DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on the HEALing Communities Study: Developing and Testing an Integrated Approach To Address the Opioid Crisis

AGENCY: National Institutes of Health; Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: This Request for Information (RFI) is intended to gather broad public input on the conduct of a multi-site national research effort to develop and test approaches for the systematic implementation and sustainability of an integrated set of evidence-based interventions across healthcare, behavioral health, justice systems, state and local governments, and community organizations to prevent and treat opioid misuse and Opioid Use Disorders (OUD). The goals are to decrease fatal and non-fatal overdoses, decrease the incidence of OUD and related infectious diseases (*e.g.,* Hepatitis C and HIV), increase the number of individuals receiving medication-assisted treatment (MAT), increase the proportion retained in treatment beyond 6 months, and increase the number of individuals receiving needed recovery support services.

DATES: The RFI is open for public comment for a period of 21 days. Comments must be received by July 20, 2018 to ensure consideration.

ADDRESSES: Comments must be submitted electronically to the following email address: *OpioidRFI@nida.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Please direct all inquiries to Redonna K. Chandler, Ph.D., National Institute on Drug Abuse; Phone: 301–443–1470; email: *redonna.chandler@nih.gov.*

SUPPLEMENTARY INFORMATION: This RFI is for information and planning purposes only, and should not be construed as a solicitation or an obligation on the part of the federal government, the National Institutes of Health (NIH), the National Institute on Drug Abuse (NIDA), or the Substance Abuse and Mental Health Services Administration (SAMHSA). NIH does not intend to make any awards based on responses to this RFI or to otherwise pay for the preparation of any information submitted or for the government's use of such information.

Terminology: This RFI is focused on the use, misuse, abuse of opioids, and OUD. Opioids include prescription and illicit opioids, such as heroin, illicitly manufactured fentanyl, and related analogs. OUD refers to the clinical diagnosis defined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5).

Problem Statement: Despite the availability of multiple effective evidence-based interventions and practices, most Americans at risk for or suffering from an OUD do not receive appropriate prevention and treatment services. Simultaneously, opioid overdose rates continue to increase.

NIDA, in partnership with SAMHSA, is exploring options for conducting a multi-site national research effort in up to three communities to develop and test approaches for the systematic implementation and sustainability of an integrated set of evidence-based interventions across healthcare, behavioral health, justice systems, state and local governments, and community organizations to prevent and treat opioid misuse and OUD. The goals are to decrease fatal and non-fatal overdoses, decrease the incidence of OUD and related infectious diseases (*e.g.,* Hepatitis C and HIV), increase the number of individuals receiving medication-assisted treatment (MAT), increase the proportion retained in treatment beyond 6 months, and increase the number of individuals receiving needed recovery support services. This research would be a part of the NIH Helping to End Addiction Long-term (HEAL) Initiative (*https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative*).

Information Requested: This RFI solicits input from the extramural research community and public stakeholders. NIDA and SAMHSA especially seek input on study elements such as, but not limited to:

Study Design:

- How can ''heavily affected communities'' be defined, including geospatial/geopolitical definitions to provide consistent boundaries for a multi-site study?
- What research designs might be appropriate to accomplish the overall goals of the study?
- How can effect size be estimated and what effect size might be expected in relation to candidate outcomes: Rates of non-fatal and fatal overdose; prevalence and incidence of opioid misuse, OUD and Hepatitis C; percent of patients screened for opioid misuse and OUD and who received a brief intervention or were referred to treatment; percent of patients initiated on MAT and retained in medication treatment beyond 6 months; rates of naloxone distribution and overdose reversals; opioid analgesic and benzodiazepine prescription rates; and implementation of prevention programs?
- What baseline data should be captured, what are potential existing sources for this data, and what challenges might exist with quality of existing data?
- How long would an integrated set of evidence-based interventions need to be in place before expecting a meaningful change in outcomes, and which combination of interventions should be implemented in communities with different characteristics?
- What confounding variables need to be considered?
- What are potential threats to internal and external study validity and what strategies could be deployed to mitigate threats?
- Are there particular strategies that can help the Coordinating Center overcome barriers to the facilitation of collaboration and coordination activities across Research Centers with regard to data harmonization, collection, integration, cleaning, analyses, and creating datasets for sharing with the research community at large?

Outcomes:

- What target metrics would be feasible for outcomes? Candidate outcomes could include, but are not limited to those listed above: Rates of non-fatal and fatal overdose; prevalence and incidence of opioid misuse, OUD and Hepatitis C; percent of patients screened for opioid misuse and OUD and who received a brief intervention or were referred to treatment; percent of patients initiated on MAT and retained in medication treatment beyond 6 months; rates of naloxone distribution and overdose reversals; opioid analgesic and benzodiazepine prescription rates; and implementation of prevention programs?
- What is the best way to gather reliable data related to candidate outcomes listed above?
- What are essential interventions for an evidence-based integrated approach to opioid prevention and treatment services, including policies and practices?
- How could ''evidence-based or evidence-informed'' be defined?
- How can fidelity to an evidence-based integrated approach to opioid prevention and treatment services, including policies and practices be measured?
- What strategies and resources would be necessary, including training and technical assistance, to have meaningful penetration of the evidence-

based integrated approach to opioid prevention and treatment services in a single community?

Health Economics:

• What economic questions should be included as part of the study to inform systems and policy change?

Implementation Research:

• What implementation research questions should be included to develop best practices for replication in other communities impacted by the opioid crisis?

• What data should be collected to help develop metrics for determining the quality of an integrated approach to opioid prevention and treatment services, including policies and practices?

• Are there examples of prior implementation research studies that highlight implementation tools that can be used to replicate and scale up integrated approaches?

Infrastructure, Partnerships, Collaboration:

• What research, prevention, and treatment infrastructure and partnerships are needed to support a community-based pragmatic trial assessing the impact of an evidence-based integrated approach to opioid prevention and treatment services?

• What is the best approach to fostering collaboration and meaningful participation between state, county, and local governments; community stakeholders; medical/clinical service providers; and researchers?

• How do we construct a research initiative with the highest likelihood of having sustainable prevention and treatment services?

• What data would be of most interest to state and community partners?

Responses to this RFI are voluntary and may be submitted anonymously. Please do not include any personally identifiable or other information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in responses. Comments submitted will be compiled for discussion and shared internally with NIDA, SAMHSA, NIH program staff, and participating leadership across the Department of Health and Human Services, as appropriate. Any personal identifiers (personal names, email addresses, etc.) will be removed when responses are compiled.

This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the United States Government to provide support for any ideas identified in response to it. Please note that the United States Government will not pay for the preparation of any information submitted or for use of that information.

Dated: June 25, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–14031 Filed 6–28–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; T1D NIDDK Review.

Date: June 29, 2018.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, *sanoviche@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–17–021: HIRN Consortium on Beta Cell Death and Survival Early T1D Biomarkers Discovery in Human Pancreas.

Date: July 23, 2018.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; T1D Clinical Trials Testing Current and Novel Closed Loop Systems (R01).

Date: July 24, 2018.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20817, 301–496–9010, *hoffertj@niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–17–020: Immune System Engineering for Targeted Tolerance in Type 1 Diabetes (R01).

Date: July 25, 2018.

Time: 11:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–7682, *campd@extra.niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; SBIR Phase II Clinical Trials.

Date: July 26, 2018.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–18–042: NIDDK Ancillary Studies (R01).

Date: July 26, 2018.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch,