Pilot Interventions to Integrate Social Care and Medical Care to Improve Health Equity RFA-DK-22-038

Pre-Application Webinar

May 15, 2023

12:00 p.m. – 2:00 p.m. EDT

Webinar Tips

- Participants may **ask questions using the chat feature.**
- Questions will be answered during the **Q&A session at the end** of the webinar.
- The webinar **slides will be available** on the NIDDK website.

Agenda

- Background and Objectives of the RFA
- Application Information
- Budget
- Selected Frequently Asked Questions
- Q&A

Background:
SDoH and Health Equity

- SDoH are “the conditions in which people are born, grow, live, work and age.” They are “shaped by the distribution of money, power and resources” and can shape health in ***both positive and negative*** ways.

- Addressing SDoH is a primary approach to achieving ***health equity***, when people of all backgrounds and ages have **fair and just opportunities** to live long, healthy, productive lives.

WHO: https://www.who.int/health-topics/social-determinants-of-health; Healthy People: https://health.gov/healthypeople/priority-areas/social-determinants-health

Background:
Social Risks vs Needs

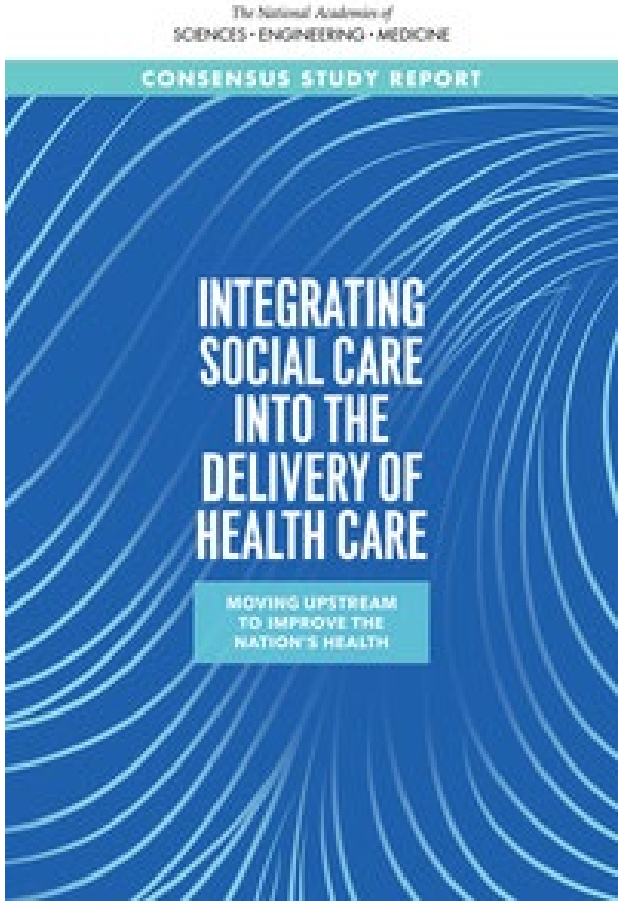
- **Social risks** are associated with ***adverse* SDoH** and contribute to poor health (e.g., food insecurity, lack of access to healthcare, lack of transportation, housing instability, etc.).
- **Health-related social needs** are ***endorsed by the person receiving care*** and reflect the social risks that the person feels are most pressing and need to be addressed. They are rooted in material deprivation, such as lack of resources and money to support the costs of living in modern society (e.g., food, rent, utilities, transportation, childcare, safety). The deprivation that leads to social needs being unmet is often related to SDOH, but social needs are not the same as SDOH.

Background: Social Risks Contribute to Health Disparities

- **Racial, ethnic and socioeconomic disparities persist** in NIDDK diseases/conditions, including diabetes, obesity, kidney disease, and many other NIDDK mission diseases.
- Because of **structural racism and discrimination**, marginalized communities experience higher rates of social risks.
- **Social risks constrain people's capacity** to obtain, engage in, or follow through on medical and/or lifestyle treatment plans or engage in healthy behaviors.

Integration of Social and Medical Care

"…**integrating social care into healthcare** delivery holds the potential to achieve **better health outcomes for the nation**."



