HEAL Justice Community Opioid Innovation Network (JCOIN) FOA Overview Webinar
Brief Technical Orientation

- This webinar is being recorded.
- All participants, except NIDA staff, have been muted.
- Today’s slides and a recording will be posted at: [https://www.drugabuse.gov/news-events/meetings-events/2019/01/jcoin-technical-assistance-webinar](https://www.drugabuse.gov/news-events/meetings-events/2019/01/jcoin-technical-assistance-webinar)
- Questions will be taken at the end and read by a moderator.
  - Submit questions to “All Panelists” using Q&A Feature.
- We will answer questions about eligibility, technical requirements, and budget requirements.
- We will not answer questions about specific designs or study ideas. Please email [jcoin@nida.nih.gov](mailto:jcoin@nida.nih.gov) to set up a time to discuss such questions.
- If you experience technical difficulties during the webinar, please send a chat to the panelists. If no response, email [shelley.su@nih.gov](mailto:shelley.su@nih.gov)
## Agenda & Participants

**JCOIN Technical Assistance Webinar**

### Agenda

<table>
<thead>
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<th>Time</th>
<th>Topic</th>
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<tr>
<td>1:00 - 1:10</td>
<td>Opening Remarks &amp; Introductions to NIDA Staff</td>
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<tr>
<td>1:10 - 2:00</td>
<td>JCOIN FOA Review and Application Requirements</td>
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<tr>
<td></td>
<td>1. Common Elements</td>
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<td>2. Clinical Research Centers</td>
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<td>3. Coordination and Translation Center</td>
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<td>4. Methodology and Advanced Analytics Center</td>
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<td></td>
<td>5. Budget</td>
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<tr>
<td>2:00 - 2:25</td>
<td>Questions from Participants</td>
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<tr>
<td>2:25 - 2:30</td>
<td>Closing</td>
</tr>
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### NIDA Participants

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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</thead>
<tbody>
<tr>
<td>Tisha Wiley</td>
<td>Program Contact Chief, Services Research Branch</td>
</tr>
<tr>
<td>Pam Fleming</td>
<td>Grants Management Contact</td>
</tr>
<tr>
<td>Jerry McLaughlin</td>
<td>Review Contact</td>
</tr>
<tr>
<td>Carrie Mulford</td>
<td>Health Scientist Administrator, SRB</td>
</tr>
<tr>
<td>Shelley Su</td>
<td>Health Scientist Administrator, SRB</td>
</tr>
<tr>
<td>William Longinetti</td>
<td>Presidential Management Fellow, SRB</td>
</tr>
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Background

- Illicit opioids, including fentanyl and heroin, accounted for more than 60% of opioid-related overdose deaths in 2016.
- The intersection of justice and community-based systems is a critical target for addressing the opioid crisis.
- The NIDA Justice Community Opioid Innovation Network (JCOIN) will establish a network of research investigators to rapidly conduct studies on quality care for opioid misuse and OUD in justice populations.
- JCOIN is part of the NIH Helping to End Addiction Long-term (HEAL) initiative.
HEAL Justice Community Opioid Innovation Network (JCOIN)

Three components:

I. Clinical Research Centers (CRC) (RFA-DA-19-025)
II. Coordination and Translation Center (CTC) (RFA-DA-19-024)
III. Methodology and Advanced Analytics Resource Center (MAARC) (RFA-DA-19-023)
Cooperative Research Mechanism

- All 3 FOAs use a **cooperative research mechanism**
- A cooperative mechanism means that NIH have substantial programmatic involvement
  - A NIH Project Scientist will be named for every award
  - Collaboration is required with other awardees
  - Data must be shared and progress reported
- Review all Terms & Conditions specified in the announcements
Key Definitions Across All 3 FOAs

- **Justice Setting**
  - Inclusive of prisons, jails, drug courts, problem solving courts, policing & diversion, re-entry, probation and parole, child welfare, juvenile justice
  - Emphasizes services provided in the community
    - Secure settings should include emphasis on transitions to/from community
Key Definitions Across All 3 FOAs

- **Community-Based Services**
  - Any setting where a justice-involved patient may engage with medical or behavioral health services that address illicit opioid use, opioid misuse, or related treatment and other service needs.
  - **Examples**: Behavioral health service providers, HIV service providers, Federally Qualified Health Centers (FQHCs), integrated primary care and behavioral health settings, office-based opioid agonist treatment providers, needle exchange sites, housing providers, opioid treatment programs, etc.
Key Definitions Across All 3 FOAs

