



**N CREW Program Webinar:
Brief Overview and Instructions for Using eRA
Commons and ASSIST
Webinar | August 30, 2023**

LAND ACKNOWLEDGEMENT

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

Webinar Housekeeping Items

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

Agenda

TOPIC
N CREW Overview
N CREW Research Opportunity Announcements (ROAs)
ROA OTA-23-007 Tribes and Native American Serving Organizations (T/NASOs)
ROA OTA-23-008 Native Research Resource Network (NRRN)
Milestones
Key Dates
Application Components
eRA Commons and ASSIST
Overview
eRA Commons Demo
ASSIST Demo
Wrap Up
Questions and Answers

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

N CREW Program Resources

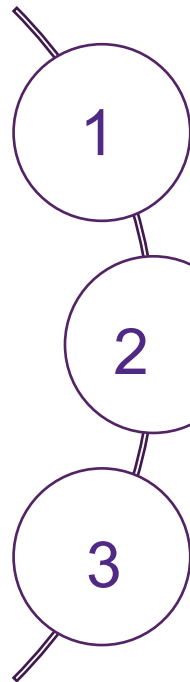
- NIH held a **webinar** on July 28 to share information on the [N CREW Program](#), associated research opportunity announcements, and answer questions
 - [Recording](#) is available on the N CREW website
 - Visit the [Questions and Answers](#) on the N CREW website
- **ROA OTA-23-007**: *Tribes and Native American Serving Organizations (T/NASOs) N CREW Research & Data Projects*
- **ROA OTA-23-008**: *N CREW Native Research Resource Network (NRRN)*

N CREW is part of the NIH HEAL Initiative

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

N CREW Program Goals

*The N CREW Program—**created in direct response to themes identified in Tribal Consultation**— supports Tribes and Native American Serving Organizations T/NASOs to conduct locally prioritized research to address overdose, substance use, and pain, including related factors such as mental health and wellness*

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1 Support T/NASOs to lead community prioritized research projects, including research elevating and integrating Indigenous Knowledge and culture.
- 2 Enhance capacity within T/NASOs to conduct locally prioritized research, by developing and providing novel, accessible, culturally grounded technical assistance and training, resources, and tools.
- 3 Improve access to and the quality of data on substance use, pain, and related health and wellbeing factors to maximize their potential use for use in local decision making.

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

Key Definitions

- Tribes and Native American Serving Organizations are federally or state recognized Tribes or organizations with **a core mission to serve and/or a track record** in serving Native Americans and that are poised to reach this population.
- Native Americans (as defined for this Program) are American Indians, Alaska Natives, or Native Hawaiians.
- Ally Organizations are organizations with the **ability to document a track record of partnering successfully** with Native American communities

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

Phase II will build on Phase I and priorities, potential opportunities and associated activities to be announced at later date

ROA OTA-23-007

**Tribes and Native American Serving
Organizations (T/NASOs)
N CREW Research & Data Projects**

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

- Solicits Phase I applications from T/NASOs to:
 - Develop, plan or implement **research studies**
 - **Improve data** (e.g., access, quality, availability)
 - **Enhance capacity** to engage in research
- Projects **must explicitly** include a focus on overdose, substance use (including opioids or stimulants), **OR** pain management.
 - Supports inclusion of related factors (e.g., wellness, mental illness, alcohol use)
- What will **NOT** be funded:
 - Direct services in the absence of a research or research capacity component
 - Capacity building that is not focused on HEAL related research/data projects
 - Projects that do not include a focus on topics or outcomes related to the HEAL Initiative

Encouraged Activities and Priority Consideration

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

Applicants are encouraged to

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

Priority consideration will be given to

- Applicants who document a commitment to advance their research capacity to participate in future NIH research
- Meritorious applicants who have not previously applied for or received NIH funding

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

N CREW NRRN - ROA OTA-23-008 – Goals

- Solicits applications from T/NASOs and/or Ally Organizations to participate in a Phase I (2 years) multi-component and agile NRRN working responsively and collaboratively to:
 - Develop and provide comprehensive, **real-time resources and support** to T/NASOs
 - **Identify effective strategies and approaches for supporting T/NASOs** as they develop and conduct HEAL related research and/or data improvement projects
 - Identify and implement activities to **maximize investments and facilitate long term sustainability** of research/data gains made by T/NASOs
- In Phase I the NRRN is structured to:
 - Provide a broad range of research support that cannot be fully predicted in advance
 - Be agile and allow for flexibility in modifying activities, partners, or formal partnership structures

