



HEAL Data2Action Program Pre-Application Webinar

January 24, 2022

Welcome to the Webinar

- This is the Pre-application webinar for the HEAL Data2Action Program.
- Webinar attendees are muted. **Attendees may submit questions at any time through the Zoom Q&A feature.**
- Questions that are not answered live will be answered through a Frequently Asked Questions document that will be posted on the NIDA Events webpage.
- The webinar slides and FAQs will be available approximately one week following this presentation.
- You are encouraged to use the project's email for general questions or to be connected to a NIDA Program Official: HEALdata2action@nih.gov



Agenda

- Introduction of Panelists
- HD2A Program Overview
- RFA Descriptions, Requirements, and Deadlines:
 - HD2A Innovation Grants (RFA-DA-22-051)
 - HD2A Data Infrastructure Support Center (RFA-DA-22-052)
 - HD2A Modeling and Economics Resource Center (RFA-DA-22-049)
 - HD2A Research Adoption Support Center (RFA-DA-22-050)
- HEAL Requirements
- Review Criteria and Process
- Q&A

Webinar Panelists

Tisha Wiley, Ph.D.

Chief, Services Research Branch
National Institute on Drug Abuse
Contact PO for HD2A Innovation Grants

Lori Ducharme, Ph.D.

Services Research Branch
National Institute on Drug Abuse
*Contact PO for HD2A Modeling/Economics
Resource Center and HD2A Research
Adoption Support Center*

Barbara Oudekerk, Ph.D.

Prevention Research Branch
National Institute on Drug Abuse
*Contact PO for HD2A Data Infrastructure
Support Center*

Trinh Tran, Ph.D.

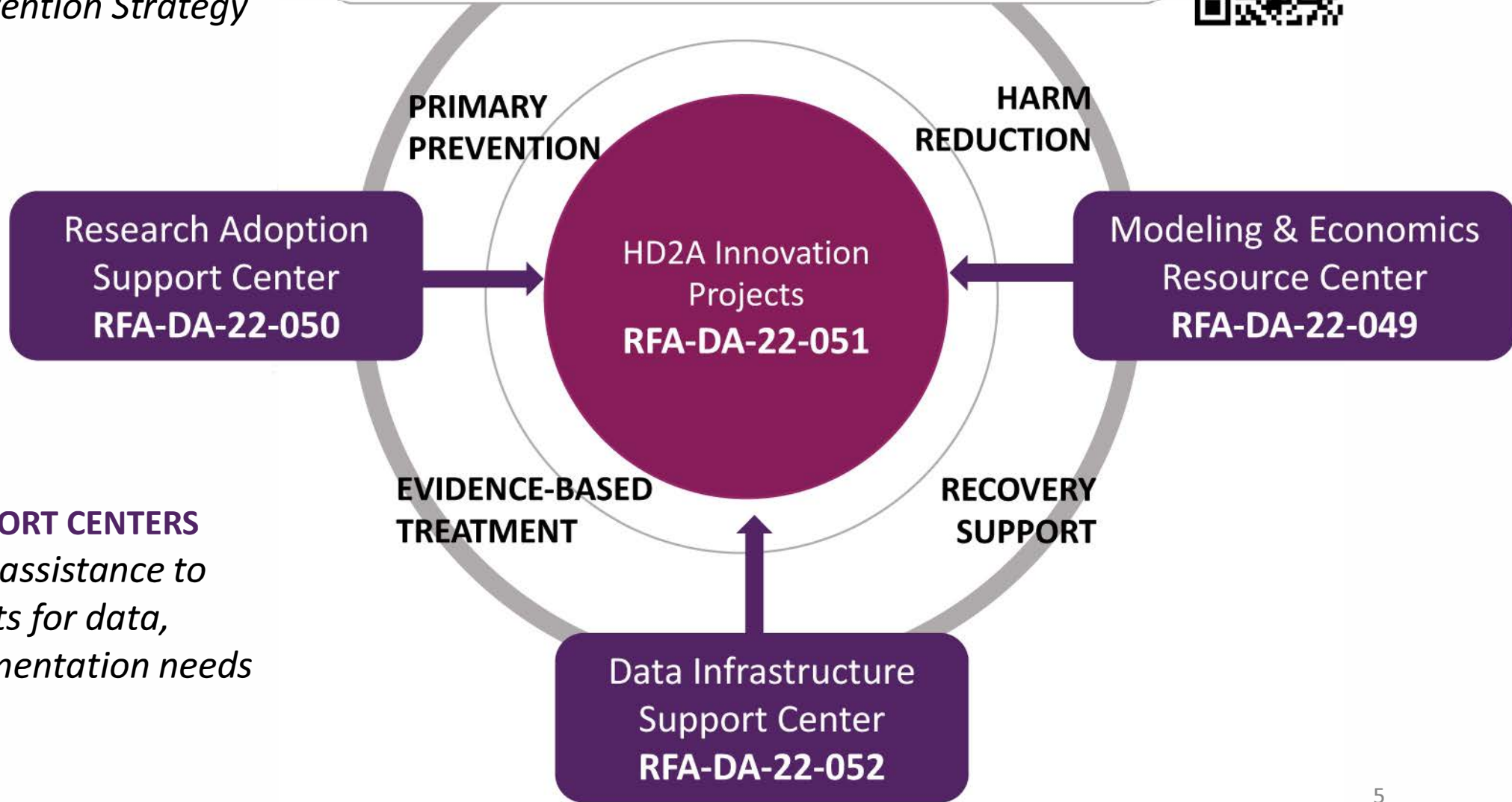
Scientific Review Officer
National Institute on Drug Abuse
Contact SRO for the HD2A Program