National Academies of Sciences, Engineering and Medicine (NASEM), 2019

- **Social risks-informed care**: modifying medical care to account for social risks (e.g., transportation to appointments)
- **Health-related social needs-targeted care**: addressing social needs directly (e.g., helping people access housing assistance)

- **Fundamental research gaps remain**:
  - Optimal **screening processes and clinical workflows**
  - **Optimal timing** for referral to supportive care & for follow up care to detect health changes
  - How to consider **patient-reported experiences**
  - How to develop **robust partnership models** with high potential for **sustainability**

Objectives of the RFA

- **Advance the science of integrating medical and social care** through interventions that meaningfully address social risks and needs.
- **Improve outcomes and health equity** relevant to diseases in NIDDK's mission, especially among people from racial and ethnic minority groups, rural populations, sexual and gender minority groups, and other marginalized communities.
- **Stimulate sustainable collaborations between healthcare systems, community-based organizations, and social service entities** to test interventions to screen for social risks and address social needs. The long-term goal should be to build community-linkages that foster mutually beneficial and sustainable services beyond the funding period, should a subsequent fully-powered trial be efficacious.
- Support pilot trials that will **generate data to support the rationale, design and feasibility of a fully powered clinical trial** to detect improvement in an important health outcome for a disease in NIDDK's mission.

https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-22-038.html

https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-22-038.html

APPLICATION INFORMATION

RFA-DK-22-038: Scientific/Research Contacts

Kidney, Urologic, and Hematologic Diseases

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Diabetes, Endocrinology, and Metabolic Diseases

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Please contact us to discuss your application!

Considerations for

PLANNING YOUR RESEARCH

Pilot & Feasibility (P&F) Trial Requirements

Funded trials must:

1) **Determine feasibility and acceptability** of screening for social risks, identifying social needs and implementing referral service linkages (e.g., addressing transportation, housing, food, and other health-related social needs) within the context of a healthcare visit;
2) **Assess fidelity of implementation** of the proposed intervention; and
3) **Follow participants to assess preliminary signals** of the intervention's impact on the s**ocial risks** and **health outcomes for diseases in NIDDK's mission.**

*Preliminary data regarding intervention efficacy are not required. However, the **premise, rationale, and operational feasibility** of the study should be **supported by the available literature** and/or **by data from the PD/PI.**

Additional P&F Trial Considerations

Proposed trials should:

- **Lay the foundation for larger clinical trials** to integrate social care and medical care and improve NIDDK outcomes.
- **Begin to delineate promising dissemination and implementation practices** for future equitable and effective “real world” implementation of social and medical care integration.

Proposed trials may:

- Include a component involving and/or evaluating **training or programs designed to mitigate implicit biases and interpersonal racism** in healthcare teams.
- Either **test a single approach** to screening and linkage or **compare multiple strategies.**
- Use **up to 1-year** of the award period to **conduct some formative and preparatory work** for the trial, if needed.
- Use **hybrid effectiveness-implementation designs.**

Screening for & Addressing Social Risks

Proposed trials should incorporate:

- **Social risk screening and ongoing shared decision making** to:
  - Ascertain evolving patient-endorsed social needs;
  - Co-develop a care plan that addresses those needs and accommodates the patient's broader social context; and
  - Adapt the care plan over time as social risks/needs are met or change.
- **"Closed loop" social needs referrals** that enable ongoing communication among the patient, providers, and social service/community organizations to assess whether patients' social needs are being mitigated.

Trial Outcomes

- Proposed outcomes **must** include:
  - Objective, clinically meaningful outcome(s) for NIDDK diseases
  - Status of social risks/needs (i.e., improved or not)

- Other outcomes of interest include:
  - Qualitative measures
  - Patient-reported outcomes
  - Process measures, especially related to screening and "closed loop" referral
  - Acceptability, feasibility, adoption, fidelity, penetration, and sustainability of the intervention

Applicants Should Apply an Equity Lens

- Consider — at each decision point in the research process — **how processes, values, assumptions, actions, and interventions** may:
  - **Affect meaningful involvement, inclusion and participation of people affected by relevant health disparities**; and
  - **Mitigate or exacerbate inequalities in opportunities and outcomes**, especially for communities who experience historical and contemporary forms of marginalization, discrimination, or oppression.
- Acknowledge that **social conditions influence health**, including laws, policies and other structural and social determinants of health.
- **View individuals and populations through an asset-based frame** that recognizes their strengths and resources.