- **Clinical Performance Site (i.e., Community)**
  - A partnership between a *justice setting* (e.g., jail, prison, drug court) and one or more *community-based service providers* (e.g., hospital, treatment center, other relevant service provider).
  - Both the justice setting and the service provider must engage with a *shared population* of justice-involved individuals who *live or receive services in a defined geographic area* (i.e., community).
  - Proposed Clinical Performance Sites must be *geographically distinct and non-overlapping* from the perspective of the population of patients engaging with services.
Clinical Research Centers
RFA-DA-19-025
Clinical Research Centers (CRCs)

- **FOA#:** RFA-DA-19-025
- **Title:** HEAL Justice Community Opioid Innovation Network (JCOIN) Clinical Research Centers
- **Clinical Trial:** Optional
- **Expected # of Awards:** 8-12
- **Budget Limit:** $1.5M Direct Cost
- **Award Period:** 5 years
- **Page Limit:** 12
- **Funding Mechanism:** UG1
  - Clinical Research Cooperative Agreements - Single Project
Study Design & Intervention Selection

- **Study designs** may include effectiveness, implementation, and hybrid implementation-effectiveness designs.

- **Interventions to be studied** can include evidence-based medications, behavioral interventions, digital therapeutics, and comprehensive, patient-centered intervention packages.
Outcome Selection

- Opioid-relevant outcomes must be included.
- Both public health & public safety outcomes must be included.
- Use of service cascade framework is encouraged to guide selection of outcomes: screening, need identification, referral, treatment engagement and service retention.
  - Examples of public health outcomes: relapse, remission, mortality, reductions in substance use.
  - Examples of public safety outcomes: recidivism, reduction in criminal activity.
- For implementation studies, relevant organizational and system-level outcomes should be considered.
- Rigorous economic evaluations are encouraged.
  - For economic evaluations, societal outcomes (e.g., costs of treatment, crime, etc.) should be considered.
- Follow-up should be at least 6 months; 1 year or longer is strongly encouraged.
Senior/Key Person Profile

- Applicants should provide evidence of expertise in the conduct of clinical trials, particularly cooperative, pragmatic, randomized clinical trials.

- Biosketches should be included for one or more senior leaders from (a) a justice setting and (b) a community-based treatment setting relevant to the proposed study to be included as key personnel.
  - These do not have to be personnel from the proposed sites.

- PIs, senior investigators, and other investigators with substantial time commitments to JCOIN should expect to actively participate in a wide variety of network activities.
Requirements for Senior Personnel

- PD/PIs must expend **two (2.0) person-months effort annually on the award** over the entire period of support.
  - In a multi-PI application, at least one PI must commit a minimum of 2.0 person-months annually over the life of the grant award.
- One or more senior leaders from (a) a relevant **justice setting** AND (b) a relevant **community-based treatment setting** should be named as Key Personnel and should each expend a minimum of .6 person-months effort annually on the award over the entire period of support.
CRC Research Plan Overview

▶ Specific Aims
▶ Section A: Research Strategy
  ▶ Detailed overview of the research design
▶ Section B: Clinical Research Center Collaboration Capacity
  ▶ Capacity of the CRC to engage with the rest of the JCOIN Network
Research concept should lay out a theoretically grounded, hypothesis-driven study design to address gaps in the continuum of care for justice-involved individuals.

Research strategy should include:
- Detailed description of research project
- Rigorous study design
- Description of study outcomes
- Justification for selected follow-up period
- Description of clinical performance sites
- Sustainability of proposed intervention
- Generalizability of clinical performance sites
Minimum of five (5) clinical research performance sites required.
- A clinical research performance site is defined as a **geographically distinct community**.
- If there is any ambiguity with regard to the geographic distinctness of the proposed clinical research performance sites, applicants must provide a clear justification for their site selection approach.

Each site must include: (a) one or more partners from the **targeted justice setting** in the community, and (b) one or more **community-based service providers**.

Actual number of clinical performance sites should be justified scientifically based on power analyses appropriate to the design and outcomes of interest.
Data should be presented on the nature, severity, and trends in opioid use, opioid-related morbidity and mortality, or other opioid-related outcomes for the targeted communities.

Capacity to recruit additional sites, if needed, should be described.

For each proposed community, letters of support from both the (a) targeted justice entity(ies) and (b) community-based service provider entity(ies) should be provided.
In general, it is anticipated that in all five performance sites, justice settings will be of the same general type (e.g., jails).

Applicants can make a case for other designs with a compelling justification.