All can be reached at HEALdata2action@nih.gov

INNOVATION GRANTS bring together stakeholders to use data to drive action relevant to the 4 pillars of the HHS Overdose Prevention Strategy

HEAL Data2Action Program Components

HHS Overdose Prevention Strategy
<https://www.hhs.gov/overdose-prevention/>



RESOURCE AND SUPPORT CENTERS provide on-demand assistance to the innovation grants for data, analytic, and implementation needs

Please note:

- Information in these slides is abbreviated and incomplete
- Carefully read the entire published RFA for full details
- Applicants are strongly encouraged to read all four RFAs to understand expectations and coordination
- After this webinar, program officers can be reached for questions at HEALdata2action@nih.gov

HD2A Innovation Projects

RFA-DA-22-051 [R61/R33]

Presented by Tisha Wiley, Ph.D.

Chief, Services Research Branch, NIDA

HD2A Innovation Projects **RFA-DA-22-051**

- **Purpose:** Phased awards to support innovative approaches to **use local data to drive action and change** related to the overdose crisis in real-world settings.
- Propose a pragmatic, action-oriented project using data to target improving outcomes relevant to at least one of the four key pillars of the HHS Overdose Prevention Strategy.
- Examples of possible actions include resource allocation; service delivery structure; staffing patterns; policy, practice or procedure changes; improving referrals and service linkages; implementation of evidence-based practices or measurement-based care; improving service quality, etc.

Each project should select one track:

- **Single System Track**
 - Target data gaps/improvements in a single system
 - e.g., integrating data from multiple service lines within a single health system
- **Cross-Sector Track**
 - Target data gaps/improvements that require cross-sector partnerships
 - e.g., integrating data from a hospital, first responders, and treatment programs within a community
- **Local stakeholders should be engaged as appropriate**
 - e.g., healthcare, public health departments, ED, behavioral health, pain clinics, criminal justice, harm reduction, recovery organizations, patient advocacy groups, payers, policy makers

Design locally-relevant, data-driven activities. Examples include:

- Use data as part of **rapid-cycle testing** to support the implementation of an evidence-based practice in OUD care, pain management, or primary prevention
- Create cross-sector databases to support **interdisciplinary patient care teams** and successful referrals to relevant services
- Develop **data dashboards and community coalitions** to identify and prioritize prevention or treatment service delivery gaps at a community level
- Improve **measurement-based pain assessment** and use of evidence-based treatments to reduce unnecessary opioid prescribing
- Integrate data from pharmacies, Prescription Drug Monitoring Programs, or patient-reported outcomes into EHRs to **inform clinician prescribing for pain management**
- Create partnerships to conduct research **integrating industry data or protected data** that are not currently accessible and use the data to improve care delivery

Innovation Projects are Phased Awards

- **R61 planning phase – 1 or 2 years. Focus on:**
 - improving aspects of data necessary to support R33 phase activities (e.g., quality, timeliness, relevance, availability, interoperability, linkage and integration, privacy issues, etc.)
 - stakeholder engagement to ensure feasibility, buy-in, sustainability, scalability
 - pilot testing the ability to use data to inform actions
- **R33 phase – 3 or 4 years**
 - should build logically on activities in the R61 phase
 - select and deploy evidence-based interventions or strategies to fill gaps in service delivery
 - utilize local data to monitor improvements in overdose-related outcomes
- *Transition to the R33 phase is not automatic or guaranteed*
- **RFA allows 2 additional pages for timeline/milestones**
 - See **RFA Section IV.2, “Other Project Information”**
 - Provide milestones that would indicate completion of major elements needed for Phase 2