For more, see the forthcoming NIDDK Health Disparities and Health Equity Report
https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/developing-inaugural-niddk-health-disparities-health-equity-research-implementation-plan

Applicants are Expected to Use Community-Engaged Approaches

- Applicants are expected to:
  - Use **community engaged approaches in designing and implementing** the trial, including integration of relevant stakeholders into the research team;
  - **Clearly describe the process they will use to facilitate meaningful *sustainable* collaboration** with patients, caregivers, family members, community members, community-based organizations, clinicians, healthcare systems, and other relevant stakeholders throughout the research process; and
  - Use **culturally appropriate research designs, questions, and materials** (i.e., outreach, recruitment, retention, informed consents).
- Meaningful engagement entails activities beyond focus groups, surveys or other activities where stakeholders are only involved as participants or respondents.

Use of Common Data Elements & Data Standards

To facilitate establishing common data elements (CDE), applicants are strongly encouraged to consider use of standards from:

- The PhenX SDOH Assessments Collection (https://www.nimhd.nih.gov/programs/collab/phenx/),
- SDOH data standards established by the Gravity Project: https://confluence.hl7.org/display/GRAV/
- The US Core for Data Interoperability: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
- Multiple Chronic Conditions (MCC) e-Care Plan Project: https://cmext.ahrq.gov/confluence/display/EC
- The NIH CDE repository: https://cde.nlm.nih.gov/home

Non-Responsive Applications

Applications proposing any of the following will be considered non-responsive and **will be withdrawn**:

- Research **outside the mission of NIDDK**
- **Animal or in vitro studies**
- **Foreign components/non-U.S. locations**

Grant funds may not be used to:

- **Build new screening tools**, although refinement of these tools may be done before starting the trial.
- **Build health IT systems**
- **Directly provide social services**

Considerations for

ASSEMBLING YOUR TEAM

Multidisciplinary Research Teams

The research team should include people with:

- **Diverse perspectives** and backgrounds, especially those under-represented in biomedical research (see NOT-OD-20-031; Plan for Enhancing Diverse Perspectives); and
- **Relevant expertise** and **requisite knowledge, skills and experience** to conduct the proposed research project, including:
  - People living with or at risk for NIDDK diseases/conditions,
  - Health equity/health disparities researchers,
  - Community-based organizations,
  - Social service agency representatives,
  - Healthcare services and systems researchers, and
  - Data scientists & health informaticists.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html;
https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp

Equitable Partnership Models

- Proposed intervention(s) are expected to enhance the development of **equitable partnership models:**
  - Between healthcare delivery and social services sectors.
  - Inclusive of all interested parties (e.g., people with NIDDK diseases; medical, community, and home-based practitioners, researchers, local businesses, and other relevant organizations).
- Long-term goal: build community-linkages that foster **mutually beneficial and *sustainable* services** beyond the funding period, should a subsequent fully-powered trial be efficacious.
- Collaboration model and entities (healthcare system, referral organizations) must be in place ***prior to application.***

Plan for Enhancing Diverse Perspectives (PEDP)

- A PEDP **must** be included with all applications.
- **1-page** summary
- **Key elements include**:
  - Summary of strategies that advance the scientific and technical merit through expanded inclusivity;
  - Timeline and milestones for PEDP; and
  - Approaches to assess progress towards meeting PEDP defined goals.

Examples of Potential Strategies

- Inclusion of personnel
  - Historically underrepresented in the clinical research workforce;
  - Representing different career stages;
  - From different types of institutions and organizations; and
  - From varying scientific fields.
- Training and mentoring opportunities for individuals from diverse backgrounds.
- Plan to use project infrastructure to support career-enhancing research opportunities for junior investigators.
- Activities to enhance recruitment of participants from diverse groups.

https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp

Considerations for

DEVELOPING YOUR BUDGET

Budget and Project Period

- **Award Budget**:
  - Limited to $300,000 in directs costs per year
    - Exclusive of F&As for sub-contracts
  - Should reflect the actual needs of the project
- **Award Project Period**:
  - The maximum project period is 3 years.