In general, it is expected that applicants will be able to pre-specify their expected clinical research performance sites.

If there is a compelling reason why this cannot or should not be done, applicants should provide similar detail to that described below regarding potential sites and what approach will be used in ultimately selecting sites.

Additional detail should be included on planned performance sites as detailed in the SF424(R&R) Project/Performance Site Locations.
CRC Research Plan Section B: Clinical Research Center Collaboration Capacity

- This research strategy section should describe CRC capacity to:
  - Participate in data harmonization and other collaborative JCOIN efforts.
  - Contribute unique expertise and research capacity to the network.
  - Demonstrate a track record of collaboration in similar efforts.
  - If multiple organizations will collaborate as part of the proposed Clinical Research Center, a plan for collaboration within the center must be presented as well.
  - Commit to provide the Coordination and Translation Center (CTC) and the Methodology and Advanced Analytics Resource Center (MAARC) with timely, accurate data to facilitate the ability of the CTC and MAARC to provide NIDA with accurate data-driven updates of network progress.
Letters of Support

- For each proposed community, letters of support from both the (a) targeted justice entity(ies) and (b) community-based service provider entity(ies) should be provided.
- If a study design proposes recruiting sites as part of a study design, strong justifications demonstrating feasibility of recruitment (e.g., letters of support from a state government official overseeing a system with multiple potential sites) and a strong justification for the selection of this strategy must be included.
Resource Sharing Plan

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

- Data Sharing Plan should explicitly acknowledge understanding that nearly all data collected as part of the JCOIN initiative will be expected to be shared with the Methodology and Advanced Analytics Resource Center for trans-JCOIN activities. Plans for transmitting this data and ensuring appropriate sensitivities with regard to personally identifying information (PII) should be outlined.
Coordination and Translation Center
RFA-DA-19-024
Coordination and Translation Center (CTC)

- **FOA# & Title:** RFA-DA-19-024, HEAL Justice Community Opioid Innovation Network (JCOIN) Coordination and Translation Center
- **Clinical Trial:** Optional
- **Expected # of Awards:** 1
- **Award Budget:** $2.5M Direct Costs
- **Maximum Award Period:** 5 years
- **Funding Mechanism:** U2C
  - Resource-Related Research Multi-Component Projects and Centers Cooperative Agreements
CTC: Scope of Activities and Purpose

- The Coordination and Translation Center will provide coordination, infrastructure, and other supports for the JCOIN network.
- The CTC will provide services and resources to the network via the following five cores:
  1. Administrative Core
  2. Rapid Response & Pilot Research Core
  3. Dissemination and Stakeholder Engagement Core
  4. Research Education Core
  5. Implementation and Translation Research Project Core
# Funding Opportunity Announcement Details

<table>
<thead>
<tr>
<th>FOA Component</th>
<th>Max Pages</th>
<th>Budget Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>6</td>
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<tr>
<td>Admin Core</td>
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<tr>
<td>Rapid Response Core</td>
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<td>$375k Total Costs</td>
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<tr>
<td>Dissemination Core</td>
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<tr>
<td>Research Education Core</td>
<td>12</td>
<td>$500k Direct Costs</td>
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<tr>
<td>Implementation Project Core</td>
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<td><strong>Total</strong></td>
<td><strong>54</strong></td>
<td><strong>$2.5M DIRECT</strong></td>
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CTC Administrative Core

- The Administrative Core of the provides overarching resources and organizational structure and management of the Cores and Projects.

- Applicants should describe plans for:
  - Establishing **External Facing Website and Communications Infrastructure**.
  - Providing **Internal Collaboration, Communication Infrastructure, and Logistical Support**.
  - Executing **Progress Monitoring and Reporting to NIDA**.
CTC Rapid Response & Pilot Research Core

- The Rapid Response & Pilot Research Core is intended to provide rapid, flexible infrastructure to support research on newly emerging policies and practices.

- The research strategy section for this core should include:
  - Plan for executing award program: timing, process, roles & responsibilities, engagement of the JCOIN Network.
  - Plan for convening stakeholder advisory committee.
  - Process for rapid and rigorous review or proposals.
  - Timeline and workflow of application process.
  - Plan for pilot awards for novel collaborations between justice settings and JCOIN investigators.

