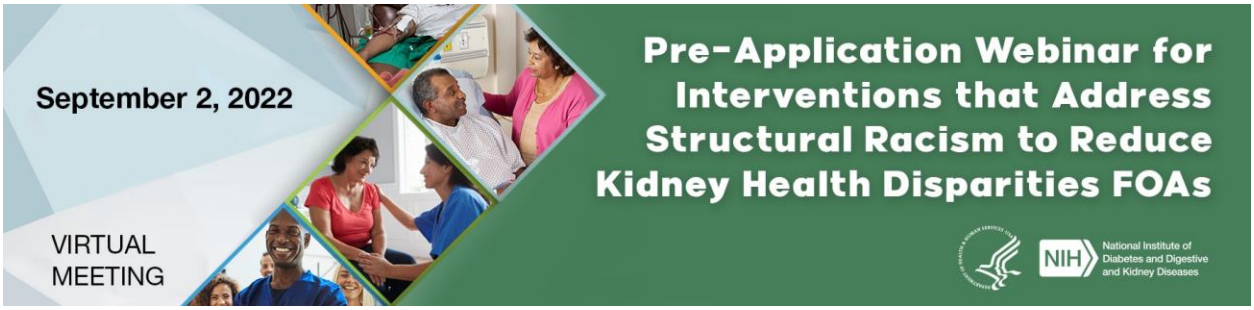

Interventions that Address Structural Racism to Reduce Kidney Health Disparities FOAs

Frequently Asked Questions

1. **Do I propose a trial for my own site or the whole Consortium?**

   Applicants should propose a trial for their own site(s). Applications for Intervention Sites will be evaluated independently, similar to the process for applying for an R01. Proposed studies should be sufficiently powered to answer the proposed research question based on recruitment from the applicant site(s)—without consideration of other Consortium sites. **After** applications are selected for funding, the Steering Committee will meet to determine how they will move forward as a Consortium, including considering the harmonization of interventions or intervention components across two or more Intervention Sites *depending on the research question/populations proposed in the funded applications*. The resulting Consortium may include up to six independent studies (one for each funded site) with common data elements and shared best practices, a single study harmonized across up to six awarded sites, or anything in between.

2. **What are the advantages of applying to this request for applications (RFA) versus the Parent Announcement for investigator-initiated trials?**

   The advantages of applying to the RFA include the following:

   - It provides an opportunity to collaborate with other investigators and with the NIH.
   - There are set-aside funds to support these projects.
   - There is a separate review panel with relevant expertise.

   The Parent Announcement for investigator-initiated trials may be a better fit if you need/prefer to conduct your study as you proposed.

3. **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. Foreign sites are not allowed.

4. **Can you submit more than one Intervention Site application?**

   Yes. Applicants must avoid scientific overlap and ensure they have sufficient calendar months to cover both activities. However, peer review will assess the merit of the applications.

We encourage you to contact us to discuss your applications prior to submission.

5. **Kidney disease takes a long time to develop, but the study period is only 5 years. How can applicants assess kidney outcomes in the allotted timeframe?**

   We encourage applicants to propose outcomes that are scientifically justified, meaningful and relevant to individuals living with kidney disease, and achievable during the funding period.

   NIH/NIDDK may be able to continue to fund studies beyond the 5-year period to achieve sufficient power if studies show sufficient progress and promise.

6. **Can applicants propose non-kidney outcomes or outcomes related to upstream kidney disease risk factors?**

   The study population must include individuals living with kidney disease. Applications that focus on populations at risk for kidney disease but do not have kidney disease will be considered non-responsive and will not be reviewed.

   Applicants can propose non-kidney outcomes as long as they also propose kidney-relevant outcomes and have sufficient funds to do both. Risk factors for kidney disease progression (e.g., diabetes, hypertension) can be included but should not be the primary outcome.

7. **Does the Research Coordinating Center (RCC) need to propose a trial?**

   No; however, the study team must have substantial and relevant clinical trial experience.

   RCC applications must include a detailed table listing the characteristics of trials that they have been involved in (Example file name: Clinical Trial Research Experience.pdf).

8. **Are there preferences for where the interventions should occur (e.g., hospital or community)?**

   There is no preference for where interventions should occur. Interventions should aim to dismantle or mitigate the effects of structural determinants that create and perpetuate disparities. This includes interventions within the health care system, community and public health interventions, or structural interventions that address the upstream causes of kidney health disparities.

9. **When developing interventions, should the interventions target only racial and ethnic minority populations? If an intervention targets all patients but is designed to specifically narrow disparities among racial and ethnic minorities, is that responsive to the RFA?**

   Interventions should aim to dismantle or mitigate the effects of structural racism impacting one or more NIH-designated racial/ethnic groups experiencing kidney health disparities, but the study population does not need to be limited only to racial and ethnic minority populations. Clinical trials that aim to assess the effectiveness of an intervention in reducing racial and ethnic disparities in kidney-relevant outcomes are responsive to the RFA.

10. **Will funding decisions be made to ensure interventions cover all populations (e.g., chronic kidney disease, end-stage renal disease, transplant)?**

    Selection of applications will be based on the scientific and technical merit of the proposals.

11. **What is defined as a kidney-relevant outcome? Might hospitalizations fit within this definition?**

    The interventions should be designed for individuals with kidney disease, and the primary outcome should be meaningful and relevant to people living with kidney disease. Refer to the RFA for a list of potential outcomes. Please contact us if you have questions specific to your application.

12. **Will a network biosample repository be expected as part of the Research Coordinating Center budget?**

    The NIDDK has established a Central Repository to support the receipt, storage, and distribution of data, biosamples, and other resources generated as part of clinical studies. The Research Coordinating Center is responsible for the transfer of all study-generated resources to the NIDDK Central Repository. Please refer to RFA-DK-22-015 for more details.

13. **How does this RFA relate to the NIH Common Fund's Community Partnerships to Advance Science for Society (ComPASS) program?**

    ComPASS is an NIH-wide initiative with the goal to develop a *new health equity research model* for **community-led,** multisectoral structural intervention research across the NIH and other federal agencies. Please refer to the **ComPASS** website for more details about this new funding opportunity.