National Institutes of Health
Turning Discovery Into Health

HEALing Communities Study
Part of the NIH Helping to End Addiction Long-term (HEAL)
Initiative in partnership with SAMHSA

Technical Assistance Webinar
October 3, 2018

Agenda

Time	Topic	Presenter
1:00 – 1:10	Opening Remarks, Introduction of NIDA & SAMHSA Staff	Jennifer Villani
1:10 – 1:45	HEALing Communities Overview & Applicant Requirements	Redonna Chandler, Chris Jones, Carol Alderson, Tracy Waldeck
1:45 – 2:25	Questions from Participants	All
2:25 – 2:30	Closing	Jennifer Villani

Background

▸ Opioid overdose fatalities continue to rise with a recognized gap between those needing and receiving interventions

▸ Multiple effective prevention & treatment interventions exist to address opioid misuse, OUD, and overdose

▸ Effective interventions have failed to penetrate community settings

▸ Strategies are needed to help communities:
   ▸ Understand their unique needs
   ▸ Develop a response strategy that integrates evidence-based prevention & treatment interventions across multiple settings

Goals of the HEALing Communities Study

▸ Develop and test strategies to help communities respond rapidly and effectively to their opioid crisis with a focus on significantly reducing opioid-related overdose fatalities and improving other outcomes

▸ Measure the impact of integrating evidence-based prevention and treatment for opioid misuse, OUD, overdose, and overdose fatalities across multiple settings (healthcare, behavioral health, justice, etc.)

▸ Determine factors (structural, organizational, policy, etc.) that contribute to successful implementation and sustainability of the community strategy and integrated care

▸ Determine the incremental costs and cost-effectiveness of a coordinated integrated evidence-based prevention & treatment system compared to standard of care

Required Study Outcomes

▸ **Primary Outcome:** Reduce opioid related overdose fatalities by 40% in 3 years

▸ **Secondary Outcomes:**

- ▸ Decrease rates of non-fatal opioid related overdose events
- ▸ Decrease misuse of opioids, OUD, progression in severity to OUD or injection drug use
- ▸ Increase # individuals receiving medication & behavioral treatment
- ▸ Increase # individuals retained in treatment beyond 6 months
- ▸ Increase # individuals receiving recovery support services
- ▸ Other related secondary outcomes determined by communities & investigators

Community Structural Changes – FOA Goals

▶ Change prescribing patterns to reduce supply of prescription opioids in community

▶ Expand prevention, treatment, recovery services in healthcare, behavioral health, and justice settings

▶ Increase number of specialized treatment programs providing medication for OUD

▶ Increase # providers prescribing/monitoring use of medications for OUD

▶ Increase availability of naloxone across a community to reduce fatal overdose

▶ Increase use of screening and brief intervention to address opioid misuse within healthcare settings

▶ Increase # partnerships between justice settings and healthcare organizations to deliver OUD care to justice population

▶ Other structural changes determined by communities & investigators

HEALing Communities Study

▸ UM1 Research Project with Complex Structure Cooperative Agreement

▸ Award Project Period: 4 years

▸ Only one (1) application per institution is allowed

RFA-DA-19-016: Research Sites (UM1 - Clinical Trial Required)

▸ Number of Awards: up to 3 Research Sites

▸ Funds Available: up to $89.5M in FY 2019, $96.5M in FY 2020 and 2021, and $48.5M in FY 2022*

RFA-DA-19-017: Data Coordinating Center (UM1 - Clinical Trials Not Allowed)

▸ Number of Awards: 1 Data Coordinating Center

▸ Funds Available: up to $6.5M in each year during FY 2019-2022*

*Subject to availability of funds

Leveraging Other Resources

▶ If appropriate, applicants are encouraged to take advantage of infrastructure supported by NIH:

▶ Examples include but are not limited to:

  ▶ Clinical Trials Network funded by NIDA

  ▶ Clinical and Translational Science Award Program funded by NCATS

  ▶ IDeA Program Infrastructure for Clinical and Translational Research funded by NIGMS

Research Site Requirements

([RFA-DA-19-016](RFA-DA-19-016))

Highly Affected Communities: FOA Specifications

- Counties, Towns, or Cities (or a justified aggregate of counties, towns, or cities functioning as one community)
- All communities must be within a single state
- Minimum of 15 communities per application
  - 30% of enrolled communities must be rural
  - Example: 15 total communities = ~4 rural communities
- Focus on states and communities burdened with higher than average rates of opioid-related overdose morbidity/mortality/health consequences
- States in top third of age-adjusted drug overdose death rates in 2016 (per CDC) are of special interest