- Carefully review and adhere to guidelines on structuring this component of the application.
Dissemination and Stakeholder Engagement Core

- The research strategy section for this core should provide detail on the following four areas:
  - Stakeholder Engagement with Network Leadership
    - **Note:** Do not solicit letters of support. Rather, outline groups that could be engaged and plan for engagement.
  - Outreach and Training for Stakeholders
    - **Note:** Emphasis is on justice- and community-based service providers. Researcher-oriented education should be specified in the Research Education Core.
  - Rapid Translation of Findings for Stakeholders
    - Material/Resource Development
    - Monitoring/Evaluation of Materials
  - Identify and Engage Potential Sites for Future JCOIN Network Activities
Implementation and Translation Research Project

The goal of the Implementation and Translation Research Project Core is to support one or more hypothesis-driven research projects that generate evidence regarding effective approaches to translating scientific findings into widespread practice via dissemination and implementation research.

Research strategy section should include:

- Outline of at least one research project.
- Also include a detailed approach to how this Core will function as a resource that evolves as the Network matures.
- Description of general framework for bringing implementation science approach to CTC Activities.
CTC Research Education Core

- The Research Strategy section must be used to upload the Research Education Program Plan, which must include the following elements:
  - Proposed Research Education Program
  - Core Leads
  - Program Faculty
    - Note: Propose Core Faculty + Outline plan for engaging JCOIN network investigators
  - Program Participants
    - Eligibility to participate should be made available to participants with appropriate educational backgrounds, irrespective of whether they are affiliated with any JCOIN network components.
    - Emphasis should be on building capacities of investigators to do work in justice settings
    - Can include research staff embedded in justice and community-based settings, but must be non-duplicative with efforts of the Dissemination and Stakeholder Engagement Core
  - Diversity Recruitment Plan
  - Plan for Instruction in the Responsible Conduct of Research
  - Evaluation Plan
  - Dissemination Plan
Methodology and Advanced Analytics Resource Center (MAARC)

RFA-DA-19-023
Methodology and Advanced Analytics Resource Center (MAARC)

- **FOA #:** RFA-DA-19-023
- **Title:** HEAL Justice Community Opioid Innovation Network (JCOIN) Methodology and Advanced Analytics Resource Center
- **Clinical Trial:** Not Allowed
- **Expected # of Awards:** 1
- **Maximum Award Budget:** $2.5M Direct Costs
- **Funding Mechanism:** U2C
  - Resource-Related Research Multi-Component Projects and Centers Cooperative Agreements
MAARC: Scope of Activities and Purpose

- The Methodology and Advanced Analytics Resource Center (MAARC) will provide analytic and data support for the JCOIN network. The MAARC will also conduct novel empirical research to ensure timely understanding of changes in current practices in the United States related to addressing opioids in justice settings.

- Expected components of the MAARC include:
  - Administrative Core
  - Data and Analytics Support Core
  - Policy & Practice Observational and Survey Research Core
  - Advanced Methodological Research Core(s)
## Funding Opportunity Announcement Details

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<tr>
<td>Data and Analytics Support Core</td>
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<tr>
<td>Survey Core</td>
<td>12</td>
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<tr>
<td>Methods Core (up to 3; Modeling Core Required)</td>
<td>12-36</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>54-78</strong></td>
<td><strong>$2.5 M Direct</strong></td>
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MAARC Administrative Core

The MAARC Administrative Core provides overarching resources and organizational structure and management of the Cores and Projects.

As part of this section, applicants should address the following:

- Governance and Coordination within MAARC
- Coordination across JCOIN
- Ensuring Rigor
- Facilitating Public Dissemination and Data Engagement (in collaboration with the Coordination and Translation Center)
MAARC Data and Analytics Support Core

- The MAARC Data and Analytics Support Core will facilitate the development of a management system for the collection, storage and quality control of data; promote the use of data standards; and provide a portal for data use and sharing.

- The research strategy for this section should address the following:
  - Trans-JCOIN Coordination
  - Data Security & Standards
  - Ensuring Data Quality
  - Analytic Support and Coordination
    - Should provide a breadth of expertise for consultation across JCOIN network
  - Integration with Other Data Sources

- **Note**: The MAARC is responsible for support of both qualitative and quantitative data.
MAARC Policy & Practice Observational and Survey Research Core

- The purpose of this core is to provide support to conduct research on existing and dynamic changes in policy and practices within the justice system as well as in community-based service provider systems that provide treatment to justice-involved individuals who use or are at risk for using opioids.

- The research plan for this core should describe:
  - Strategies for real-time or near-real time tracking of policy changes
  - Using surveys or other data collection approaches to fill knowledge gaps
  - Scientific rigor of approaches
  - Rapid translation of findings through the CTC
MAARC Advanced Methodological Research Project(s)

- The Advanced Methodology Research Project(s) will provide methodological consultation in novel analytical techniques and will leverage these advanced analytical approaches to conduct novel research using existing data and data acquired through the network.