Considerations for

SUBMITTING YOUR APPLICATION

Key Dates

- **Letter of Intent:** September 19, 2023 (not required)
- **Application Due Date: October 19, 2023**
  - **by 5pm local time of applicant organization**
- **Peer Review:** March 2024
- **Council Review:** May 2024
- **Approximate Start Date:** July 2024

https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-22-038.html

Page Limits

Section of Application	Page Limit
Specific Aims	1
Research Strategy	12
Plan to Enhance Diverse Perspectives (PEDP)	1
Biosketch(es)	5 each

SF424 (R&R) Application Guide

Unique Entity ID (UEI) Requirements

UEI: number assigned by SAM.gov to identify an entity across all federal award systems

Applicants

- **Must have a complete entity registration and an assigned UEI at the time of application submission.**
- Go to SAM.gov to register your entity: https://sam.gov/content/entity-registration.
- Registering in SAM.gov can take time. **Start the process early.**

Sub-recipients/sub-contractors

- Are not required to register in SAM.gov.
- Are **highly encouraged**, but not required, to **have a UEI** at the time of application submission.
  - SAM.gov provides a **simplified process to request a UEI** without full SAM.gov registration. Video tutorial: https://www.youtube.com/watch?v=C87wSCYKTcE.

Application Due Date: October 19, 2023

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html

eRA Commons IDs

An eRA Commons ID is required in the SF424 Senior/Key Person Profile form for:

- Project Director/Principal Investigator (PD/PI) and multiple-PD/Pis;
- Component leads of multi-project applications;
- At least one Signing Official (part of eRA Commons organization registration); and
- Anyone doing application data entry in ASSIST.

Getting an eRA Commons ID **for people not affiliated with a registered organization**:

1. The **person's organization** can register in eRA Commons and provide the Commons ID – **if time allows**. Registration can take **several weeks** to complete.
2. The **applicant organization** can create an eRA Commons account for the person and assign a role that is solely used for reporting purposes. – **Quickest option**
3. The person can **register themselves** as an organization using Special Instructions for Unaffiliated/Independent Applicants, **if time allows**. - Good option for independent consultants

More information: https://grants.nih.gov/faqs#/applying-electronically.htm?anchor=52076.

Application Submission Contacts

- **eRA Service Desk** (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

- **Finding Help Online**: https://www.era.nih.gov/need-help (preferred method of contact)
  Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

- **General Grants Information** (Questions regarding application instructions, application processes, and NIH grant resources)
  Email: GrantsInfo@nih.gov (preferred method of contact)
  Telephone: 301-637-3015

- **Grants.gov Customer Support** (Questions regarding Grants.gov registration and Workspace)
  Contact Center Telephone: 800-518-4726
  Email: support@grants.gov

Considerations for

APPLICATION REVIEW

Review Process

- Evaluation by **Scientific Review Group(s) (i.e., special emphasis panels)** convened by NIDDK Review Branch.
- Determination of scientific merit will include **standard** and **RFA-specific review criteria.**
- Following peer review, recommended applications will receive a **second level of review by the NIDDK Advisory Council.**
- Considerations in making 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**, including the **plan for enhancing diverse perspective (PEDP).**

Review Criteria Specific to this RFA (1 of 2)

In addition to standard review criteria, note the following RFA-specific criteria:

Significance	• How likely is it that the **proposed intervention(s) will reduce inequities** in health, behavioral, patient-centered, psychosocial, organizational or community-level outcomes? • To what extent do the efforts described in the **Plan for Enhancing Diverse Perspectives further the significance of the project**?
Investigators	• How **experienced** is the study team in **health disparity/health equity** research and **community-engaged** approaches? • How well do **letters of support indicate a commitment for partners** and collaborators to be active participants throughout the research process? • To what extent will the efforts described in the **Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise** required for the project?
Innovation	• How innovative are the **approaches to integrating the medical and social care** systems? How likely is it that the proposed approach, if proven effective, could support future equitable and **effective "real world" implementation** of social and medical care integration? • To what extent will the efforts described in the **Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation**?

Complete review criteria: https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-22-038.html#_Section_V._Application

Review Criteria Specific to this RFA (2 of 2)

In addition to standard review criteria, note the following RFA-specific criteria:

Study Design	• Does the design include an **appropriate assessment of an NIDDK disease health outcome**? • How meaningful is the **plan to engage all appropriate stakeholders** likely to be affected by or involved in the proposed trial? How likely is it that the plans proposed will **sustain stakeholder engagement** throughout the research process? How **feasible are the plans for integrating patients and community partners** into the study? • To what extent have the investigators **applied an equity lens** to guide their intervention development, implementation and evaluation? • How appropriate are the **proposed plans for capturing data to measure social determinants of health** (SDoH) and **assess social risks and needs** of participants to the overall study design? • Are the **timeline and milestones associated with the Milestone Plan and the Plan for Enhancing Diverse Perspectives** well-developed and feasible? • Does the application specify **appropriate measures for assessing feasibility and acceptability** of the proposed intervention? • Does the design include **assessment of whether the targeted social risk/need has been mitigated**?

