



May 19, 2022

NIH HEAL Initiative Research-Dissemination and Engagement Center (R-DEC)

OTA-22-005

**Participating Organization(s):** National Institutes of Health

**Components:** This Other Transactions Research Opportunity Announcement (OT ROA) is part of the *Helping to End Addiction Long Term® Initiative, or NIH HEAL Initiative®*. The research opportunity will be administered by the NIH Immediate Office of the Director.

**Funding Instrument:** The funding instrument is the Other Transactions (OT) Award mechanism. OT awards are not grants, cooperative agreements, or contracts, and use an Other Transactions Authority, provided by law. Policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the recipient and details specific terms and conditions for that award.

**Research Opportunity Purpose:** The purpose of this announcement is to invite applications from eligible organizations to implement and support activities in the role of the **HEAL Research Dissemination and Engagement Center (R-DEC)**. **The successful applicant(s) will work closely** with the NIH HEAL Initiative and with other awarded organizations to meet the needs of the overall program.

Given the urgency of the evolving opioid crisis, the results of HEAL research must reach affected people and communities as quickly as possible. HEAL intends to disseminate findings and data as broadly as possible, including to pain and addiction researchers, the broader research community, and various non-researchers and community groups. The evidence built upon decades of NIH efforts in community-engaged research supports the benefit of enabling a more robust focus on meaningful engagement within the NIH HEAL Initiative infrastructure. To successfully reach these audiences and engage them in meaningful ways, HEAL will fund the R-DEC to interface with the HEAL research community, key partner organizations, and the intended beneficiaries of this research. The R-DEC will work closely with the existing HEAL Data Ecosystem that accelerates sharing of HEAL-generated data and enabling HEAL data to be searched, analyzed, and used to make new discoveries. Most importantly, this partner will understand and translate data and findings in ways understood at the community level to address needs and priorities of communities standing to benefit most from HEAL research.

The R-DEC will generate, manage, and coordinate processes and products that connect the growing evidence base of HEAL research with communities, organizations, government entities, and other potential beneficiaries of HEAL research results. Applications should include proposals for the initial planning phase of the HEAL dissemination and community engagement program to define and develop culturally appropriate, inclusive ways to communicate with the beneficiaries of HEAL research. The R-DEC will identify diverse stakeholders both within and outside the research contexts that are impacted by the opioid crisis and underlying challenges with pain and pain management, and apply community engagement strategies to create awareness, provide education, and build strong bidirectional relationships with these groups. Applications may include multiple organizations as needed to ensure



the best balance of expertise and capabilities. During award phase, the R-DEC will be expected to identify and support additional partners to sustain community engagement activities and augment the skills and expertise to achieve the tasks outlined under the core functions described below, and other areas of need identified during the initial year and planning activities.

**Objective Review:** NIH will convene an appropriate review group comprised of internal NIH program staff who have expertise in running community engagement and outreach projects to evaluate applications. See the Objective Review section of this opportunity for further details.

**Eligibility:** See the Eligibility section of this opportunity.

**Funds Available and Anticipated Number of Awards:** The budget for this activity is planned for up to \$25 million over a 5-year period, including the operations and support for the R-DEC as well as any proposed activities, sub-projects, infrastructure, or investments, once established. The OT mechanism allows for significant flexibilities to make adjustments as needed to pursue new and transformative activities. HEAL intends to issue up to four (4) awards as a result of this ROA. Award levels may increase or decrease over time based on programmatic needs, funding availability, and recipient performance. Requested budgets must be justified based on proposed milestones and deliverables.

**Award Project Duration:** Project duration is anticipated to be five years, but may be shortened or extended, as needed.

**Authority:** Other Transactions awards will be made pursuant to current authorizing legislation, including Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n), as amended.