- Up to three projects may be proposed. A project focused on modeling must be included.
  - Examples of modeling techniques: simulation modeling, agent-based modeling, system science, network analysis, etc.
  - Describe how methodologies developed and applied in the proposed project could lead to additional projects leveraging data from JCOIN network.

- The research strategy should address the following:
  - Uniqueness and value of proposed project
  - Justification of data sources and analytical techniques
  - Participant recruitment and retention plan
  - Timeline for data acquisition and analysis
  - Plan and framework for leveraging methodologies
  - Coordination with MAARC Data and Analytics Support Core
Matching requirement for for-profit organizations

- Matching: either cost matching or documented in-kind contributions is required for for-profit organizations responding to these FOAs.

- The for-profit awardee is required to match funds or provide documented in-kind contributions at a rate of not less than 50% of the total NIDA award (direct plus F&A costs), as stipulated by Public Law 115-141, the Consolidated Appropriations Act of 2018.

- This requirement does not apply to non-profit applicants that include a for-profit consortium in their application.
Budget preparation: CRCs

- In the budget justification, provide budget breakout for activities under each sub-section of the research strategy
- See details in the FOA, Section IV., 2. R&R Budget
- **Budgets should include funds for:**
  - Personnel
  - Travel to kickoff meeting and steering committee meetings
  - Data harmonization and trans-JCOIN activities
Budget preparation: CTC and MAARC

- In the budget justification, provide budget breakout for activities under each sub-section of the research strategy
- See details in the FOA, Section IV., 2. R&R Budget
- Budgets should include funds for:
  - Personnel
  - Travel and support to coordinate a kick-off meeting and steering committee meetings
Budget preparation: reminders

- Your budget is a fiscal expression of your science
- Prepare a detailed budget justification
- Any programmatic escalation in future years should be described clearly in your budget justification
- Justify, justify, justify!
Summary
# Summary of FOAs

<table>
<thead>
<tr>
<th>FOA</th>
<th>Award Budget (Direct Costs)</th>
<th>Clinical Trial</th>
<th>Number of Awards Expected</th>
<th>Unique Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Centers (RFA-DA-19-025)</td>
<td>$1.5M</td>
<td>Optional</td>
<td>8-12</td>
<td>Contact PI Commitment of ≥ 2 Person Months</td>
</tr>
<tr>
<td>Coordination and Translation Center (CTC) (RFA-DA-19-024)</td>
<td>$2.5M</td>
<td>Optional</td>
<td>1</td>
<td>Support for Steering Committee Chair</td>
</tr>
<tr>
<td>Methodology and Advanced Analytics Resource Center (MAARC) (RFA-DA-19-023)</td>
<td>$2.5M</td>
<td>Not Allowed</td>
<td>1</td>
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</table>
Coordination and Translation Center

Steering Committee

Methodology and Advanced Analytics Resource Center

Clinical Research Centers

Multisite Study

- Justice setting(s)
- Community-based service provider(s)

8-12 CRCs expected

Communities (≥ 5 per CRC)

Administrative Core

- Rapid Response & Pilot Research
- Research Education
- Implementation and Translation Research Project
- Dissemination and Stakeholder Engagement

NIDA Oversight Committee(s)

NIDA (SOs & POs)

Federal Advisory Board

External Stakeholder Advisory Board

Administrative Core

- Advanced Methodological Research
- Policy & Practice Observational and Survey Research
- Data and Analytics Support
- Core 2 (Opt)
- Core 3 (Opt)
- Modeling Core
Cooperative Agreement Terms & Conditions

- As cooperative agreements, the FOAs outline responsibilities for:
  - PD(s)/PI(s)
  - NIDA Project Scientists
  - NIDA Program Officials
  - NIH as funder
  - Areas of joint responsibility

- Grantees accepting an award via this FOA agree to these terms and conditions
Key Dates

- Earliest Submission Date: January 27, 2019
- Letter of Intent Due Date: January 27, 2019
- Application Due Date: February 27, 2019
- Scientific Merit Review: June/July 2019
- Advisory Council Review: October 2019
- Earliest Start Date: September 2019
Contacts

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    Email: pfleming@mail.nih.gov
Questions

For a copy of today’s webinar and slides, please go to:

https://www.drugabuse.gov/news-events/meetings-events/2019/01/jcoin-technical-assistance-webinar

Email Inquiries: jcoin@nida.nih.gov