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

Technical Assistance Areas

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

Partnership Development

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

Other Categories

- As proposed by applicants

Coordination & Reporting

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

Spur Innovation & Accelerate Progress

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

Milestones

Milestones for OTA –23-007 & OTA-23-008

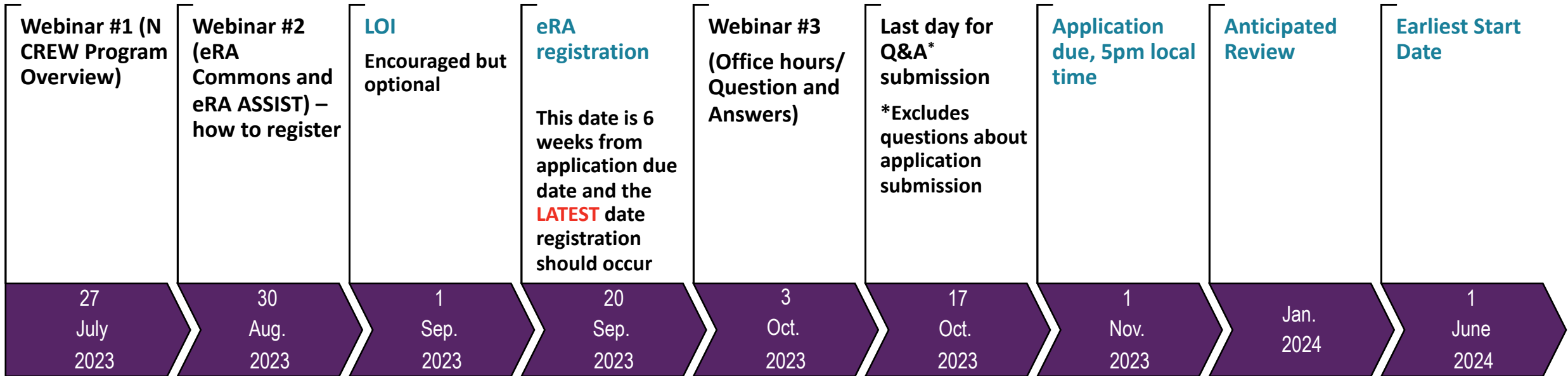
- Applicants must submit a set of draft milestones, and final milestones will be negotiated.
- Milestones should be measurable and indicate progress and/or completion of each proposed task with timelines.

Milestone Examples

- Example 1:
 - Poorly Defined: Collaborate with partners
 - Well-Defined: Attend 4 Teaming or Partnership Development Meetings within the first 12 months
- Example 2:
 - Poorly Defined: Decide how to build research capacity
 - Well-Defined: 1. Engage 7-15 community members in bi-monthly meetings to develop research capacity objectives. 2 Submit research capacity objectives within the first 12 months.

Key Dates

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



Application Components

Application Components

- All applications require multiple components
- Details about each component can be found in the “Developing Applications” section of the ROAs
- Components not discussed in this webinar were discussed in webinar 1 (see recording)

Component
1. Title Page
2. Abstract
3. Specific Aims
4. Planned Activities, Approaches, and Key Personnel
5. Data Management and Sharing Plan
6. Budget
7. Fiscal Management Plan
8. T/NASO Documentation (<u>only</u> for ROA OTA-23-007)
9. Letters of Support (As Relevant)

Letter of Intent (Optional)

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

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

Application Budget Reminders OTA 23-007

- **There are no required budget forms or templates for the application.**
- Proposed budgets must provide a realistic and well-justified cost proposal for performing the proposed work over a period of **up to 2 years**.
 - Budgets for individual awards are expected to vary, depending on the proposed activities and resources. NIH anticipates annual total budgets will range from \$200,000 to \$550,000 depending on the proposed activities and resources, **but there is no annual budget limit.**
 - **The budget must reflect the needs of the proposed work.**
- If applying with a consortium or partners, please provide a detailed budget for each year **and** for each consortium/partner.

Application Budget Reminders OTA 23-008

- **There are no required budget forms or templates for the application.**
- Proposed budgets must provide a realistic and well-justified cost proposal for performing the proposed work over a period of **up to 2 years**.
 - Budgets for individual awards are expected to vary, depending on the proposed activities and resources. NIH anticipates annual total budgets will range from \$500,000 to \$1,300,000 depending on the proposed activities and resources, but there is **no annual budget limit**.
 - **The budget must reflect the needs of the proposed work.**
- If applying with a consortium or partners, please provide a detailed budget for each year **and** for each consortium/partner.

