUs be signed prior to an award.

Letters of support that strengthen the application are encouraged.

Budget

30. How should we interpret the milestone-based budget requirements? Is there an example to reference for clarity?

The milestone-based budget table will look similar to this table provided on page 22 of [OTA-26-001](#). The table will not include the specific aims, but rather you will draft 1 high-level, measurable milestone that is linked to each of your specific aims. The milestones should reflect major benchmarks toward completing each aim. If helpful, you can think about it in these steps (using year 01 as an example):

Step 1: Define Your Research Milestones for Year 01

- Based on your aims for Year 01, consider the high-level indicators that will demonstrate progress toward each aim within the first year.
 - For example, if Aim 1 is to implement a study testing the efficacy of an opioid prevention program, an associated Year 1 milestone for Aim 1 might be to complete all study pre-launch activities (e.g., hire and train staff, select measurement instruments, etc.)
- This milestone-based budget table is created annually, so in this example the Year 01 should reflect major benchmarks towards completing each aim in year 01.
- Ensure the milestones are objective and clearly define what constitutes successful completion.

Step 2: Assign Costs to Each Milestone

- Allocate specific dollar values to each payable milestone rather than standard line-item costs.
- If the aims have similar costs, this could be the total cost of the award split between the aims. If certain aims have higher associated costs, this would be reflected in the table by estimating higher costs for those aims.
- The costs are estimates – just be as accurate as you can based on what you know at application.

Step 3: Format by Quarter

- Organize these milestone costs into a quarterly timeline for Year 01.
- Again, this is based on your best estimate

Note that the Year 01 milestone-based budget table is most important. Although the ROA requests a draft milestone-based budget for each project year, recipients will negotiate their budgets annually in accord with their progress and aims.

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

Yes, please include direct AND indirect costs.

32. 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.

33. 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.

34. Can you provide guidance on indirect costs?

Applicants should apply the correct F&A rate consistent with their current negotiated indirect cost rate agreement in the total costs and the total award amount. If the applicant does not have an approved facilities and administrative costs rate agreement, they may propose the 10% de minimus rate.

35. Do we need to create our own budget document?

Yes, each applicant may develop their own budget document that best allows them to represent and justify their budgetary needs. Please note that both ROAs require a milestone-based budget plan.

36. Can Cost of Living Allowance be included in the calculation of salary?

Applications will be awarded and negotiated on an annual basis therefore only actual salaries should be requested in the application and post-award budget submissions.

37. Are staffing costs or the addition of new staff considered allowable expenses under these ROAs?

For both ROAs, N CREW applications may certainly propose to pay new and current staff effort (commensurate with their work and experience) as long as those efforts are clearly delineated and dedicated to the N CREW project. If new staff are not yet hired, they may be indicated as To Be Determined, with a description of the expected duties and role.

Submitting your application

38. 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.

39. My organization wants to apply but is not registered in eRA Commons yet. Is it too late?

No! It is not too late. Please register your organization in eRA Commons as soon as possible. It can take 2 weeks or longer to complete registration, which must be completed before you can submit your application in ASSIST. The [eRA Commons webinar](#) recording on the N CREW website is a great resource for registering and submitting applications. You can also reach out to the [eRA Commons helpdesk](#).

40. Can the Signing Official and the PI be the same person?

It is strongly recommended that two different people hold the roles of PI and SO to ensure proper administrative oversight. However, if one person serves both roles, it is important to remember that the recipient organization is the awardee, not the PI.

If the same individual must serve both roles, recent system enhancements no longer require a separate set of credentials (e.g., username, email, passwords). eRA Commons will now allow you to merge credentials into a single username and password. Once logged in, you can toggle between your SO and PI profiles. When submitting an application, please ensure the SO account is selected, as PI accounts do not have submission authority.

This [website](#) provides helpful information on account roles in eRA Commons and how to register.

41. The eRA commons registration is for the organization correct? I myself am already registered in eRA commons for other grant work/reviews.

Yes, the eRA commons registration is for the applicant organization.