Highly Affected Communities: FOA Specifications – Overdose Deaths

- Minimum threshold of Opioid Overdose Deaths:
  - At least 150 opioid related overdose fatalities and rate of 25 opioid related overdose fatalities per 100,000 persons or higher, based on most recent complete year of data available **across all communities in the application**
    - Can average most recent two years to make stronger case of highly affected community
    - Encourage states and communities to use 2017 mortality data if available
  - At least 22 opioid related overdose fatalities experienced by the rural communities (i.e., 15% of 150) in aggregate
    - 15% requirement does not apply proportionally once threshold number of deaths is reached
  - Need to ensure sufficient number of deaths occurring in the study communities to detect a difference over the study period
    - Ensure rural areas included are impacted by the opioid crisis

Research Site Personnel Requirements

▶ PD/PI must commit minimum of 5 person months annually over duration of grant award

▶ Highly involved governmental official (e.g., high-level official in the state substance abuse agency) must be included as key personnel. This person must:

   ▶ Have documented ability to influence the contracting, type, quality, and integration of multiple systems across all communities involved with the research site to develop a systematic approach opioid crisis

   ▶ Assist in data collection & provision of prevention/treatment interventions

Research Plan Components

▸ **Specific Aims**

▸ **Required Sub-sections**

  ▸ A – Research Plan: 12 pages

  ▸ B – Infrastructure, Partnerships, Collaborations: 6 pages

  ▸ C – Community Engagement & Outreach: 6 pages

  ▸ D – Data Collection, Management, Harmonization: 6 pages

  ▸ E – Systems Science, Implementation & Sustainability: 6 pages

  ▸ F – Health Economics: 6 pages

  ▸ G – Research Site Overview, Management, Operations: 6 pages

▸ **Optional Sub-section**

  ▸ H – Scientific Research Supports: no more than 3 per application with strong justification, 6 pages each

Sub-Section A: Research Plan

▸ **A) Data:**

  ▸ Sources and modeling to determine nature, severity, trends of opioid crisis in communities participating in study

  ▸ Data related to opioid overdose fatalities and mortality rates for past 2 years of data available for communities

  ▸ Plans to improve quality of existing data for primary outcome

  ▸ Plans collect baseline and follow-up data for primary and secondary outcomes

  ▸ Plans to track factors outside study that could impact primary outcome or confound results

▸ **B) Conceptually driven approach to organizing, developing, deploying, measuring, adjusting community driven response**

▸ **C) Approach to selecting, developing, delivering integrated set of evidence-based prevention, treatment, recovery interventions expected to impact primary outcome and other secondary outcomes linked to primary outcome**

  ▸ Diagram labeled "Research Site Organization" that explains the overall structure of the research site and how the subsections of the RFA fit within the overall program

Sub-Section A: Research Plan (cont.)

- D) Rigorous stepped wedge or other group randomized trial study design with detailed power analysis; designs proposing "control" communities should propose how all communities receive some benefit and will not be harmed from participation

- E) Justification for communities selected, how they meet requirements for "highly affected"
  - Data for each community must be included in a table labeled "Community Data Part One"*
    - Overall population, # individuals affected by opioid misuse, OUD, opioid overdose deaths, mortality rates by year for most recent 2 years of available data, indication of whether trend is stable, escalating, or de-escalating

- F) Justification & commitment for all organizations delivering prevention, treatment, recovery services including roles, responsibilities, and services within each community
  - Required to partner with healthcare, behavioral health, justice
  - Encouraged to partner with other community organizations
  - Community based organization data must be in table labeled "Community Data Part Two"
  - Letters of support should include specific information about roles, responsibilities, services provided by organization & involvement in research

*Table shell for "Community Data Part One" available on NIDA website soon

Sub-Section A: Research Plan (cont.)

▶ G) Anticipated set of evidence-based prevention, treatment, and recovery interventions to be implemented

  ▶ Required interventions at individual & structural level

  ▶ Data for evidence-based prevention, treatment, and structural interventions to be implemented must be included in a table labeled "Evidence-Based Prevention and Treatment Interventions"

▶ H) Other proposed secondary aims and outcomes (individual and community impact of opioid crisis)

Sub-Section A: Research Plan (cont.)