HD2A Innovation Projects RFA-DA-22-051

- Award type: R61/R33 Phased Award
- Budget limits – recommended (may exceed with strong justification)
 - R61 phase: \$350,000 direct per year, up to 2 years
 - R33 phase: \$750,000 direct per year, up to 4 years
- For budgeting purposes, the RFA includes meeting and travel details
- Milestones are required 2-page attachment in “Other Project Information”
- Number of awards anticipated: up to 12
- Letter of Intent due date: February 10, 2022
- Application due date: March 10, 2022
- *Late applications will not be accepted*
- Awards made no earlier than September 2022

Entire project = 5 years

HD2A Data Infrastructure Support Center (DISC) RFA-DA-22-052 [U24]

Presented by Barbara Oudekerk, Ph.D.

Program Officer, Prevention Research Branch, NIDA

HD2A Data Infrastructure Support Center (DISC)

RFA-DA-22-052

- Purpose: provide centralized support, resources, and coordination of all data-related needs for the HEAL D2A Innovation Projects.
 - **Meet grantees where they are** in their process of building capacity for using data to select, deploy, and monitor the impact of evidence-based services to address OUD and pain.
 - Articulate a strong scientific vision for providing ***flexible, individualized data infrastructure support***, addressing data-related barriers around using existing data to improve service delivery (not surveillance), and translating and disseminating data-related lessons learned.
 - Collaborate with the Research Adoption Support Center & the Modeling and Economic Resource Center; coordinate with the HEAL Data Ecosystem Team.

Research strategy to address 4 areas of support:

1. Data infrastructure support and tools

- Assist Innovation Projects in selecting and accessing a broad array of tools, platforms, and other resources needed for modernizing, collecting, sharing, storing, linking, visualizing, and analyzing data.
- Identify & facilitate access to potential key datasets that may be of broad interest to the Innovation Projects and/or to the HEAL D2A Program at large.

2. Data measurement, analytic, and visualization support and coordination

- Respond to a broad range of data-related consultation needs.
- Assist in identifying data visualization opportunities.
- Routinely (virtually) convene staff across the Innovation Projects to share and learn.

3. Data training and resources

- Provide direct assistance or consultation with technical data aspects.
- Conduct a training needs analysis and develop and implement a series of trainings that address the most pressing and common challenges.
- Build a public-use library of resources related to sharing and accessing data, including a core set of trainings to be made publicly available.

4. Rapid data infrastructure modernization support (Rapid DIMS)

- A plan for administering the Rapid DIMS program.
- At least \$200,000/year in direct costs will assist HEAL D2A projects in overcoming unforeseen barriers, adapting to newly established policies or procedures affecting data sharing or linkage plans, or supporting unexpected opportunities for project enhancements.

HD2A Data Infrastructure Support Center (DISC)

RFA-DA-22-052

- Budget limits: \$1M direct costs per year (5 years)*
- Award type: U24, cooperative agreement
- For budgeting purposes, the RFA includes meeting and travel details
- Number of awards anticipated: 1
- Letter of Intent due date: February 10, 2022
- Application due date: March 10, 2022
- *Late applications will not be accepted*
- Award made no earlier than September 2022

HD2A Modeling & Economic Resource Center (MERC) RFA-DA-22-049 [U24]

Presented by Lori Ducharme, Ph.D.

Program Officer, Services Research Branch, NIDA

HD2A Modeling & Economic Resource Center (MERC)

RFA-DA-22-049

Purpose: support the HD2A Innovation Projects in making informed decisions about the selection of evidence-based practices for implementation to improve gaps identified with local data.

- Provide expertise in a variety of **simulation modeling** (predictive, agent-based, geospatial, etc.) and **economic analyses and methods**.
- Consult with the HD2A Innovation Projects on applying these methods and insights in their local implementation activities.
- Conduct original research applying state-of-the-art economic and simulation modeling expertise to understand and address the overdose crisis.

Provide Technical Assistance (Consultation) to Innovation Projects

- Discuss plans and **capacity to develop or adapt** existing agent-based, predictive, geospatial, or other simulation models to inform Innovation Projects' decision-making about the selection and deployment of evidence-based practices to address local service delivery needs.
- Anticipate the needs of a diversity of Innovation Projects and describe how these tools could be further refined once the specific locations and needs of these projects are known.
- Describe capacity to provide consultation to the Innovation Projects on the designing and using **behavioral economic strategies** to support implementation of evidence-based practices.
- Articulate a vision for how this project will function in tandem with the DISC and the RASC to provide coordinated, non-duplicative consultation to Innovation Project grantees.