42. Who can I reach out to for help with eRA or ASSIST?

If you are having technical difficulties, email or call the [eRA Commons Service Desk](#). In your correspondence, be sure to clearly identify you are an Other Transactions Authority (OTA) applicant and specify with ROA you are applying to -- OTA-26-001 **or** OTA-26-002.

If you would like assistance more generally on how to use the system, we strongly encourage you to watch the recording of the [webinar](#) of the live demonstration on how to submit your application. The step-by-step instructions on how to use eRA Commons and ASSIST is also a helpful resource.

If you need immediate help (i.e., you are within two days of the deadline), [call](#) the Service Desk. If you are unable to get help from the Service Desk, email NCREW@nih.gov.

After submitting your application

43. Will reviewers be internal to NIH, NIDA, N CREW or external? Will the 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. More information about Objective Review is available on page 24 of the [OTA-26-001 Research Opportunity Announcement](#).

44. Can you please talk more about the review process given no written feedback will be given?

Applications will be reviewed through an objective review process by federal and external subject matter experts with expertise in areas of science relevant to the applications received. Upon request by applicants not selected for negotiation, NIH staff may be able to meet by phone with applicants to discuss review. Applicants selected for negotiations will have an opportunity to address any issues or concerns raised in review. For more information regarding the review process please refer to the Research Opportunity Announcements.

45. What does the negotiations process look like?

Unlike traditional grants, Other Transaction Awards are more dynamic and changes can be negotiated to projects and project budgets between NIH and the applicant. After review, some applicants will be selected for further consideration and negotiation before an initial award is made. For sites that receive awards, negotiations will continue to occur annually. Negotiations support achieving alignment on the planned activities including the science, the partnership structures, and the budgets before any funds are released. These negotiations are one way that OTA facilitates agility. The negotiation process is anticipated to be highly collaborative. The negotiations process includes:

- A tailored 'Just-in-Time' process. You'll receive what we call a "Just in Time" request with specific questions unique to your project. This is our

chance to clarify anything that wasn't fully clear in your application or to address feedback that came up during the review. You will be asked to respond to the Just In Time Request in writing.

- Negotiation calls. These conversations are a chance for us to work side-by-side to make sure the scientific plans, budgets, and partnerships are fully aligned and set up to support your community's goals while adhering to NIH policies and requirements. We can also go through the Just In Time request together to discuss any questions or share viewpoints.

There might also be other kinds of communication activities with applicants, determined on a case-by-case basis. For example, NIH may request a site visit to help us address questions.

Please note that the Just In Time request, and all official communications, will always go directly to your organization's Signing Official and the Contact PI only. However, your team is welcome to invite any key partners or team members you want to participate in negotiation conversations.

46. How will awards be selected for funding?

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

If a limited number of responsive applications are received and/or there are significant gaps in the research areas proposed, NIH may determine a need to invite additional organizations to submit an application for consideration after the posted due date. Invited applications will undergo an internal review process based on the criteria specified above.

47. How concerned should we be about the grant being shutdown mid-project due to changing priorities of the administration?

HHS has renewed the public health emergency declaration to address the national opioid crisis as recently as June 4, 2026. All individual projects require NIH prior approval. NIH reviews projects for priority alignment prior to approval.

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

Institution and staff eligibility

48. 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.

49. 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.

50. 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.

51. 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.

52. Does a PI need a terminal degree?

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.

53. 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.

54. Are MPIs allowed on the OTA-26-001 and if yes, do both need to be part of a T/NSO? The co-PI of the prime award is a NSO but the other co-PI is at an academic institution whose core mission is not to serve Native Americans.

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.

Program structure, application options, and timeline

55. 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.

56. What will be expected collaborations across T/NSOs look like? For example, in-person meetings, virtual meetings? And in what frequency?

The N CREW Program is designed as a highly collaborative, co-constructed program with active partnerships that will evolve as T/NSOs advance on their project aims. In Phase II, Tribes and Native Serving Organizations remain at the center of a cooperative network that includes T/NSOs, Native Research Resource Partners and NIH staff, all working together to support community-prioritized research and achieve N CREW Program goals.

