

**NIH  
HEAL  
INITIATIVE**

Helping to End  
Addiction Long-term

**Preventing Opioid Misuse and Co-Occurring Conditions by  
Intervening on Social Determinants (NIH RFA-DA-22-036)  
Pre-Application Technical Assistance Webinar**

Moderated by Drs. Amy Goldstein, Aria Crump  
and Barbara Oudekerk, NIDA

# Welcome to the Webinar!

- Welcome to the Pre-application TA webinar for [RFA-DA-22-036](#): Preventing Opioid Misuse and Co-Occurring Conditions by Intervening on Social Determinants.
- Webinar attendees are muted. **Attendees may submit questions at any time through the Zoom Webinar Q&A feature.**
- Questions that are not answered live will be answered through a Frequently Asked Questions document that will be posted on the [HEAL Prevention website](#) after the session.
- The webinar recording, slides, and FAQs document will be available approximately one week following the presentation.
- You are encouraged to email RFA contacts for consultation regarding your proposal (see Section VII of the RFA).

# Pre-application TA Webinar Agenda

- Webinar Panelists; Funding Opportunity Participating Organizations
- Focus on Social Determinants
- RFA Programmatic Goals and Description
- Application Information and Key Dates
- Reminders for All Applicants
- Peer Review Process and Review Criteria
- Q&A Session



# Webinar Panelists

## **Amy Goldstein, Ph.D.**

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## **Eve Reider, Ph.D.**

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## **Aria Crump, Sc.D.**

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## **Devon Oskvig, Ph.D.**

Program Director  
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## **Barbara Oudekerk, Ph.D.**

Social and Behavioral Sciences Administrator  
Prevention Research Branch  
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## **Sheila Pirooznia, Ph.D.**

Scientific Review Officer  
National Institute on Drug Abuse  
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# RFA-DA-22-036: Participating Institutes and Offices

## Institutes

National Institute on Drug Abuse (NIDA)

National Institute of Mental Health (NIMH)

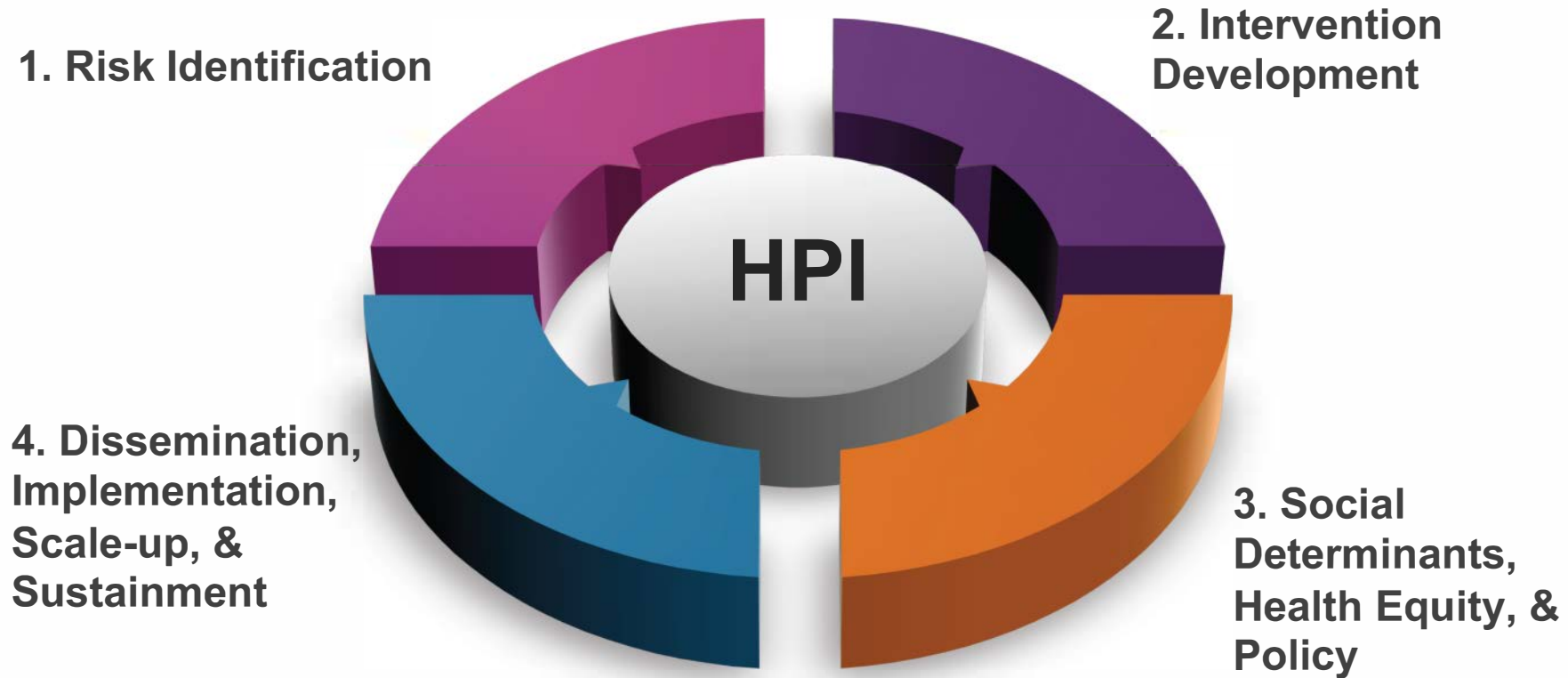
National Institute on Aging (NIA)

