

Technical Assistance Webinar:

Responding to Opioid Use Disorders (OUD) in Tribal Communities in the Context of SAMHSA and CDC Funding (R61/R33 - Clinical Trials Optional)

RFA-DA-19-013



Goal of RFA-DA-19-013

- To support culturally relevant and community engaged research leveraging an opportunity made available by SAMHSA or CDC funding for tribal opioid response to further knowledge about how best to address the opioid crisis in tribal communities.
- Potential topics include, but are not limited to:
 - Treatment, prevention, recovery, or epidemiologic research (See FOA for more detail)
- *Note: Clinical Trial Optional*

Leveraging SAMHSA and CDC funding

- Examples of relevant SAMHSA and CDC funding include *BUT ARE NOT LIMITED to*:
 - SAMHSA TI-18-016 (Tribal Opioid Response Grants), TI-18-015, and TI 17-014
 - CDC-RFA-OT18-18030101supp
- List of tribes that received SAMHSA TOR funding and amount:
 - <https://www.samhsa.gov/grants/awards/TI-18-016>

Dates and Funds

- Receipt Date: November 29, 2018
- Letter of Intent (not required): October 29, 2018
- Scientific Review: February/ March 2019
- Funds Available: NIDA intends to commit \$3,000,000 in FY2019 to fund 3-4 awards

Budget and Project Period

- Award Budget:
 - Direct costs will vary with the scope of the project.
 - Direct costs for the R61 phase may not exceed \$500,000 in any one year.
 - Direct costs for the R33 phase may not exceed \$500,000 in any one year.
- Project Period – total of five years
 - 1-2 years in R61, 3-4 in R33 = total cannot exceed 5 years

Working with the Community

- Community Engagement or Community Based Participatory Research
 - Most projects will likely be CBPR but in some cases communities might prefer not to use this approach and instead would require community engagement
 - Community Involvement and Community Support are important for both strategies.

Demonstrations of Community Engagement and Support

- Include, for example:
 - Tribal Staff as Key Personnel
 - Research consistent with community attitudes and desires
 - Interventions culturally appropriate
- Document the community-research partnership under Research Strategy
 - Note that not all communities will choose the same way to be engaged but must document their involvement

Letters of Support

- If the applicant(s) is working with tribes/tribal governments then tribal/community resolutions of support, or equivalent documents, must accompany the application.
- See FOA for further details on letters of support
 - Also addresses when working with more than one community

Specific Aims, Significance and Innovation, and Preliminary Data

- The specific aims for both the R61 and R33 phases must be presented together on one page
- The R61 and R33 must both be described in the single 12-page research strategy
- Separate Significance and Innovation sections may be included but they could also be combined into a single section within the R61 section as appropriate.
- It is not necessary to repeat any information or details in the R33 section that are described in the R61 section.
- Preliminary data, extensive background material or preliminary information are not required for an R61/R33 application; however, they may be included if available. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data.

Milestones Section Must be Included

- Must propose at least 3 milestones for completion of the R61 phase, a discussion of the suitability of the proposed milestones for assessing success in the R61 phase, and a discussion of the implications of successful completion of these milestones for the proposed R33 study.
 - Milestones should be specific, quantifiable, and scientifically justified; they should not be simply a restatement of the R61 specific aims.
 - At least one milestone must involve an assessment of the continued feasibility and value of the proposed R33, using information obtained in the R61 phase, and specifically considering any changes in the Opioid Tribal funding program.
- An example of a basic milestone might involve a power calculation demonstrating that the planned sample size is sufficient for the goals of the project.

Study Design

- Applications focused on interventions that propose to use only pre- post-test designs without employing strong statistical methods designed to mitigate bias and support causal inferences are NOT responsive to this FOA and will not be reviewed or considered for funding
- Applicants should choose rigorous study designs that will provide convincing evidence regarding the research questions and where applicable to test the efficacy or effectiveness of the proposed intervention. While randomized designs are ideal for reducing threats to internal validity, other research designs will be given consideration. Applications must address concerns related to the quality of the research such as outcome variables and anticipated magnitude of change, psychometrics for planned measures, expected attrition, power estimation, and statistical analyses planned. Applicants should also provide plans for assessing fidelity of implementation and other relevant process measures, where relevant

Miscellaneous

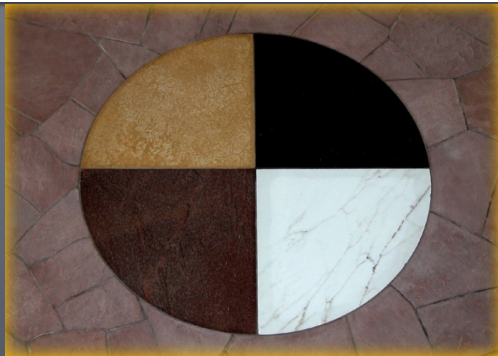
- PDs/PIs must plan to use some of the funds awarded by this FOA to attend an annual meeting of investigators funded under the FOA and engage in other activities, such as periodic conference calls
- Appendix
 - Suggest not putting any materials in the appendix
- Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Suggestion: Read the Review Criteria!