This collaboration includes in-person and virtual meetings to share updates, hold program relevant discussions, advance on goals, build relationships, and learn from one another. There will also be many other opportunities to collaborate through workgroups and Special Interest groups focused on specific topical or technical areas, webinars, publications, network evaluation activities, and other collaborative efforts that emerge based on community and program needs.

The frequency of these collaboration activities will vary. For example, the in-person teaming meetings are held twice per year, with up to two virtual teaming meetings annually. Workgroup and Special Interest Groups might meet monthly or more frequently as needed. Sites will meet with NIH staff typically at least two times a month. While each T/NSO will remain focused on advancing its own community-prioritized research project, there will be many opportunities to collaborate across the Network, and we encourage T/NSOs to engage in those activities whenever they align with their interests and project goals.

57. 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.

58. 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.

59. For ROA OTA-26-001, can Option A, or the planning period, be used for capacity building, as well? For example, for building out data dashboards, bolstering IRBs, administrative aspects, and any other priorities communities have for capacity building?

Yes. Developing or advancing research capacity and infrastructure are important goals for both Option A and Option B, though more of these activities may be needed in a planning period. However, all activities must relate to capacity and infrastructure needed specifically to conduct research to address overdose with a focus on pain or substance use. And just as a reminder, for Option A, applications should describe how they will be ready to launch a research study by year 2 or 3.

60. 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.

61. 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.

62. For ROA OTA-26-001, are projects that use the 2-year planning option more or less likely to be funded?

All applications will be reviewed based on their individual merit referencing the criteria identified in the ROA. N CREW Phase I recipients applying under Option A should provide strong justification for additional planning time.

63. Does NIH have a preferred outline with subheadings for planning grants?

You can select the headings that make the most sense for your proposal. For applications to Option A, please include the content outlined on page 19 of the [ROA](#):

- 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 HEAL Initiative research focus area(s) the project will address.
- Applicants must 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.

64. 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.

65. Is the current OTA-26-001 the only funding opportunity of its type or will there be another one in the future?

As of now, ROA OTA-26-001 is the only N CREW ROA issued that focuses on Tribes and Native Serving Organizations. NIH has other funding mechanisms that seek to directly fund Tribes. If you are interested in learning about these, please email us.

66. 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.

Research scope and compliance

67. Can youth be involved in research?

Yes, youth can be involved in research under ROA OTA-26-001. Please ensure that all necessary human subjects protections are considered, including appropriate parental or guardian consent (with consideration of active versus passive), as you build out the research study and associated protocols. You can learn more about Human Subjects Research and associated requirements [here](#).

68. If we're planning to use community based participatory research for at least part of the project how flexible is the award to changes in the study or studies?

Unlike traditional grants, Other Transactions Authority allows the NIH to negotiate directly with Tribes and Native Serving Organizations (T/NSOs) to alter research projects in real-time, adapting to community priorities. See [question 7](#) for more information about Other Transactions.

69. 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.

70. “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.

71. Are multiple small studies acceptable? For instance, needs assessments and then a prevention study from there? Are primary prevention studies likely to be funded or are clinical trials more desirable or similar studies? What about training studies?

The Research Opportunity Announcement OTA-26-001 allows for a phased approach by applying under Option A, which funds up to two years of planning and development (which can include needs assessments) followed by three years of implementing a research project.

The N CREW Program supports T/NSOs to conduct locally prioritized research to address overdose, substance use, and pain, including related factors (e.g., mental health, wellness, resilience). The study should be designed to provide robust evidence to address identified research questions and should reflect community priorities. Clinical trials may be appropriate, but other designs and approaches could be acceptable, depending on the context. . The review criteria (discussed on pages 24 – 28) provide information on how applications will be reviewed. If you receive an award in Phase II for a clinical trial, there will be additional regulatory requirements. Learn more about clinical trials at NIH [here](#).