## Offices

Office of Behavioral and Social Sciences  
Research (OBSSR)

Office of Disease Prevention (ODP)

# HEAL Prevention Initiative (HPI) Strategic Areas



For more information on the HEAL Prevention Initiative, see <https://heal.nih.gov/research/new-strategies/preventing-opioid-use-disorder>



# The Importance of Social Determinants

- NIH held a [HEAL Initiative-sponsored Workshop](#) in September, 2020
  - To identify research gaps and priorities to advance our understanding of how social determinants impact the opioid crisis.
  - To explore opportunities for high-impact, scalable strategies to intervene on malleable factors to prevent opioid misuse and improve other drug use outcomes.
- Need for a comprehensive approach to address the opioid crisis. Attention to modifiable “upstream” factors has been largely missing.
- Research can provide evidence needed to inform the public sector response.

# Description of RFA-DA-22-036: Preventing Opioid Misuse and Co-Occurring Conditions by Intervening on Social Determinants

- Goal is to support research that tests multi-level prevention strategies for intervening directly on social determinants of health to reduce the risk for opioid misuse and co-occurring conditions.
- Research should seek to reduce health inequities in a population or population subgroup affected by the opioid crisis.
- Research project must examine mechanisms of intervention effects.
- Research project must include economic analysis to inform decisions about intervention adoption.
- Funding Mechanism: R01 (Clinical Trials Optional)



# Key concepts

## **Social Determinants:**

conditions that lead to health disparities through systematic, direct and indirect effects on the development and progression of disease as well as access to health resources. Also see: [Healthy People 2030 Objectives](#)

## **Multi-level Intervention:**

strategy to intervene on two or more ecological levels of influence, e.g., the individual, interpersonal, community, and societal levels. Also see [NIMHD Research Framework](#)

# Outcome variables

- Studies must specify an opioid misuse-related prevention outcome as a primary outcome. Examples include:
  - initiation of opioid misuse or polysubstance use
  - progression from opioid misuse to OUD or injection drug use
- Studies must specify a co-occurring condition as a secondary outcome. Examples include:
  - other substance misuse
  - mental health conditions
  - suicidal behavior

# Responsiveness Criteria

Applicants must...

- propose a multi-level intervention addressing social determinants
- identify 1) opioid misuse-related indicator and 2) co-occurring condition as dependent variables
- provide justification for selection of population or population subgroup affected by the opioid crisis
- test mechanisms of action or mediational processes linking social determinants of health to study outcomes
- describe plans for economic analysis

# Other considerations

- Theoretical basis for intervention
- Rigor of study design and study measures
- Plan for Enhancing Diverse Perspectives ([PEDP](#))
- Demonstration of commitment from collaborators and partners
- Potential of intervention for timely, wide-spread adoption and sustainability
- Ethical considerations

# National Institute of Mental Health

- Interested in applications relevant to RFA priorities and support the [NIMH Strategic Plan for Research](#)
- Committed to supporting research that reduces disparities and advances equity in mental health interventions, services, and outcomes.
- Applications proposing clinical trials should follow NIMH's [experimental](#) therapeutics approach to intervention development and testing
- Encourages a deployment-focused model of intervention and services design and testing that takes into account the perspective of relevant stakeholders and the key characteristics of the settings that are intended to implement optimized mental health interventions.
- Encourages effectiveness research on potentially scalable preventive, therapeutic, and services interventions that focuses on practice-relevant questions.