**Release Date of this Research Opportunity Announcement:** May 18, 2022

**Informational Webinar (optional):** June 1, 2022

**Letters of Intent Due Date:** June 13, 2022

**Application Due Date:** July 18, 2022

**Earliest Start Date:** October 2022

**Kickoff Meeting:** TBD

#### Agency Contacts

Scientific Research Contact(s): Address questions to [HEALOTCorrespondence@od.nih.gov](mailto:HEALOTCorrespondence@od.nih.gov) using the subject line "HEAL Engagement ROA/name of your institution or organization".

Agreements Officer: Quintin Hackshaw; [quintin.hackshaw@nih.gov](mailto:quintin.hackshaw@nih.gov)

Agreements Specialist: Dianna Bailey; [dianna.bailey@nih.gov](mailto:dianna.bailey@nih.gov)



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Outline of this Opportunity

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## Overview of the HEAL Research Dissemination and Engagement Center

### Background

In response to opioid crisis, NIH launched the [Helping to End Addiction Long-term \(HEAL\) Initiative](#), a trans-NIH effort spanning basic, translational, clinical and implementation science on opioid misuse, addiction, pain, and related condition. By the end of FY 2021, HEAL funded nearly \$2 billion [in research](#), representing more than 600 research projects across the United States. These projects aim to identify new therapeutic targets for both pain and opioid use disorder, reduce the risk of opioids through nonpharmacological strategies for pain management, and improve overdose and addiction treatment in a variety of settings.

Biomedical research aims to improve human health, and data dissemination is key to implementing and interpreting findings appropriately across communities. Rapid availability of publications and the primary data behind them promotes dissemination of new knowledge, enhances reproducibility, and accelerates the ability to make new discoveries. The NIH HEAL Initiative intends to disseminate research findings and data as broadly as possible to pain and addiction researchers, along with the broader research community and non-researcher groups through the [HEAL Data Ecosystem](#) and other efforts. To that end, the overarching goal of this research opportunity announcement (ROA) is to develop and implement a new central NIH HEAL Initiative resource, referred to as the HEAL Research Dissemination and Engagement Center (R-DEC). The awardee will be an integral part of the Data Ecosystem and is expected to lead engagement, partnerships, activities, and training towards enhanced dissemination.

The R-DEC will also be expected to work closely with HEAL investigators and other HEAL Data Ecosystem awardees to create a feedback loop of communication. The R-DEC will sit at the interface between the general public, HEAL researchers, and the HEAL Data Ecosystem, ensuring that all input is integrated into



data sharing and result dissemination practices. By encouraging interdisciplinary collaboration and partnerships, the HEAL Research Dissemination and Engagement Center will ensure that HEAL research results are broadly and appropriately disseminated.

## The HEAL Research Dissemination and Engagement Coordinating Center

Building and sustaining trusted partnerships with groups impacted by the opioid crisis and related health conditions (e.g., pain, sleep, mental health, behavioral health, etc.) are core elements of the R-DEC. These partnerships will inform various activities along the HEAL Initiative's research development pipeline, including but not limited to results dissemination, study planning, and training development for the HEAL investigator community. It is expected that communities engaged through the R-DEC will vary in terms of their research interests and knowledge around data sharing. A one-size-fits-all approach to infrastructure, training, research directions, or engagement will not achieve the goals of the NIH HEAL Initiative. Applications to this solicitation must address each component below, either through their own expertise, collaborative applications, or inclusion of plan(s) to formally solicit, identify, and support additional expertise.

All applicants are expected to demonstrate their ability to leverage existing resources and expand community partnerships (e.g., Tribal governments and agencies, academic, private, safety-net health systems, grassroots organizations, public health departments, community and faith-based organizations, and schools or childcare settings) and employ strategies that enhance outreach and dissemination activities to inform communities about HEAL research and its findings. Establishing an additional Community Engagement Advisory board(s) that complement and augment the efforts of the [HEAL Community Partner Committee](#) and consists of diverse membership in expertise, demographics, and knowledge is a requirement of the R-DEC. Approaches such as team science, community-engaged research, participatory action research, and related approaches should be used to engage communities and underserved and/or disproportionately affected populations to enhance bi-directional relationships between these groups, HEAL, and the HEAL researchers. Study budgets should include funds to support the community partners to be fully engaged and successfully participate in research design, implementation, and results dissemination.