- Ensure you have addressed all factors. In particular, note:
- Significance – generalizability to other populations not necessary, but address how results advance science
- Investigator – adequate community and tribal representation?
- Approach – Support from tribal leaders and, if relevant, community members? Constructs and approaches important to the community? Study design justified and appropriate?
- Study Timeline – Adequately consider additional time it can take to conduct research in tribal communities?

The R61/R33 Mechanism

Exploratory/Developmental Research Grant



R61 – Phase 1 Exploratory/Developmental Grant

- Provides support for 1-2 years and allows for development of the project including, where relevant, development and pilot testing of study elements including measurements, the study design, and/or adaption of intervention. This phase will identify and meet pre-specified milestones ensuring that the results of this phase inform and provide a foundation for the second phase of the research.
- Seeks to foster the introduction of novel scientific ideas, model systems, tools, agents, targets, and technologies
- Is for hypothesis-driven projects supported by limited or no preliminary data to allow investigators to demonstrate feasibility of the proposed product, developed technology, or innovation.

R33: Exploratory/Developmental Research Grant Phase II Award

- The R33 awards will be based on program priorities, the availability of funds, and the successful completion of negotiated scientific milestones as determined by NIH staff within the context of the peer review recommendations.
- Provides the second phase of support for the research initiated under the (or R61) phase for a period of up to four additional years (But total project time CANNOT exceed 5 years)

Suggestion: Look at What Was Funded Under Similar FOAs

- Expanding Medication Assisted Treatment for Opioid Use Disorders in the Context of the SAMHSA Opioid STR Grants (R21/R33)RFA DA 18-005
- Behavioral Interventions for Prevention of Opioid Use Disorder or Adjunct to Medication Assisted Treatment-SAMHSA Opioid STR Grants (R21/R33) RFA AT 18-001
- Clinical Trials or Observational Studies of Behavioral Interventions for Prevention of Opioid Use Disorder or Adjunct to Medication Assisted Treatment-SAMHSA Opioid STR Grants (R21/R33)RFA AT 18-002

Suggestion: Use NIH Reporter and search these FOAs!

Example of a Funded Project from 2018 RFA

Abstract: This study leverages recent federal and state opioid use disorder treatment initiatives as a platform for testing a promising mind-body intervention, Mindful Awareness in Body-oriented Therapy (MABT) as an adjunct to MAT in two clinical settings funded through the Washington Opioid State Targeted Response (STR) program. MABT, a novel mindfulness-based intervention, uniquely addresses aspects of awareness, interoception, and regulation that may be associated with pain, mental health distress, and behavioral control that increase risk of relapse and poor treatment outcomes. Each setting employs a variation of the nationally recognized Massachusetts Nurse Care Manager model. Using a randomized, two- group, repeated measures design, we will compare those who receive MABT+ MAT to MAT only. The overarching goal of this application is to test MABT to improve MAT health outcomes among patients receiving buprenorphine to treat OUD.

Example Specific Aims: R21

- Solidify partnerships with proposed clinical program sites, develop plan for implementing the study intervention and procedures, and to finalize study related documents necessary for the R33, including: study protocols, data collection and informed consent forms, intervention manuals and fidelity assessment checklists, training plans for research staff, data safety and monitoring plans.

Example Specific Aims: R33

- Evaluate the effectiveness of MABT + MAT compared to MAT only (treatment-as-usual) in reducing opioid use (primary outcome), opioid craving, MAT discontinuation, and non-opioid drug use (secondary outcomes) at the six-month time point.
- Examine the effectiveness of MABT + MAT for improving mental health distress (i.e. depression, anxiety, somatization, emotion regulation difficulties) compared to MAT only at 6 months.
- Explore the effectiveness of MABT + MAT compared to MAT only in reducing co-morbid pain severity and interference (Brief Pain Inventory) and pain sensitivity (cold pressor test).

Resources

- Frequently Asked Questions | NIH Grants & Funding - http://grants.nih.gov/grants/frequent_questions.htm
- Frequently Asked Questions | Applying Electronically - <http://grants.nih.gov/grants/ElectronicReceipt/faq.htm>
- Applying Electronically | Avoiding Common Errors - http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm#10check
- Are You Using the Correct Forms For Your Application - http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf

Resources

eRA Training: Video Tutorials

- eRA Commons: Features and Functions You Need to Know
- Institution Registration and Account Creation
- Understanding Status

https://era.nih.gov/era_training/era_videos.cfm

Kathy Etz
ketz@nih.gov

Sarah Duffy
duffys@nida.nih.gov

