NIH HEAL INITIATIVE

RFA-DA-23-046
Pre-Application Webinar

Presented by: Sarah Duffy, PhD (NIDA), Trinh Tran, PhD (NIDA), Laura Kwako, PhD (NIAAA), and Peter Murray, PhD (NCCIH)

9/28/2022

Welcome!

- Participants muted

- Please submit questions to "All Hosts" using Q&A feature

- Topics: Information in the RFA (*e.g.,* eligibility, technical requirements, review criteria)

- Hitting the high points. Make sure you read the **entire** RFA, including links, and **all applicable SF424, PH 398** instructions. Reach out with any questions!

- Slides, recording, to be posted on the NIDA Meetings & Events Page here

- Technical difficulties, please send chat to Malik Lucas or email him at malik.lucas@nih.gov (first 15 minutes)

- For project-specific questions, please contact program official (Sarah Duffy, Peter Murray, or Laura Kwako after the meeting)

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RFA-DA-23-046

- Title: HEAL Initiative: Research to Foster an Opioid Use Disorder Treatment System Patients Can Count On (RM1 - Clinical Trial Optional)

- Clinical Trial Optional

- Expected # of Awards: 5-6

- Budget Limit: $1.5 Million Direct/Year

- Award Period: 5 Years

- Activity Code: RM1

- From the NIH Helping to End Addiction Long-term® Initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis.

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AGENDA

- FOA Scope and Application Instructions - Sarah

- Receipt, Review, Selection - Trinh

- Q&A – Laura, Peter, Trinh, and Sarah

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FOA Scope and Application Instructions

Sarah Duffy, PhD, National Institute on Drug Abuse

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Key Dates

Earliest Submission Date	January 2, 2023
Letter of Intent Due Date	January 2, 2023
Application Due Date	**February 2, 2023**
Scientific Merit Review	July 2023
Advisory Council Review	August 2023
Earliest Start Date	**September 2023**

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FOA Background

- Individuals with Opioid Use Disorder (OUD), families, payors need information to select quality treatment

- Treatment quality could be improved – *e.g.,* evidence-based interventions not routinely provided

- Quality measurement and improvement strategies exist, rigorous research could advance, including but not limited to:

  - Examining whether improved performance on measures improve patient outcomes
  - Developing benchmarks
  - Developing, testing, case mix adjustment
  - Etc.
  - Your ideas!

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OUD-QM^{2}RCs

- Multi-project Opioid Use Disorder Quality Measurement and Management Research Centers (OUD-QM^{2}RCs)

- RM1 = Research Project with Complex Structure

- Researchers, partner organization(s) with deployed or in-development quality measurement and management strategy for OUD treatment

- Rigorous, scientific research could advance QM^2

- Ultimately: Feasible, efficient quality measurement and management system providing information to help

  - Patients, families, and payors fairly compare and select providers

  - Clinicians, providers improve patient outcomes.

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OUD-QM^{2}RCs Should

- ID key aspects of partner's QM^2 strategy that require additional research

- Conduct research

- Rigorously test or prepare to test the resulting strategy to determine if it improves patient outcomes

- QM^2 at a minimum:

  - Collects data on quality measures

  - Reports information back to

    - Individuals, families, and payers to help select providers

    - Clinicians, providers, and health care systems to promote quality improvement

- Include activities to support the acceptability, feasibility, scalability, sustainability of the system; equity clinician/provider selection and treatment delivery

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OUD-QM²RCs Continued

- 2-3 interrelated research projects

  o Up to 2 to substantially advance the chosen strategy

  o At least 1 to rigorously test or prepare to rigorously test the effect on patient outcomes

- Meaningful involvement of the partner organization

- Participation in HEAL activities

  o Investigator meeting

  o Other coordination/sharing activities

  o Data sharing

Eligibility

- Only US organizations may apply

  - Higher Ed, non-profit, for profit, state, local, and federal governments, tribal organizations, faith- or community-based organizations, regional organizations

- Project may include foreign components

- Principal investigator(s) with skills, knowledge, resources necessary to carry out the research

Application – Specific to This RFA

- Budget:

  - Possible in-person convenings: 3 people, 2-day meeting in DC area in 1st and 4th year of award.