Training studies may be appropriate, if they are designed to specifically address overdose, substance use, and pain, including related factors (e.g., mental health, wellness, resilience).

72. Can youth be involved in research?

Yes, youth may be involved in research with appropriate parental or guardian consent (with consideration of active versus passive).

73. 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.

74. Do T/NSOs have to have their own IRBs or external IRBs be used?

No, T/NSOs do not need to have their own IRB. You can partner with an external IRB, including an academic partner's IRB, an Indian Health Service Area IRB, or a commercial IRB. Keep in mind some tribes have their own specific requirements, codes, or resolutions about what IRBs must be used for research involving their community members or lands. Any alternative IRB agreements will need to be discussed with NIH. If the IRB determines that your human subjects in non-exempt, a valid Federalwide Assurance, or FWA, is required. You can learn more about FWA [here](#).

75. Are there additional forms that must be filled out if a project is not applying as 'non-exempt' for human subjects research?

Please refer [to page 14 of the ROA](#) for a list of requirements and we provide more detail below.

The following documentation can be submitted as part of your application, but if not, must be submitted during negotiations or prior to the start of human subjects data collection:

- Obtain a [Federal Wide Assurance \(FWA\)](#) from the DHHS Office for Human Research Protections (OHRP; note FWA only required for non-exempt clinical research). If your organization has an FWA, provide it in your application.
- Submit a copy of the IRB approval to NIH. If your organization is relying on another organization's IRB, provide a countersigned reliance agreement.
- Provide documentation that all personnel and partners engaging in human subjects research have completed Human Subjects Education Certified Training, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," found here: (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>).
- Provide planned enrollment reports in the [Human Subjects System](#). This means you will provide the # of participants you plan to recruit by sex, race/ethnicity, and age - NIH will monitor progress made toward recruiting that number.
- Comply with [45 CFR 46](#)
- 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.

Budget

76. 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.

77. 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.

78. 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

Institution and staff eligibility

79. 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

80. Can a university apply to ROA OTA-26-002 to support a research project in partnership with a Tribe, if the research project is identified as a priority for the Tribe?

OTA-26-002 does not invite applications from universities as the applicant organization to conduct an already identified research project with a Tribe. NIH has other funding mechanisms that invite this type of application. This ROA invites Ally Organizations and T/NSOs to apply to serve as Resource Partners, supporting the successful applicants of ROA OTA 26-001 and advancing the overall N CREW Network and Program. The ROA does allow applicants to propose Key Functions other than those identified. It is possible that this could include establishing ways to fund T/NSO research development projects that enhance T/NSO research capacity and support T/NSOs to engage in innovative research as a pathway for the T/NSO to successfully receive funding directly from NIH in the future. However, in this case it must be clear that the applicant is centering T/NSOs and their leadership of research and providing support for the T/NSO to advance on a pathway to directly receiving funding.

If the Tribe would like to apply for funding to conduct their research project, they can apply under ROA OTA-26-001. They are welcome to apply with University faculty or staff as a partner.

For community based participatory research projects where the university holds the funding, you may consider NOFOs such as Intervention Research to Improve Native American Health or NOFOs supporting traditional NIH mechanisms.

81. For ROA OTA-26-002, do subject matter experts need to be included in the application or can the application include a core team that would think about and could propose mentors or partners in the future as need emerges?

Reviewers are asked to evaluate the feasibility of the proposed projects and the expertise of the proposed team. Applicants may not have to detail all involved personnel in the application, but they must provide sufficient information for the reviewers to evaluate according to the review criteria. The NRRP likely needs a more flexible staffing structure to have the ability to meet emerging needs. Thus, while applicants may not need to propose all staff in their application, it will be helpful to understand the staffing plan and its flexibility to address emerging needs.

Research scope and key functions

82. 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?

Yes, the workplan may vary from what is initially proposed in your application. The foundational benefit of the N-CREW program is its ability to make needed changes in real time and co-constructed design. This provides the necessary flexibility to meet T/NSOs where they are on the research readiness continuum and allows awardees to pivot as circumstances and community needs arise and change.