# Awardee participation in NIH HEAL Initiative

NIH HEAL Initiative recipients should expect to participate in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting, as well as other activities.

In accordance with the HEAL Initiative Public Access and Data Sharing Policy (<https://heal.nih.gov/about/public-access-data>), all applications are required to include a Data Management and Sharing Plan outlining how scientific data and any accompanying metadata will be managed and shared.

# RFA-DA-22-036: NIH HEAL Initiative—Preventing Opioid Misuse and Co-Occurring Conditions by Intervening on Social Determinants

<b>Key</b>	Pre-application TA Webinar	<b>January 6, 2022</b>
<b>Dates</b>	<i>Non-binding</i> letter of intent due date	<b>February 2, 2022</b>
	Application Receipt date*	<b>March 2, 2022</b>
	Scientific Merit Review	<b>June, 2022</b>
	Earliest Project Start Date	<b>September, 2022</b>

\*All applications are due by 5:00 PM local time of applicant organization.

# Application guidelines

- Maximum project period is 5 years; scope of project should determine the project period.
- Application budget is not limited, but must reflect the actual needs of the proposed project.
- Non-U.S. entities and non-U.S. components of U.S. organizations are ***not*** eligible to apply.
- Foreign components are ***not*** allowed.

# Peer Review Process & Review Criteria

Presented by Dr. Sheila Pirooznia, NIDA

# APPLICATION REVIEW

- Administrative review carried out by NIH staff
- Submissions evaluated by NIH staff for
  - Completeness and compliance (See [NOT-OD-17-105](#))
  - Adherence to NIH formatting guidelines
  - Biosketch and Other Support Format page requirements (See [NOT-OD-21-073](#))
  - For clinical trial applications:
    - Check to determine if your study is a [NIH-Defined Clinical Trial](#).
    - Be certain to comply with [requirements for NIH-Defined Clinical Trials](#).
- If applicable, use a single IRB as required by the [NIH Single IRB Policy](#)
- Include **only** allowable appendix materials as per the application instructions.
- FOA Requirements: Inclusion of Special Considerations listed in the FOA

Incomplete applications or applications not adhering to the FOA requirements may be returned without review



# PEER REVIEW



- Peer review of applications conducted at NIDA
- Special Emphasis Panel created by the SRO based on the areas of science described in the application
- Conflicts of interest are managed for all panel members
- At least three reviewers assigned to evaluate each application
- Panel will receive guidance from NIH staff on how to evaluate the application
- Panel members have at least 30 days to evaluate the application
- Meeting roster is publicly available 30 days before the meeting

# APPLICATION REVIEW CRITERIA

## Section V of FOA

### Core Review Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

### Additional Review Criteria

- Study Timeline (for CT applications only)
- Protection of Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan

### Overall Impact

Likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

### Additional Review Considerations

Select Agents, Resource Sharing Plan, Authentication, Budget

# APPLICATION REVIEW CRITERION DETAILS

## Section V of FOA

*Clinical trial requirements and FOA specific questions listed under individual core review criteria in addition to the standard requirements*

### **Specific to this FOA:**

#### **Significance:**

Test multi-level intervention outcomes on prevention measures for opioid misuse and co-occurring conditions. Address long-term impacts on disparities. Engage stakeholders and potential adopters to support long-term sustainment of effective strategies.

#### **Investigators:**

Multidisciplinary team with appropriate expertise and track record of research in relevant study domains

Contd...

# APPLICATION REVIEW CRITERION DETAILS

## Section V of FOA

### Specific to this FOA:

#### **Innovation:**

Expand understanding of multi-level interventions. Inform mechanisms of action of social determinants

#### **Approach:**

Feasibility of multi-level intervention strategy

Meaningful engagement of community collaborators and/or stakeholders

Adequacy of recruitment and retention plans. Reasonable study timeline

Appropriate and robust data collection and management procedures,

Rigorous study design and analytical plan for stated aims

# PEER REVIEW OUTCOME

- As part of the scientific peer review, all applications will receive a written critique (*summary statement*)
- Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score
- Summary statement will be available within 4-6 weeks after the peer review meeting



# Q&A

Moderated by Dr. Barbara Oudekerk, NIDA

**Please enter your questions in the Zoom Webinar Q&A box**

# Thank you for attending!

For more information, please see RFA-DA-22-036 and consult with RFA contacts (see Section VII of the RFA).