▶ I) Measures, use of existing datasets, de novo data collection

  ▶ For de novo data collection, include plan to assist organizations with infrastructure, data management & information systems, staff support, consultation, training, supervision, other resources needed to collect data

    ▶ Information on study measures, existing data collection platforms, de novo data collection must be included in table labeled "Study Measures, Data Tools, and Resources"

▶ J) Approach and timing of baseline and follow-up data collection

▶ K) Analysis plan including quantitative and qualitative analyses and modeling for change over time

▶ L) Data harmonization, integration, and sharing across sites

Sub-Section B: Infrastructure, Partnerships, Collaborations

▸ Academic, government, community, & other partnerships needed to achieve the goals of the research and experience in developing and maintaining successful research collaborations

▸ Resources available (toolkits, decision support tools, platforms, infrastructure, funding) to address opioid crisis including activities like prevention and treatment services, data collection, physician training, etc.

▸ How HHS (SAMHSA, HRSA, CDC) funding for prevention and treatment services will be utilized

▸ Describe plans to reduce health coverage payment barriers related to medication for OUD and supporting services, such as behavioral health services via healthcare exchanges, CMS programs, other payment initiatives

Data related to infrastructure, partnerships, collaborations resources must include table labeled "Infrastructure, Partnerships, and Collaborations"

Sub-Section C: Community Engagement and Outreach

▸ Experience, expertise, and track record of working collaboratively with communities and community-based organizations

▸ Evidence-based approach to community engagement and community coalition building

▸ Plan to actively engage communities in all aspects of the research

▸ Application of principles from community-based participatory research paradigms

▸ Establishment and regular meetings of a Community Advisory Board that includes patients, customers, and family members

Sub-Section D: Data Collection, Management, Harmonization

▸ Plan for data collection, management, quality control, integration, harmonization across common data elements

▸ Approach to dealing with these issues between research sites, and collaboration with the data coordinating center including data sharing

▸ Plan for *collecting* high quality data & *improving* quality of existing data for:

  ▸ Opioid overdose fatalities and fatality rates, including discussion of the medicolegal death investigation system and infrastructure

  ▸ Required secondary outcomes

  ▸ Required structural outcomes

  ▸ Any other opioid-related secondary outcomes of study

Sub-Section E: Systems Science, Implementation, Sustainability Research

▸ Plan for integrating systems science to create a learning healthcare system for opioid misuse and OUD

▸ How emerging effective prevention and treatment interventions will be incorporated, and how the prevention and treatment interventions will be adapted depending on impact

▸ Plan for implementation & sustainability research to understand factors that contribute to successful implementation & sustainability of an integrated evidence-based prevention and treatment system; generalizability of the research-based model developed through this study to other communities dealing with the opioid crisis

Sub-Section F: Health Economics

▸ Approach to interfacing with Data Coordinating Center to develop & collect data needed to address health economics questions

Sub-Section G: Research Site Overview, Management, & Operations

▸ Plan for leadership, coordination, administration, and organization of the research site

▸ Organizational chart explaining overall structure of the research site and how the Subsections of the RFA fit within the overall program

  ▸ Information must be included in flow chart labeled "Management and Operations Overview"

▸ Overall programmatic structure to effectively promote interactions with communities and providers involved with the research, other research sites, the Data Coordinating Center, NIH and SAMHSA, and other key stakeholders

▸ Administrative organization with roles, responsibilities, and clear lines of authority for personnel involved in the center

▸ Project management plans listing study milestones, deliverables, timelines, metrics

▸ Processes for monitoring, reporting, and meeting milestones

▸ Quality control to ensure rapid problem identification and resolution, prioritization of resources, high quality data and publications

▸ Clear communication plan across the research site and their partners, the NIH and SAMHSA, other research sites, and the Data Coordinating Center

  ▸ Information related to meetings, teleconferences, communication platforms must be included in diagram labeled "Communication Plans"

Sub-Section H: Scientific Research Support Unit(s) (Optional)

▸ Up to 3

▸ Other scientific research support units are those necessary to support the research agenda

▸ Not included in other sections

▸ Full description with strong justification needed

Letters of Support

- Required:
  - Letter documenting approval for the high-ranking state official to participate as key personnel in the research
  - Letters from all community based organizations (healthcare, behavioral health, justice, police, fire departments, faith-based organizations, housing, employment, paramedics, and others) indicating a willingness to adapt, change, expand prevention and treatment services; provide existing data or assist in de novo data collection; and participate in other activities related to the study
  - For-profit applicants must include letter(s) of support confirming that the required secured cost matching (cash; in-kind commitments such as salary, consultant costs, equipment) is available and confirm that the essential personnel have the authority within the organization to allocate resources
- Also encouraged are support letters from state and local government entities to demonstrate strong commitment and support for the applicant to conduct the proposed research study in their communities