## R-DEC Core Components

### **BUILD AND SUSTAIN COMMUNITY PARTNERSHIPS**

Communication and outreach functions include assessing the HEAL research portfolio and current community engagement landscape across HEAL awards, identifying areas for new and increased partnerships, and establishing long-term, bidirectional relationships with community members and organizations who understand the dynamics of, and serve populations impacted by the opioid crisis and affected by conditions studied through HEAL research. The team completing this work should include individuals who have expertise in relationship development that involves building new relationships and improving existing relationships with or within communities.

It is important that the community engagement activities are inclusive and not focused on a particular professional organization or community group. Representation from diverse individuals and communities is essential for success, along with an understanding of differences in health and health



care that are closely linked with social or economic disadvantage. Under this core, the successful applicant will be expected to:

- Conduct a landscape analysis to understand HEAL’s portfolio, current outreach methods, and outreach needs;
- Develop an engagement and outreach plan tailored to HEAL and informed by the landscape analysis;
- Build trusted partnerships with communities and individuals that are part of and affected by NIH HEAL Initiative research, including but not limited to clinicians and community care providers; advocacy groups with interest in pain, addiction and other research areas relevant to HEAL such as mental and behavioral health; patients and people with lived experience; and service organizations or community-based organizations in HEAL’s focus areas;
- Effectively engage with at risk population such as racial and ethnic groups, low - income individuals and families, individuals who are incarcerated and those who have been incarcerated, individuals with disabilities, individuals with mental health conditions, youth and young adults, and American Indians and Alaska Native communities;
- Interface and collaborate with programs across HEAL, including NIH program staff, HEAL awardees, and the communities that they engage with;
- Run focus groups and listening sessions to determine culturally appropriate data dissemination approaches and inform other aspects of HEAL research processes;
- Establish communications channels and mechanisms to provide feedback and input to Data Ecosystem awardees and report back on progress to community groups; and
- Establish and administer Board(s) that include a diverse ecosystem of partners and leaders engaging in and working with impacted communities across the country.

#### **SUPPORT HEAL RESEARCHERS TO MEANINGFULLY SHARE FINDINGS**

HEAL researchers have a wide range of expertise and skill levels relevant to data dissemination and communication. Under this core, the successful applicant(s) will develop resources and provide services to support investigators in the dissemination of study results to the broader community. This includes distilling complex research findings into audience appropriate and culturally appropriate summaries, data visualizations, and other products. The resources and services will help to broaden HEAL investigators’ incorporation of evidence-based engagement and outreach strategies, and support appropriate consumption of HEAL Initiative research findings. Under this core, the successful applicant will be expected to:

- Serve as a central resource for new and existing HEAL-funded programs by connecting them to appropriate community partners in order to better understand the best ways to incorporate their concerns, needs and values into all levels of the research processes, including data and results dissemination;
- Identify HEAL research groups with ongoing engagement support; collate for central dissemination research findings and communication materials prepared by these groups and their partners;



- Coordinate with new and existing partners to translate HEAL research findings, and develop communication products based on unique community needs;
- Develop appropriate communication, data visualization, and infographic products for HEAL, where HEAL research and communications teams are not already doing so;
- Develop HEAL data use cases that include examples of community needs to inform Data Ecosystem data displays and dissemination mechanisms;
- Develop culturally tailored trainings on community engagement and best practices for HEAL researchers to leverage as they integrate community input into their study planning and results dissemination;
- Develop resources for investigators to understand and integrate culturally appropriate measurement strategies and assessment selection, and support implementation for different populations; and
- Develop resources for appropriate procedures for non-English speakers, for example translating measures and documents to non-English languages.