Provide Cost Estimation Tools and Resources

- Develop tools to support Innovation Projects in estimating costs relevant to implementation, sustainability, and system outcomes.

Conduct Original Research Projects

- Plan to conduct 2-4 methodological projects during the 5-year award; at least 1 must have a cost/economic focus. Topics are open, but projects should:
 - apply state-of-the-art modeling techniques to understand and address the overdose crisis
 - be informed by the HHS Overdose Prevention Strategy
 - inform or be informed by the work of the Innovation Projects
- Describe first project in detail
 - leverage existing data with goal of being useful to Innovation Projects during their first phase
- Remaining projects will be delayed onset studies developed in consult with NIDA

HD2A Modeling & Economic Resource Center (MERC)

RFA-DA-22-049

- Budget limits: \$1M direct costs per year (5 years)*
- Award type: U24, cooperative agreement
- For budgeting purposes, the RFA includes meeting and travel details
- Number of awards anticipated: 1
- Letter of Intent due date: February 10, 2022
- Application due date: March 10, 2022
- *Late applications will not be accepted*
- Award made no earlier than September 2022

HD2A Research Adoption Support Center (RASC) RFA-DA-22-050 [U2C]

Presented by Lori Ducharme, Ph.D.

Program Officer, Services Research Branch, NIDA

HD2A Research Adoption Support Center (RASC)

RFA-DA-22-050

- Provides overall coordination infrastructure for the HD2A Program
- Provides implementation support to the Innovation Projects
- Convenes key stakeholders from SUD and Pain communities
- Conducts rapid-turnaround research projects to address stakeholder-identified barriers to adoption of EBPs
- Conducts a formative evaluation of the HD2A Program

RASC is a multi-component research center with 4 cores:

Administrative Core

- Develop HD2A web portal, document sharing, and other **communications infrastructure** to allow Innovation Projects to seek TA from RASC, DISC, and MERC.
 - Grantees provide their own telecom and computing resources; RASC provides needed support to facilitate communication among HD2A projects
- Logistical support for project meetings
 - VIRTUAL program kickoff Fall 2022; IN PERSON late Year 1 and early Year 3; ongoing VIRTUAL among RASC/DISC/MERC and with Innovation Projects

SUD Implementation Support Core

- **Curated catalog of evidence-based and promising practices for SUD** (align w/HHS OD Strategy)
 - Searchable/sortable online catalog for use by Innovation Projects
 - Select & justify definition of “evidence” and apply consistently to catalog
 - Borrow links etc. from existing registries – do not reinvent existing resources
 - Integrate existing resources for implementation strategies, measures, other useful tools
 - Plan to generate brief evidence summaries for emerging practices as needed
 - *May not conduct clinical trials to assess efficacy/effectiveness of interventions*
- **Technical Assistance to Innovation Projects**
 - Development of logic models; selection of EBPs, strategies and outcome measures
 - Innovation Projects do the work; RASC provides consultation/information
- **Plan for Engaging Key SUD Stakeholders**
 - Plan for identifying/engaging regulators/funders/insurers/clinicians/patients
 - Convene virtual meetings at least annually
 - Do not recruit stakeholders prior to award – this will be done in collaboration with NIDA

Pain Implementation Support Core

- Directly parallels SUD Implementation Support Core, but with focus on EBPs for pain management, including opioid prescribing guidelines
- RASC will develop one comprehensive catalog of EBPs for both SUD and Pain, but application must discuss plans separately

Research and Evaluation Core

- **Formative evaluation of HD2A Program**

- Plans for gathering data on needs of Innovation Projects, and amount and nature of TA provided by RASC/DISC/MERC
- Include baseline needs assessment and “exit” meetings with Innovation Projects
- Interim reports to NIDA in Years 1, 3, 5
- Reminder: questionnaire/interview respondents are human subjects

- **Rapid Turnaround Research Projects**

- Projects to further explore barriers to EBP adoption identified by stakeholder panel
- Must propose Project #1 = role of insurance/financing/reimbursement on adoption of MOUD. Project should identify modifiable barriers and propose next steps for implementation or research. This is not an implementation trial.
- Plan 4 additional delayed onset studies to emerge from stakeholder discussions.