Application Budget Reminders Both ROAs

- Please provide the overall expected cost for each category: (e.g. personnel, travel, subawards/subcontracts, materials and supplies, other direct costs, and total costs (with indirect costs included). Provide a budget justification for all budget items for all years of the project.
- If applicable, subawards/subcontracts/consultants must provide details of cost breakdown per annum.
- F&A (indirect) costs – if an applicant has an approved facilities and administrative costs rate agreement with the federal government, the approved rate should be reflected in the budget request. **If the applicant does not have an approved facilities and administrative costs rate agreement, they may propose a rate for NIH review and consideration.**
- Total cost (with indirect costs included)

Budget Justification Narrative – Both ROAs

- All applications are encouraged to include a detailed budget **and** narrative that explains the expenditures broken out by the cost categories.
 - e.g. Personnel, Travel, Equipment, Software, Supplies, Other costs such as subject incentive payments, data management costs
- The budget narrative should match the costs identified in the table/excel sheet. If applicable, each Subaward should also have its own budget breakdown and narrative.

Sample Only: Detailed Budget for Initial Budget Period

12 Month Budget Period From June 1, 2024 – May 31, 2025

Name	Description	Cal Months	Salary Requested	Fringe Benefits	TOTAL
K. Etz	Principal Investigator	3.6	\$27,777	\$8,333	\$36,110
TBN	Research Assistant	12	\$55,000	\$14,482	\$69,482
TBN	Behavioral Health & Cultural Lead	12	\$60,000	\$16,251	\$76,251
Materials and Supplies	Software, Hardware, Electronic Supplies	N/A			\$4,500
Travel	4 in person Teaming meetings required by FOA				\$12,000
Publications	Open Access				\$4,000
Research Participant Payment Incentive					\$15,000
Training	Training to recruit individuals to complete surveys and/or participate in interviews and focus groups				\$10,000

Sample Only: Detailed Budget for Initial Budget Period

12 Month Budget Period From June 1, 2024 – May 31, 2025

Name	Description	Cal Months	Salary Requested	Fringe Benefits	TOTAL
Consortium Costs (Direct & Indirect)	Separate Detailed budget included				\$150,000
Subtotal Direct Costs					\$377,343
Indirect Costs @ 10% * IDC base of \$227,343	If the applicant does not have an approved facilities and administrative costs rate agreement, they may propose a rate for NIH review and consideration.				\$22,734
TOTAL COSTS					\$400,077

How to Submit an Application

- Applications for Other Transactions are required to be submitted through the [Application Submission System & Interface for Submission Tracking \(ASSIST\)](#).
- Resource for Other Transactions Authority (OTA) users of ASSIST
 - This step-by-step instruction guide, together with the forms and information found in the research opportunity announcement (ROA), should be used to prepare and submit OT applications using ASSIST.
 - [Instruction Guide for OTA Submissions via ASSIST](#)

Prepare to Apply

- Prior to submission, the Principal Investigator and their organization must be registered in [eRA Commons](#).^{*} Please select the “[Register Organization](#)” link for more details.
- Required eRA Common Roles to Submit Application
 - Principal Investigator (PI) & Signing Official (SO)**
- **It is desirable**, though not required, that other key personnel/whole applicant team are also registered in eRA Commons.
- If an application is awarded, additional registrations (e.g. [System Award Management](#)) will be required
- OT applications must be submitted through [NIH's ASSIST](#), Users can access ASSIST directly or through eRA Commons
- To complete the application, users must have access to a browser, a pdf generator, and Adobe Reader Software. There should be 4 components to the completed application: a core form page, the abstract, aims, and one pdf attachment
- Ensure all information is directly visible in your PDF.
 - If you need to combine information from different sources into a single document prior to uploading, **do not use “bundling” or “portfolio” features** which combine multiple documents into a single file by providing links to the individual files.

**Note that registration in eRA Commons may take up to two-four (2-4) weeks of more to complete-please start early*

OTA Applications – Registration and Submission

- Specific instructions in ROAs: [ROA OTA-23-007](#) and [ROA OTA-23-008](#)
- Registration and application submission assistance are available from the [eRA Service Desk](#).
- Should anyone have technical assistance questions about their registration or application, please reach out to the eRA Service Desk by submitting a [web ticket](#) or calling them at:

Toll-free: 1-866-504-9552 (Press 1 for eRA Commons or ASSIST)

Phone: 301-402-7469 (Press 1 for eRA Commons or ASSIST)

- Should anyone reach out to the Service Desk, please indicate that you are requesting assistance for an Other Transactions application for OTA-23-007 or OTA-23-008, so it is clear from the beginning of the request.
- If issues persist after you have reached out to the eRA Service Desk, please reach out to NCREW@nih.gov.
- For any questions regarding your application content, please reach out to NCREW@nih.gov

eRA Commons and ASSIST: Overview and Demo

Agenda

- Organizations need to be registered in eRA Commons- a streamline process is available that does not require a UEI
- Must have individuals registered with the role of signing official (SO administrator, signing authority) and Principal Investigator/Program Director (PD/PI- scientific role)
- Accessing ASSIST (Application Submission System and Interface for Submission Tracking)
- Completing application
- Submitting application
- Tracking application