Resource Sharing Plan

▶ All applications, should provide a plan for sharing data with other research sites and the Data Coordinating Center

▶ Data Sharing Plan detailing how data will be made publicly available

Review

- HEALing Community Research Sites
  - Review is planned for January/February 2019
  - There is a strong possibility that review may involve a site visit to evaluate the strength of infrastructure, partnerships, and resources proposed to support the research
  - The timing and details of the site visit forthcoming
  - NACDA performs the second level of review

Funding Decisions

▸ HEALing Community Research Sites

  ▸ Scientific and technical merit of the proposed project as determined by scientific peer review.

  ▸ Availability of funds

  ▸ Relevance of the proposed project to program priorities

  ▸ Research site infrastructure, community networks and organization

  ▸ Infrastructure and resources available to deliver and support prevention and treatment services

  ▸ There is a need to maximize geographic diversity to enhance the understanding of the opioid epidemic across the country. Therefore, **NIDA intends to only make one award per state**

  ▸ The HEALing Communities Study is designed to examine the impact of a comprehensive set of prevention and treatment interventions in the most highly burden communities in the U.S. Therefore, there is special interest in funding applications from states ranking in the top third of per capita age-adjusted drug overdose death rates in 2016, based on mortality data from the CDC

Data Coordinating Center

(RFA-DA-19-017)

Data Coordinating Center Personnel Requirements

▶ PD/PI must commit minimum of 5 person months annually over duration of grant award

Data Coordinating Center Research Plan Components

▶ **Specific Aims**

▶ **Required Sub-sections**

    ▶ A – Research Plan: 12 pages

    ▶ B – Coordination & Communication: 6 pages

    ▶ C – Data Management: 6 pages

    ▶ D – Health Economics: 6 pages

    ▶ E – Data Coordinating Center Overview, Management, Operations: 6 pages

▶ **Optional Sub-section**

    ▶ F – Scientific Research Supports: no more than 3 per application with strong justification, 6 pages each

Sub-Section A: Research Plan

- Describe overall approach to providing:
  - Logistical support for collaborations/communications between NIH, federal partners, SAMHSA, HEALing Communities Study steering committee, research sites
  - Supporting steering committee, research sites
  - Providing data management, modeling, analysis support
  - Conducting health economics research to determine cost, cost effectiveness, and economic models related to study
    - Diagram labeled, "Data Coordinating Center Organization" explaining the overall structure of the DCC and how the subsections of the RFA fit within the overall program

Sub-Section B: Coordination & Communication

- Plan to support cross-site collaborations & communications including at minimum:
  - Operational & logistic support for activities & meetings of cooperative, including working groups (Steering Committee, workgroups, subcommittees)
  - Public project website
  - Study metrics, collect data, develop and maintain web-based metric dashboards (use 4DX framework)
  - Web-based project collaboration platform to facilitate communication collaboration, document sharing/storage
  - Maintain up-to-date versions of policies and procedures for cooperative
  - Support steering committee in all study related activities
  - Conceptually driven dissemination plan
  - Assist research sites in development of materials to use with communities and community-based organizations
    - Table or diagram required illustrating how DCC will facilitate communication labeled "Coordination and Communication Plan"

Sub-Section C: Data Management

▸ Provide expertise and coordination to ensure compliance with all government policies & requirements related to clinical research & protection human subjects – Central IRB, expertise on use of personally identifiable health data, harmonization of consent across research sites

▸ Develop & implement common data elements, instruments, case report forms, approaches to data collection, improving quality existing data, collection of de novo data for primary and secondary outcomes

▸ Lead development of policies, procedures, data use agreements, data collection, use, sharing, analyses

▸ Provide federally compliant online infrastructure support submission/transmission research data, including clinical data

▸ Monitor data quality

▸ Compile integrated datasets, develop codebooks, data file documentation

▸ Support requests from NIDA/SAMHSA for data files

▸ Prepare de-identified public use data files

Sub-Section C: Data Management (cont.)