HD2A Research Adoption Support Center (RASC)

RFA-DA-22-050

- Budget limits: \$2M direct costs per year (5 years)*
- Award type: U2C (multicomponent center), cooperative agreement
- For budgeting purposes, the RFA includes meeting and travel details
- Number of awards anticipated: 1
- Letter of Intent due date: February 25, 2022
- Application due date: March 25, 2022
- *Late applications will not be accepted*
- Award made no earlier than September 2022

HEAL Requirements (for all HD2A RFAs)

Each HD2A RFA describes expectations and requirements for participation in:

- Annual HEAL Investigators Meeting (one PI per project)
- HEAL Data Sharing Policy

For more information about the HEAL Initiative, visit

<https://heal.nih.gov>

Peer Review Process & Review Criteria

Presented by Trinh Tran, Ph.D., Scientific Review Officer, NIDA

APPLICATION REVIEW

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

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

PEER REVIEW

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

APPLICATION REVIEW CRITERIA

Section V of FOA

Core Review Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

Additional Review Criteria

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

Overall Impact

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

Additional Review Considerations

Select Agents, Resource Sharing Plan, Authentication, Budget

APPLICATION REVIEW CRITERION DETAILS

Section V of FOA

Each of the HD2A RFAs includes specific requirements for

- Clinical trials
- HEAL data sharing plans
- FOA specific review criteria – these are listed under individual core review criteria, and are in addition to the standard requirements

APPLICATION REVIEW CRITERION DETAILS

Section V of FOA

HD2A Innovation Grants (RFA-DA-22-051):

Significance:

Does the project address a critical data-related gap or inefficiency that if addressed, could lead to significant improvements in service delivery?

Does the application address issues of sustainability and scalability?

Does the application build on relevant efforts in the targeted system or community?

Investigators: Are key partners included as co-investigators or collaborators?

Innovation: Does the proposed project have the potential to lead to innovations that could improve the utilization of data to support and sustain action-oriented approaches to reduce overdoses or improve opioid-relevant outcomes not just in the targeted system or community, but more broadly?

APPLICATION REVIEW CRITERION DETAILS

Section V of FOA

HD2A Innovation Grants (RFA-DA-22-051):

Approach:

- Are the milestones well specified and appropriate?
- Does the R33 phase build logically on the work of the R61 phase?
- Are there plans for stakeholder engagement, patient engagement, and consideration of equity?
- Does the application show a well-thought-out consideration for how it might take advantage of the infrastructure and resources offered through the HD2A program?
- Does the application include sufficient resources dedicated to interfacing with other elements of the HD2A program?

APPLICATION REVIEW CRITERION DETAILS

Section V of FOA

HD2A Data Infrastructure Support Center (RFA-DA-22-052):

Significance: scientific vision; support for HD2A mission; contribution to local data capacity; potential to contributing generalizable resources

Investigators: capacity/expertise in data infrastructure, analytic/visualization support, technical assistance; breadth of experience with diverse data sets/systems; collaboration potential

Innovation: plan for assessing/responding to needs of Innovation Grants; plans for training and resource sharing

Approach: proposed plans for support, training, technical assistance; plans for rapid data infrastructure modernization support

APPLICATION REVIEW CRITERION DETAILS

Section V of FOA

HD2A Modeling & Economic Resource Center (RFA-DA-22-049):

Significance: contribution to HD2A program and generalized knowledge

Investigators: expertise/capacity to provide technical assistance to Innovation Grants

Approach:

- plans for collaborating with DISC/RASC
- vision for integrating simulation modeling & economic analyses
- plans for working with Innovation Grants
- capacity/expertise/experience in behavioral economic strategies to promote implementation in real-world settings
- plans for cost estimation tools
- plans for at least 1 original research project

APPLICATION REVIEW CRITERION DETAILS

Section V of FOA

HD2A Research Adoption Support Center (RFA-DA-22-050):

Investigators: Note additional specific review criteria for each Core, including:

- leadership structure
- expertise in implementation science, SUD, pain, evaluation
- experience working with practitioners in real-world settings

Approach: Note additional specific review criteria for each Core, including:

- HD2A coordination/communication infrastructure
- familiarity with evidence-based practices, implementation strategies
- plan for conducting needs assessments of the Innovation Grants and providing support
- plans for identifying and convening stakeholder groups
- plans for rapid-turnaround project on insurance/financing barriers to medication adoption
- plans for developing additional projects in subsequent years
- quality of plans for conducting a formative evaluation of HD2A program

PEER REVIEW OUTCOME

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

For More Information



These slides and FAQs will be posted on the NIDA Events webpage for this webinar, at: <https://www.drugabuse.gov/news-events/meetings-events/2022/01/pre-application-information-webinar-heal-data2action-program>

To contact NIDA program staff about your application, please email: HEALdata2action@nih.gov. This email is monitored by multiple program officers.

Questions