#### ADMINISTRATION AND PROJECT MANAGEMENT

Under this core function, the successful applicant(s) are expected to lead and manage the R-DEC and its partnerships and sub-awards. This will require substantial project management capabilities to ensure coordination among the different activities and strict adherence to timelines and budget. The administrative function must be rigid in its planning and tracking, yet flexible enough to meet the progressing needs of the NIH HEAL Initiative and its various partners and stakeholders. Under this competency, the successful applicant will:

- Manage overall project, including but not limited to careful tracking and reporting of partnerships, sub-projects, meetings, and other administrative tasks;
- Apply expertise in the development and use of research instruments (surveys, assessment tools, etc.) to measure HEAL's needs and successes related to community engagement;
- Develop processes for transparent reporting on project status;
- Establish processes to communicate and share information across groups, including internal and external partners (e.g., NIH, other HEAL awardees, sub-awardees to this award);
- Manage and track budget;
- Manage and track sub-awards.

#### Partnering with other applicants and other teaming arrangements

To ensure the best balance of expertise and capabilities, individual applications may be submitted by multi-institutional partners. Once established, the **HEAL Research Dissemination Center (R-DEC)** is expected to identify and manage sub-awards beyond those included in the initial NIH award to support engagements, assessment, pilot projects, and capacity building with community partners. The R-DEC will identify, compete (as needed), justify, and manage these contractual arrangements and associated relationships in partnership with NIH as subject to the OTA award.



Team science is critical to the success of the R-DEC, which will bring together teams with broad arrays of expertise, as well as technical and non-technical backgrounds in a multi-team system. The R-DEC must include the expertise and diverse viewpoints needed to support team science across all core components, and work closely with other teams across HEAL.

It is anticipated that the R-DEC program may begin as a multidisciplinary endeavor, with each team member bringing individual expertise. During negotiations, if it is determined that more than one award will be made, it is expected that each team will work collaboratively to integrate the core components based on their unique strengths, sectors and viewpoints into a synergistic team to accomplish project goals. Teaming enables interdisciplinary and inclusive team science within the R-DEC, including:

- Task integration, creating a governance structure and shared common workflows within the R-DEC, including representation from the broader HEAL Data Ecosystem as appropriate.
- Relationship Building and Social integration, from individual relationships to establishing a culture in which a diverse array of participants can thrive, to promote optimal team formation and functioning, efficiency in communication and decision making, and leadership development of participants throughout career stages.
- Team Formation, identifying needed areas of expertise and brokering new partnerships as needed, including partnerships with individuals from diverse social, cultural, economic, academic, industrial, and technical/non-technical backgrounds.
- Executing core elements of the R-DEC, with focus on recruitment strategies, career development and mentoring opportunities, outreach and partnering with various groups and communities, and other strategies to advance inclusivity in alignment with the program goals.

## Eligibility

Applications that do not meet the eligibility criteria or are otherwise non-responsive to the terms of this ROA will not be considered. The following types of projects would generally not be appropriate and may be deemed non-responsive:

- Applications from entities that lack direct experience in community engagement with a broad range of diverse partners.
- Applications that do not demonstrate an understanding of the breadth of the HEAL Initiative needs.
- Applications that do not demonstrate an understanding of health disparities.
- Applications that do not demonstrate an ability to engage and collaborate with diverse researchers, non-researchers, and various organizations.
- Applications that do not explicitly address and advance the NIH HEAL Initiative goals.
- Applications that do not meet the eligibility criteria above or that do not explain how these criteria are met.

## Organizations

Non-domestic (non-U.S.) Entities (Foreign applicants) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components **are not** allowed.



Foreign consultants are allowed if approved by the NIH official in advance of the full application submission.