▸ Provide consultation to research sites on accessing & integrating existing data related to study

▸ Conduct cross-site analyses for research questions

▸ Maintain expertise on state of the art and emerging study designs, methodologies, statistical & analytical techniques

▸ Assist research sites in development and collection of baseline data and follow-up data

▸ Develop & collect metrics data to monitor study activities & research site performance

  ▸ Table titled "Data Tools and Resources" required listing tools for data related activities

Sub-Section D: Health Economics Research

▸ DCC responsible for designing & conducting health economics research

▸ Propose scientifically rigorous economic evaluation to determine incremental cost, cost effectiveness of hypothetical coordinated integrated evidence-based prevention/treatment system compared to standard of care across communities participating in research with respect to reducing overdose fatalities by 40%

▸ Study aims, approach, design, measures, datasets, de novo data collection, analysis plan should be described

▸ Propose simulation modeling (existing, adapted, or new) that can be used to add to scientific yield of study; show how data from multiple sites with different protocols might be incorporated into model to address additional questions

▸ Any additional health economics studies that advance overall goals of study

Sub-Section E: Data Coordinating Center Overview, Management, and Operations

▸ Plans for DCC leadership, coordination, administration, operations

▸ Organizational chart with overall structure of DCC

▸ Overall programmatic structure to promote collaboration and communication

▸ Administrative organization with roles, responsibilities, lines of authority

▸ Project management plans and processes

▸ Quality control to ensure rapid problem identification, resolution, prioritization of resources, data, publications

   ▸ Diagram of management and operations including meetings & teleconferences to facilitate communication required labeled "Management and Operations Overview"

Sub-Section F: Scientific Research Support Unit(s) (Optional)

▸ Up to 3

▸ Other scientific research support units are those necessary to support the research agenda

▸ Not included in other sections

▸ Full description with strong justification needed

Letters of Support

- Letters from key partners involved with DCC activities
- Letters demonstrating institutional commitment, commitment from other organizations assisting with data platforms, tools, services

Resource Sharing Plan

- Data Sharing Plan across cooperative
- Data Sharing Plan detailing how data will be made publicly available

Review

- HEALing Communities Data Coordinating Center
  - Review is planned for January/February 2019
  - Site visit is not planned for this review
  - NACDA performs second level of review

- Funding Decisions
  - Scientific and technical merit of the proposed project as determined by scientific peer review
  - Availability of funds
  - Relevance of the proposed project to program priorities.
  - Data Coordinating Center infrastructure and prior experience of the PD/PI in coordinating complex research programs

Budget Information

Budget preparation: reminders

‣ UM1 mechanism: 4 years

‣ 1 Data Coordinating Center (funds available $6.5M per year)

‣ 2-3 Research Sites: (funds available $89.5M FY 19; $96.5M FY 20-21; $48.5M FY 22)

‣ The PI of the Research Sites and DCC must commit five person months over the life of the award.

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: Research Sites

- In the budget justification, provide budget breakout for activities under each sub-section of the research strategy
- See details in the RFA, Section IV., 2. R&R Budget
  - Personnel
  - Travel to kick off meeting, steering committee meetings, and workgroup meetings
  - Support to research site
  - Support for communities and CBOs
  - Some support to address gaps (see RFA) may be included; however, it is expected that research sites will draw on federal, state, local, other resources to cover prevention and treatment services

Budget preparation: Data Coordinating Center

‣ In the budget justification, provide budget breakout for activities under each sub-section of the research strategy

‣ See details in the RFA, Section IV., 2. R&R Budget

  ‣ Personnel

  ‣ Travel and support to coordinate a kick off meeting, steering committee meetings, as well as workgroup and subcommittee meetings

  ‣ Data Coordinating Center budget to support Steering Committee Chair travel and level of effort

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!

▸ How to prepare a competing detailed budget

▸ https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#personnel

Cooperative Agreement Terms & Conditions

- As cooperative agreement FOA outlines responsibilities for:
  - PD(s)/PI(s)
  - Data Coordinating Center
  - Steering Committee
  - NIDA and SAMHSA Project Scientists
  - NIDA Program Official
  - 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   November 11, 2018
- Letter of Intent   November 11, 2018
- Application Due Date   December 11, 2018
- Scientific Merit Review   January/February 2019
- Advisory Council Review   May 2019 (expedited)
- Earliest Start Date   February 2019

Contacts

▸ For more information contact:

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Questions

▶ For slides and other information from today's webinar go to:

https://www.drugabuse.gov/drugs-abuse/opioids/nih-heal-initiative/healing-communities-study