DEMO

Take Home Messages

- Your organization must register in [eRA Commons](#)- there is a streamlined OTA registration that does **NOT** require a UEI
- The person who registers the organization will have the role of Signing Official (SO). They will need a username and password
- The SO must affiliate at least one person with the role of Principal Investigator. Other individuals can be affiliated as needed. To access ASSIST, a user must have Commons credentials. They will need a username and password. If one person is serving both roles, they will need 2 separate sets of credentials

- Carefully **READ** through the funding announcements (more than once). The sections of the application should be combined and uploaded as one attachment, titled TNASO_PI_Last Name_ Org Name.pdf.
 - Each filename **MUST be unique and 50 characters or less.**
- In addition to the single pdf submission, applicants will be required to enter the abstract and specific aims sections into specified fields within ASSIST.
- Someone with eRA Commons credentials needs to log into [ASSIST](#) to initiate the application. Once they have logged in, the announcement number must be entered into the field in the following format OTA-xx-xxx

- On the landing page, the organization data will be pre-populated. The user is required to enter a project title (can be edited later) and has the option of entering information about the PD/PI.
- Summary tab: NOTE: each application is assigned a unique identifier (application identifier) you want to write that number down so you can come back to the application if you need to work on in over several sessions.
- Click on the CORE tab to begin the application
- ASSIST supports multiple users. When the “edit” button is clicked the form is only accessible to that user. Save and release makes the form available to other users.

- On the lefthand navigation panel the Optional form tab allows the Human Subjects Clinical Trials (HSCT) form to be included in the application. Check your application instructions to determine if this form will be required
- Any field marked by a * must be completed.
- Ensure all information is directly visible in your PDF.
 - If you need to combine information from different sources into a single document prior to uploading, **do not use “bundling” or “portfolio” features** which combine multiple documents into a single file by providing links to the individual files.

- It is recommended that the user completes and saves the Core form, completes and saves the PD/PI information and then completes the HSCT form as directed.
- If you don't have an EIN number, enter 12 ones (111111111111)
- **PDFs required by the FORM** are to be attached at the specific field names (e.g. Abstract and Specific Aims). These will be assembled in the order the fields appear on the Core form. The one pdf attachment required by the ROA should be attached in field 12 under **Attachments**.
- In the lefthand panel, the **validation** button will check your application against business rules and guide the user through the corrections of missing or incorrect entries
- **Preview** (form and application) allows the user to see what the assembled application image

- To submit an application, the application **MUST** be error free (so good idea to keep checking validations). First go to lefthand navigation panel and select **Update Submission Status**, a pop-up box will appear and select “ready to submit” from the dropdown menu and then click the “add comment button” (adding a comment is not required). **Once the application is in “ready to submit” the person at your organization with the role of the SO must login to ASSIST and submit the application**
- **MOST IMPORTANT** once the application is submitted click on the view status button on the resulting pop-up summary and continue clicking on that link until you see a tracking, number and then finally an accession number. Clicking on that number will allow you to view your submitted and assembled application image in Commons. If you don’t see that link within a few minutes, contact the eRA service desk.
- **“If you can’t see it, we can’t see it, we can’t review it and we certainly cannot fund it”. If you can see it in Commons- we can see it in Commons!!**

Wrap Up

Wrap Up: Highlights

- N CREW Program is designed to provide novel, accessible, culturally grounded training, resources, and tools to build research capacity in community
 - Advance application and integration of Indigenous Knowledge in NIH research
- Leverages OTA to facilitate the N CREW Program and participants quickly pivoting in response to lessons learned and new or evolving needs
- Register your organization in eRA Commons as soon as possible. Once you have your credentials (PD/PI or SO) try to access ASSIST
- Follow the directions on how to complete an applications. For submission-related issues contact the [eRA Service Desk](#)

Upcoming Technical Assistance

Webinar for Questions and Answers

Oct 3rd from 2-3pm EDT

- NIH staff will answer questions about the N CREW Program, the two ROAs, and the submission process
- Register [here](#).

Questions

- Please email ncrew@nih.gov with your questions

Common Questions and Answers

- Questions and Answers are updated regularly on the NCREW website



Kathy Etz



Barbara Oudekerk



Jaclyn Smith



Angela Walden



Carly Marshall

NIH N CREW Team Contact Us! NCREW@NIH.GOV

Plus many other staff - not pictured



Nakia Brown



Jennifer Cho

Questions and Answers

Email:
ncrew@nih.gov

Website:
heal.nih.gov/ncrew



Thank you!

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

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