  - HEAL Investigator meetings: PI at 2-day, in-person meeting in DC area annually

- Research Strategy

  - Page limit

    - 30 pages total if proposing 3 research projects

    - 24 pages total if proposing 2 research projects

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Application Continued

Section	Page Limit	Content
A – Background and Overview	6	Partner QM^2 strategy, research gaps, how filling gaps will advance system
B – Research Project 1	6	Substantially advance the QM^2 strategy – Research Plan instructions
C – Research Project 2	6	Substantially advance QM^2 strategy or rigorously test or prepare to test – Research Plan instructions
D – Research Project 3 (Optional)	6	Rigorously test or prepare to test – Research Plan instructions
E – Activities to support acceptability, etc. of system	3	See RFA
F – Leadership/Admin/ Organization	3	See RFA

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Data Management and Sharing Plan

- Required for research funded in whole or in part by NIH that results in the generation of scientific data

  - Outlining how scientific data, accompanying metadata will be managed and shared

  - Should describe data types, file formats, submission timelines, etc.

  - Expected that shareable data generated will be submitted to study-appropriate repository

  - Etc.

  - Updated application package should be available soon: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html

- If data cannot be shared, provide a justification

- Will be reviewed

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Notices and Policy Updates

Two places to look:

	Disorder Treatment System Patients Can Count On (RM1 - Clinical Trial Optional)
Activity Code	RM1 Research Project with Complex Structure
Announcement Type	New
Related Notices	• NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 • **August 30, 2022** - Notice of Pre-Application Technical Assistance Webinar for NIDA RFA-DA-23-046, "HEAL Initiative: Research to Foster an Opioid Use Disorder Treatment System Patients Can Count On (RM1 - Clinical Trial Optional)". See Notice NOT-DA-22-073

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Receipt, Review, Selection

Trinh Tran, PhD, National Institute on Drug Abuse

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Receipt, Review and Selection Process

- Receipt
  - Review for completeness, compliance with instructions (NIH Center for Scientific Review)
  - Responsiveness (NIDA)
  - Incomplete/non-compliant/nonresponsive not reviewed
  - Assignment to most appropriate NIH Institute/Center (may happen after review)
- Review
  - Scientific Review Group convened by NIDA in accordance with NIH peer review policy and procedures
  - All applications will receive written critique
  - May review/provide overall impact score for only the most meritorious (usually top 50%).
- Selection
  - Applications will compete for available funds with all other recommended applications submitted in response to this FOA
  - Following will be considered
    - Scientific and technical merit as determined by scientific peer review
    - Availability of funds
    - Relevance of proposed project to program priorities

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Standard review criteria +

- Overall Impact: Likelihood for project to exert sustained, powerful influence on the research field, etc. Based on scored criteria:

  - Significance – Important problem? Rigor of prior research? If aims are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?, etc.

  - Investigators – PD(s)/PI(s) collaborators, other researchers well-suited?, Etc.

  - Innovation – Utilizes novel theoretical concepts, approaches, methodologies, instrumentation, or interventions, etc.

  - Approach: Overall strategy, methodology, and analyses well-reasoned, appropriate to accomplish specific aims?, etc.

    - ***For this FOA:*** How appropriate is the involvement of the partner organization(s), and how well does that involvement promote the OUD-QM^{2}RC's success?

    - ***For this FOA:*** How well does the Data Sharing Plan address how scientific data and any accompanying metadata will be managed and shared?

  - Environment: Scientific environment contribute to probability of success?, etc.

- Also, standard clinical trial-specific criteria in each section

Additional Review Criteria (Standard)

- Evaluated while determining scientific and technical merit, and providing overall impact score, but not individually scored:

  - Study timeline (for clinical trials)

  - Protection of Human Subjects

  - Inclusion of women, minorities, individuals across the lifespan

  - Etc.

- Evaluated, but not considered in scoring

  - Budget

  - Resource sharing plan (though data management and sharing plan is)

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Q&A

Laura Kwako, PhD, National Institute on Alcohol Abuse and Alcoholism

Peter Murray, PhD, National Center for Complementary and Integrative Health

Trinh Tran, PhD, National Institute on Drug Abuse

Sarah Duffy, National Institute on Drug Abuse

Please submit questions to "All Hosts" using Q&A feature

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