The R-DEC OT may be awarded to organizations that are domestic, public, private, non-profit, or for-profit. Eligible organizations include small businesses, federal institutions, institutions of higher education, and other non-profit organizations such as community-based organizations. The full list of entities that are eligible to apply under this ROA include:

*Higher Education Institutions*

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

*Nonprofits Other Than Institutions of Higher Education*

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Faith-based or Community-based Organizations
- Regional Organizations

*For-Profit Organizations*

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

*Governments*

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- American Indian/Native American Tribal Governments (Federally Recognized)
- American Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession Other
- Independent School Districts
- Native American Tribal Organizations (other than Federally recognized tribal governments)

**Multiple Principal Investigators**

More than one individual may be named as Principal Investigator in the application. One individual must be identified as the contact Principal Investigator. The contact Principal Investigator must be employed by or affiliated with the applicant organization. If a multiple Principal Investigator application is submitted, a leadership plan is required.

**Financial and Risk Assessment**

Applicants may be subject to financial analysis and risk assessment conducted by NIH staff.





## Cost Sharing

Cost Sharing is not required; however, applicants may voluntarily choose to propose a financial plan that includes non-federal resources. The budget submission must clearly identify and justify the use of these resources. Any voluntary cost share must be supported in the application by including a letter of support from the providing organization(s)/individual(s).

## Application Submission Instructions and Contact Information

Complete applications should be submitted under OTA-22-005 via eRA ASSIST not later than the “Application Due Date” shown at the top of this notice, by 5 PM Eastern Time.

To submit an application via ASSIST, the applicant organization must be [registered in eRA Commons](#) (see instructions). Organizations already registered in eRA Commons do not need to reregister. Once the organization is registered, the individual(s) with the role of Signing Official (SO) and Program Director/Principal Investigator (PD/PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process.

Use OTA-22-005 in the field requesting FO Announcement.

Here are [instructions for submitting via the NIH eRA ASSIST system](#). In the future, instructions will also be available in the [ASSIST online help \(look for the OTA section\)](#).

Technical help is available at the [eRA Service Desk](#).

Questions about the scientific scope of the studies should be addressed to [HEALOTCorrespondence@od.nih.gov](mailto:HEALOTCorrespondence@od.nih.gov).

## Developing Applications

Full applications are due by the “**Application Due Date**” shown at the top of this notice. Applicants may also be invited to a virtual, presentation-style review including question and answer time during the application review period. For more details on the review process, see section 6 (Objective Review) below. Partnerships among institutions with complementary skills and expertise to meet the expectations of this ROA are encouraged.

## Letter of Intent

Interested applicants should submit a Letter of Intent (LOI) of no more than 2 pages, no later than June 13, 2022, outlining the following:

- Cover page, as described below for the full application.
- A brief description of the planned activities and approach.
- How the proposed activities will meet the needs of the NIH HEAL Initiative program.
- How the team’s prior experience meets the eligibility requirements, stated above.
- Anticipated institutional or corporate partners.
- Estimated overall budget per year, for all years of the award.
- Current eRA and SAM registration status.



LOIs are not binding, does not guarantee an award(s), and will be used only to help structure review boards and plan review timelines. Letters of intent must be submitted by email as a .pdf attachment to [HEALOTCorrespondence@od.nih.gov](mailto:HEALOTCorrespondence@od.nih.gov).

## Application

Applications will be accepted only from Organizations listed in the Eligibility section of this Announcement. Applications must be prepared and submitted using NIH's ASSIST. The NIH will not review and will return applications submitted from organizations not included in the Eligibility section. Complete applications must be submitted by the Authorized Organizational Representative. The organization must be registered in eRA Commons with one person designated as the primary investigator (PI) and one person designated as the Signing Official (SO). The Signing Official's signature certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the OT award-supported project or activities resulting from the application. Plans must be submitted by the due date, in text-recognizable PDF (Adobe) format, use 11-point font with 1" margins, be single-spaced, may not exceed 12 pages, and the file size must be no greater than 20 MB. The sections of the application should be loaded as separate attachments and should be titled as specified in each section (title included in parentheses following each section).