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 to avoid duplication of effort while also ensuring all program needs are addressed comprehensively.

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. You can look at rePORTER to learn about who is funded as an NRRP for Phase I and what kinds of activities they proposed.

83. 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 and through use of NIH's Human Subjects System for human subjects research.

84. In Objective Review Criterion 2, on page 30 of ROA OTA-26-002, one of the guiding assessment questions asks 'How likely is it that the applicant will be able to provide the proposed scientific subject matter expertise in substance use and/or pain research, or other critical areas of expertise, as well as research and data resources to support and/or contribute to research projects?' Who defines what is an 'other critical area of expertise'?

Since N CREW is funded through the HEAL Initiative, there must be expertise in substance use and/or pain. Other critical expertise is driven by the proposed project and activities. In their proposals, applicants should clearly indicate what the subject matter expertise requirements are for their specific project and how they plan to meet them.

85. Do the resources created by the Native Research Resource Partners need to be tribe specific?

No. Resources created by the NRRP do not need to be tribe specific. NIH will prioritize resources with the broadest utility – including resources generalizable to multiple T/NSOs or resources developed or designated for one T/NSO but adapted for others. NIH expects all T/NSO specific resources to be developed in partnership with the T/NSO.

86. Are there any gaps in the NRRPs in Phase I right now that NIH hopes can be filled in Phase II?

ROA OTA 26-002 indicates the key functions that NIH anticipates will be needed in Phase II, also indicating that applicants may propose other functions that they believe would be helpful to achieve NRRP goals. Keep in mind that the needs of the NRRP are partially based on the funded T/NSOS, and it is currently unknown who will be funded in Phase II. Thus, having some agility to augment expertise as needs are identified will be helpful. Some examples of common needs and challenges across programs that support organizations to develop research capacity and infrastructure as well as conduct research for possibly the first time include addressing staffing (including turnover), developing and advancing a research study, award management (including budgeting), holding and analyzing data, finding partners to provide needed expertise for research projects, and sustaining research activities.

87. 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?

One helpful way to think about this is that Key Function 1 (coordination) is focused on how the network runs operationally. That is somewhat different from Key Function 5 (collaboration), which is more focused on the broader shared vision, partnerships, and collaboration across the network.

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.

88. Will pilot, feasibility, or other developmental research projects be permitted under this ROA?

The purpose of ROA OTA-26-002 is to invite Ally Organizations and T/NSOs to apply to serve as Resource Partners, supporting the successful applicants of ROA OTA 26-001 and advancing the overall N CREW Network and Program. The ROA does allow applicants to propose Key Functions other than those identified, and it is possible that this could include establishing ways to fund T/NSO research development projects (e.g., feasibility or pilot projects). In this case –

- It must be clear that the applicant is centering T/NSOs and their leadership of research and providing support for the T/NSO to enhance research capacity and engage in innovative research as a pathway for the T/NSO to build their own research infrastructure and, for example, successfully receive funding directly from NIH in the future.
- All proposed projects must focus on overdose, substance use (including opioids or stimulants), or pain.

Per page 21 of the ROA, in the planned activities section you will describe how the pilot/feasibility projects will align with and advance N CREW program goals.

Of note, final activities performed by NRRPs will be determined by the needs identified in the T/NSO research applications (via ROA OT-26-001), other NRRP applications, and in real-time over the life of the N CREW Program, in collaboration with NIH. Other Transactions Awards require negotiations on project parameters prior to award. NIH maintains the right to award applications as proposed or negotiate awards to modify milestones, activities, budgets, or include/exclude certain components.

Budget

89. Is the recommended budget annual range of \$400K-\$2.5M per year in direct cost include subaward indirect costs or is it excluded? Do you allow second tier subawards? For example, if we include a subaward to an institution, are they allowed to issue a subaward to another institution?

Subaward indirect costs are excluded from the recommended annual range per year for direct costs. Second tier subawards are generally not permitted. However, NIH will review each proposal on a case-by-case basis taking into consideration the justifiable need for a second tier subaward.