For a full list of the review criteria, see: https://grants.nih.gov/grants/guide/rfa-files/rfa-dk-22-038.html#_Section_V._Application

Considerations for

POST AWARD

Virtual Meeting Series for Awardees

- **Facilitate sharing information about barriers, problem-solving, promising approaches and best practice**s related to integrating social and medical care.
- Includes **NIDDK staff and all awarded study teams.**
- **Three meetings** anticipated: at approximately **six months** and **18 months** after the award is made, and **near study end.**
  - Meetings could take place more frequently if helpful for the awardees.

FREQUENTLY ASKED QUESTIONS

Frequently Asked Questions

- What is the advantage of applying to this RFA versus the Small R01 Announcement (PAS-20-160) for investigator-initiated trials?

  The RFA provides:

  – Set aside funds to support these projects

  – A separate review panel with relevant expertise

  – An opportunity to collaborate with other investigators

  – Larger maximum annual budget

Frequently Asked Questions

- Will the NIDDK be receptive to a submission recruiting from multiple sites?
  - Yes. Multiple local or out-of-state sites are allowed. The number and location of sites must be scientifically justified and be realistic within budget limitations. No foreign sites are allowed.

Frequently Asked Questions

- Can applicants propose outcomes that are not specific to NIDDK mission diseases/conditions?
  - Yes, as long as applicants also propose NIDDK-relevant outcomes and have sufficient funds to do both
  - If you are uncertain about whether your outcomes are in scope for NIDDK, speak with program staff

Frequently Asked Questions

- The RFA language says screening for social risks should occur "***during*** a healthcare visit." Is this intending to include healthcare adjacent activities, such as pre-appointment screening?
  - Yes, the RFA is intended to support trials to assess feasibility and acceptability of screening for social risks, identifying social needs and implementing referral service linkages ***within the context of a healthcare visit*** – including activities that might occur before, during, or after a visit

Frequently Asked Questions

- Can costs to community-based organizations (CBO), such as navigation services, key personnel, and incentive funds, be included in the budget?
  - Yes, costs born by partnering CBOs that are ***directly related to components of the intervention***, such as implementing referral service linkages, ensuring patients access needed support, and "closing the loop" on the referral are appropriate
  - But, funding to support the following activities is ***not allowed***:
    - Building health IT systems
    - Directly providing social services

Frequently Asked Questions

- Are hybrid effectiveness-implementation studies eligible (i.e., studies to test the effects of clinical and social risk screening/referral interventions, while observing and gathering information on implementation)?
  - Yes, hybrid effectiveness-implementation models that include outcomes related to acceptability, feasibility, adoption, fidelity, penetration, and sustainability of the intervention are welcome
  - However, primary outcomes must include 1) objective, clinically meaningful NIDDK disease outcomes and 2) the status of social risks/needs (i.e., improved or not)

Frequently Asked Questions

If you have questions specific to your application,

PLEASE CALL US

Please Contact Us!

Kidney, Urologic, and Hematologic Diseases

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Diabetes, Endocrinology, and Metabolic Diseases

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Participant Questions

Examples of Relevant Health Related Social Risks/Needs

- **Referral to food bank or other services to address food insecurity in coordination with medical nutrition therapy** (e.g., medically tailored diets to improve glycemic control in diabetes and/or hyperphosphatemia and/or hyperkalemia in progressive CKD; or calorie restricted diets to promote weight loss in patients with obesity)
- **Connection to resources to address housing insecurity or related needs** (e.g., HUD-supported or community programs) to improve or intensify treatment effects of efficacious interventions for NIDDK mission area diseases and patients' adherence to medical treatments
- **Access to transportation services to facilitate travel to healthcare appointments** to improve screening, prevention, and management strategies for diseases in NIDDK's mission
- **Referral to existing national and local programs** (e.g., home visiting programs, WIC) that can address multiple social needs that hinder efforts to prevent or treat diseases in NIDDK's mission