Cover (label as "Cover.pdf"; no more than 1 page, 11-point font with 1" margins, single-spaced)

1. Number and title of this Research Opportunity Announcement
2. Project Title
3. Core(s) targeted in the application (see "R-DEC Core Components" section above)
4. Names of key personnel, institutional affiliation, title, and percent effort
5. Other involved personnel names, roles, and organizations (multiple Principal Investigators, co-Investigators, collaborators, contractors, authors of letters of support, etc.)
6. Name and address of the submitting organization and department
7. Authorized Organizational Representative first and last name, title, institution, mailing address, email address and phone number
8. Approximate budget per year per core component (direct and total)
9. Proposed Project Period Dates
10. Confirmation that the work involves human subjects or data from human subjects
11. Agreement that any and all parts of the application can be shared among other applicants

Senior/Key Personnel and Other Significant Contributors (label as "Senior/Key.pdf"; no more than five pages per individual, 11-point font with 1" margins, single-spaced). At a minimum, the information in the biosketch should include the name and position title, education/training (including institution, degree, date (or expected date), and field; list of positions and employment in chronological order (including dates); and a personal statement that briefly describes the individual's role in the project and why they are well-suited for this role. The format (<https://grants.nih.gov/grants/forms/biosketch-blankformat.docx>) used for an NIH grant application is acceptable.



Applications may include letters of support from potential partners or organizations and institutions that have existing relationships with the applicant. Letter of support are not included in the application page limit.

Application research plan (label as "Application.pdf"; no more than 12 pages including any charts or figures, 11-point font with 1" margins, single-spaced) should be organized into the following sections to facilitate review:

**Section 1: Planned activities and approach:**

**All applications** should describe the proposed activities and approaches for each targeted core component (see "R-DEC Core Components" section above) and how these will meet:

- the overall goals of the NIH HEAL Initiative;
- the specific expectations for each core component, as described above;
- and the eligibility requirements as described above.

Appendix: PHS Human Subjects and Clinical Trials Information (appendix to study plan; no page limit)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" you will need to go to the optional forms and select the Human Subjects and Clinical Trials Information form. This will then appear on your forms tab and you can complete as it applies to the study. You must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record located in the optional forms in ASSIST for this OT.

- **Study Record: PHS Human Subjects and Clinical Trials Information** ○ All instructions in the SF424 (R&R) Application Guide must be followed.

- **Delayed Onset Study** ○ Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

Have questions about whether you are conducting a clinical trial? Please reference the following website to learn more: <https://grants.nih.gov/ct-decision/index.htm>

Additional information to include in the submission:

- Institutional Letter of Support ("Institutional Support.pdf"): A letter of support from the applicant's organization indicating institutional commitment for the project, e.g., relaying support for contributions (including, but not limited to, support for training activities or consortium meetings, licenses, and other resources) and preparations to enter into negotiated other transactions agreements
- Letters of support from proposed collaborators ("Letters of Support.pdf"; e.g., school districts, school related organizations or associations, tribal schools or nations, health care partners)



- A bibliography (“Bibliography.pdf”; no more than 1 page)
- Additional Information (“Additional Information.pdf”; no more than 1 page)
- Information on Select Agents
- Plan for Authenticating Key Biological and Chemical Resources

## Budget Details

The NIH may elect to negotiate any or all elements of the proposed budget. Budget (“Budget.pdf”; no page limitations): Applicants can model their budgets on SF424 budget pages for this section of the application which are available as optional forms in ASSIST or a format that best fits their program. All budgets must be readable by ASSIST. Applications must provide a budget and cost estimate for performing the work. The budget should address costs associated with the Applicant’s group and any collaborators. Budgets for individual awards are expected to vary, depending on the scope of the work proposed, including the number of collaborations involved. NIH anticipates that because of the nature of this project, the awardee may need to modify its award budget during performance to accomplish the award’s programmatic objectives. Therefore, NIH provides some flexibility for awardees to deviate from the award budget, depending on the deviation’s significance to the project or activity. More significant post-award changes require NIH prior approval. Outyear budget estimates must also be provided, but these budgets will be reassessed as the project proceeds and may be increased or decreased depending on progress, the needs of the program, and funds available.

**Provide the overall expected cost for each of the following categories:** personnel, travel, funds for consortium partners or other stakeholders (if applicable), subawards, other direct costs, and total cost (with indirect costs included). Provide a budget justification. Subawards need to provide details of cost breakdown.

**Milestones and Deliverables (“Milestones and deliverables.pdf”:** Applicants must provide a description of the scientific goals and milestones, completion criteria, due dates, how success is defined for a given milestone (e.g., Go/No-Go criteria), and payment/funding schedule (e.g. Gantt chart).

Proposed Milestones and Deliverables table must be as detailed as possible and tied to a project plan and/or Gantt chart with associated estimated budget details.

**Additional requirements for Budget:** budget estimate must include projected expenditures for each year, based on meeting the requirements of the core components, and must include:

1. Breakdown for all personnel by base salary, % of effort, fringe. Note: All salaries shall not exceed the [NIH Salary Cap](#).
2. Detailed line-item budget that shows costs related to travel, equipment, consultants, etc.
3. Provide budget detail by core component, per year
4. Offeror must provide a milestone-driven, cost-allocated plan for the proposal. Cost models can be cost-sharing, fixed-price, or adjustable (cost-reimbursable), or have a hybrid approach. A five-year cost proposal including indirect costs must be submitted. Budget details must be specific



enough for the reviewers to understand the connection between the funds requested and activity to be conducted.

## Objective Review

Applications to Other Transactions Research Opportunity Announcements (ROAs) are not reviewed using the standard NIH peer review process, but using custom processes referred to as Objective Review. Objective Review will involve the submission of written critiques by internal NIH subject matter experts against the Review Criteria described below, and interactive individual discussions between those experts and NIH program staff. Those discussions may also include proposing teams in later stages of the review.

### Scored Review Criteria:

Applications will receive a cumulative score ranging between 0 (worst score) - 60 (best score). The following individual review criteria and their scores will contribute to the final cumulative score

#### Overall components

- The ability of the proposed research teams to implement each of the core functions, and their potential impact if successfully implemented **[30pts total]**
  - Build and Sustain Community Partnerships (10pts)
  - Support HEAL Researchers to Meaningfully Share Data (10pts)
  - Administration and Project Management (10pts)
- Past performance and experience of the team members and complementarity with other recipients **[5pts]**
- The adequacy and appropriateness of the Multiple PI/PD plan, budget, resources, data and resource sharing, and collaboration plans **[10pts]**
- The extent to which a well-developed and feasible timeline and milestones are described, and will contribute to the success of the project through an enhanced environment (e.g. collaborative arrangements, geographic diversity, institutional support) **[15pts]**

#### BUILD AND SUSTAIN COMMUNITY PARTNERSHIPS

- Display ability to build a successful national engagement program with ability to maintain personalized, local relationships in distributed locations across the US, while also facilitating engagement and outreach at a national scale.
- Propose specific plans to develop and manage a flexible model that can be adapted to meet the needs of a variety of external partners.
- Display established connections and a strong track record of working with a variety of groups impacted by pain, opioid use and addiction, mental health, and other health conditions that are prominently studied as part of the NIH HEAL Initiative research portfolio.
- Have expertise in data-intensive, community engaged research or conducted large-scale research efforts that have established long-term relationships with communities.
- Show willingness to work with other program recipients in a collaborative manner.



