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

1. **What is the advantage of applying to this request for applications (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
   - A larger maximum annual budget

2. **Will the NIDDK be receptive to a submission recruiting from multiple sites?**

   Yes. Recruitment from multiple local or out-of-state domestic sites is allowed. The number and location of sites must be scientifically justified and realistic within budget limitations. No foreign sites are allowed.

3. **Can applicants propose outcomes that are not specific to NIDDK mission diseases/conditions?**

   Yes, as long as applicants also propose NIDDK-relevant outcome(s) among the primary outcome(s) and have sufficient funds for all proposed outcomes. The NIDDK-relevant outcome(s) should be clinically meaningful and serve to inform or support potential larger, fully powered trials in the future. If you are uncertain about whether your outcomes are in scope for NIDDK, we strongly encourage you to speak with the scientific contacts for this RFA.

4. **The RFA language says screening for social risks should occur "*during* a health care visit." Is this intending to include health care–adjacent activities, such as preappointment 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 health care visit*—including activities that might occur before, during, or after a visit. Screening activities ***do not*** need to occur within the physical bounds of a health care setting, but *data resulting from the screening must be made available to the clinical care team* to facilitate the delivery of health care informed by the patient's social context.

5. **Can costs to community-based organizations (CBO), such as navigation services, key personnel, and incentive funds, be included in the budget?**

   Yes, costs to partnering CBOs that involve staff time and/or incentives for activities *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.

However, funding to support the following activities is ***not allowed***:

- Building health IT systems
- Directly paying for social services, such as transportation, food, and housing

6. 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 the testing of clinical interventions and implementation strategies (outcomes focused on the adoption or uptake of clinical interventions by providers and/or systems of care) are appropriate.

However, primary outcomes must include both objective, clinically meaningful NIDDK disease outcomes and the status of social risks/needs (i.e., improved or not).

7. Will indirect costs be provided in addition to the $300,000 per year, or do they come from the $300,000? Does the $300,000 include costs for subawards?

Application budgets are limited to $300,000 in *direct costs* per year, exclusive of indirect costs on subcontracts. This $300,000 ***does not*** include indirect costs. However, budgets need to reflect the actual needs of the proposed project.

8. Is this a one-time submission RFA, or do you anticipate additional cycles?

Currently, NIDDK has only one submission date planned for this opportunity.

9. Is there a requirement to test the implementation fidelity of a service referral after the social risk screening is complete?

The expectation of the RFA is that the social need(s) referral(s) will not represent a unilateral action from the health care provider team but will be part of a "closed loop" referral process that results in ongoing communication among the provider(s), patient, and social service/community organization(s). Although implementation fidelity of the referral is not specifically required, applicants are expected to propose studies that can determine whether the patient accessed the referred service(s).

10. Are community partners required to have an eRA commons account and/or a biosketch?

Requirements for an eRA commons account and/or biosketch will depend on the role of the community partner in the study.

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 multiproject applications
- At least one Signing Official (part of eRA Commons organization registration)
- Anyone doing application data entry in ASSIST

Submission of a biosketch is required for each proposed senior/key personnel and any other significant contributors on a grant application. Information on the NIH biosketch is available here: https://grants.nih.gov/grants/forms/biosketch.htm.

For this RFA, NIDDK strongly encourages, but does not require, applicants to include community partners in leadership positions, including PD/PIs and/or senior/key personnel.

- If community partners are included as a PD/PI (or multi-PD/PI), they will require both an eRA commons ID and a biosketch.
- If community partners are included as senior/key personnel, they will require a biosketch.

11. What are the benefits of submitting a letter of intent (LOI) versus just the final application?

Applicants are strongly encouraged, but not required, to submit an LOI. The information in an LOI allows NIDDK staff to plan the peer review panel and identify any unique scientific expertise that needs to be included. Reviewers will not see the LOI, so it will not affect how they score an application.

In addition, an LOI may help NIDDK staff spot potential issues that need to be addressed before applying.

12. Can the award budget be used to support navigation to social services?

Yes, the award budget can include personnel time to support navigation of patients to community resources. However, funding cannot directly support the delivery of social services.

13. Can funds be used to develop an app to provide patients with reminders about social service referrals to address their social needs?

Applicants should consider adaptation or modification of existing applications rather than developing novel applications to accomplish such activities. Per the RFA, grant funds may not be used to build new screening tools, but refinement of existing tools is allowed. Funds also cannot be used to directly build health IT system infrastructure to support exchange of clinical and social data across health systems and CBOs.

14. Can Early Stage Investigators (ESI) serve as lead/contact PI? Is there priority given to ESI applicants?

Yes, ESIs can serve as the lead/contact PI. Unlike the parent R01, where ESIs benefit from a more lenient payline, no formal process exists to advantage ESIs through this RFA. However, ESI status may be considered during programmatic review when making funding decisions.

15. Can studies address multiple social risks/needs simultaneously, or should they focus on just one?

Applicants are encouraged, but not required, to address more than one social risk/need, based on the interests of the community, the needs and preferences of individual patients, and budgetary considerations.

16. Who are the scientific contacts for this RFA?

The scientific contacts for this RFA are:

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