### **SUPPORT HEAL RESEARCHERS TO MEANINGFULLY SHARE FINDINGS**

- Have experience delivering innovative training and education opportunities to diverse communities with a wide range of skill levels and resources.
- Implement team science foundations to enhance collaborations and manage cross-disciplinary teams and recognize how these processes are related to scientific discovery and translation.
- Show experience with clinical trial design and incorporating participant input into human subjects studies.
- Demonstrate expertise in developing lay-friendly communication materials from publications and/or data covering diverse research topics.
- Recognize various levels of health literacy, and demonstrate ability to develop materials, including graphics, data visualizations, and other products, for audiences with varying interests and expertise.
- Inclusion of science writer(s) and other communications experts skilled in explaining technical content to non-research audiences.

### **ADMINISTRATION AND PROJECT MANAGEMENT**

- Propose sophisticated and automated approaches and solutions to managing large, diverse projects.
- Demonstrate expertise in the development and use of research instruments (surveys, assessment tools, etc.) to measure HEAL's needs and track successes.
- Demonstrate experience and expertise in team process factors, such as the development of shared understanding of team goals and roles, by drawing on aspects of team science—(e.g. composition, professional development, and leadership).
- Display expertise in leading large, complex initiatives.
- Display staff depth to manage meetings, budget, sub-awards, and other tasks and activities relevant to the R-DEC's success.
- Display experience needed to coordinate large projects amongst multiple collaborators.
- Demonstrate willingness to work with other OT award recipients and the HEAL Data Ecosystem in a collaborative manner.

Note that past performance and experience includes not only traditional measures of scientific productivity such as publication counts, invited presentations, or past funding success, but also proposers' demonstrated track record of particular behaviors, community participation, collaborative efforts, openness to sharing data and resources, etc.

Other Transactions agreements will be negotiated with eligible entities whose applications are determined to be the most advantageous and provide the best value to the NIH. Funding decisions will be based on the outcome of the Objective Review and on the desired portfolio balance within the R-DEC program. Up to four projects may be funded. The level of funding for each award made under this solicitation has not been predetermined but will depend on (1) the objectives proposed by the applicants and their fit to the goals of the HEAL Initiative, (2) the quality of the applications received, and (3) availability of funds. Following the review of applications, NIH may combine teams from



different applications in the construction of Other Transactions awards to be made, or individual cores from distinct applications might be selectively funded to achieve the program goals. Additionally, if over the duration of the project, some of the core competencies outlined above either gain or lose relevance to programmatic goals, the funding for such core functions may be increased, decreased, or discontinued.

NIH reserves the right to:

- Invite all, some, one, or none of the Principal Investigators submitting applications in response to this solicitation to present their applications in a web-based videoconference;
- Share applications between and among any proposer(s) as necessary for configuring teams, economizing work, and prioritizing activities;
- Select for negotiation all, some, one, or none of the applications received in response to this solicitation;
- Accept applications in their entirety or select only portions of plans for award. Appeals of the objective review will not be accepted for plans submitted in response to this ROA.

### Special Award Terms and Information

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers and provides the NIH the flexibility to alter the course of awarded activity in real-time to meet the overarching goals. This may mean that an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary. As a result, the NIH reserves the right to:

- Fund projects in increments and/or with options for continued work at the end of one or more phases;
- Fund projects of two or more entities (potentially across different applicants) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Request additional documentation (certifications, etc.); and
- Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.

Applications selected for award negotiation may or may not result in the issuance of an OT award, dependent on the outcome of negotiations, the nature of the work proposed, changing external conditions, and other factors. The NIH reserves the right and sole discretion to engage in negotiation with the selectees applying under this solicitation during all phases of the application lifecycle.

Protests or Appeals: Awards made under Other Transactions Authority (OTA) are not subject to the Federal Acquisition Regulations (FAR) or Uniform Guidance, therefore, the right to protest or appeal shall not apply.

ADDENDUM  
June 10, 2022

For the duration that this research opportunity remains open, the HEAL Initiative will be posting updates, information about upcoming webinar(s) and recordings from past webinar(s), questions received from interested applicants and answers from program staff, and other relevant news and information at this [page](#). This page will be updated regularly and as needed. Please continue to check there for further information.