



National Institute of
Diabetes and Digestive
and Kidney Diseases

Interventions that Address Structural Racism to Reduce Kidney Health Disparities FOAs

Pre-Application Webinar

September 2, 2022

10:00 a.m. – 12:00 p.m. EDT



National Institute of
Diabetes and Digestive
and Kidney Diseases

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 FOAs
- Application Information
- Budget
- Selected Frequently Asked Questions
- Q&A

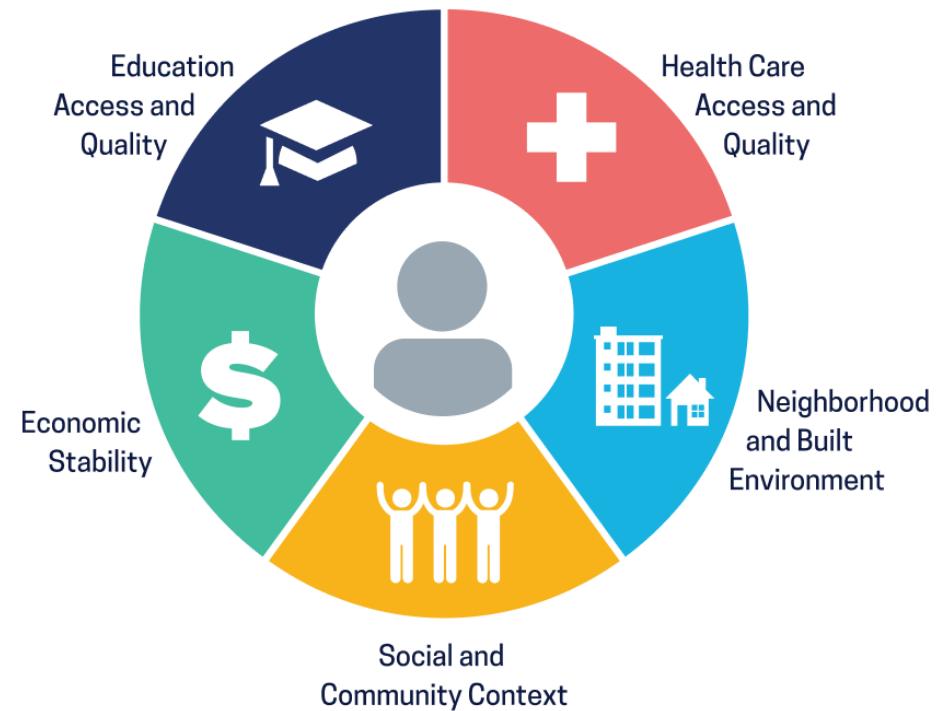
Background

- Racial and ethnic minority populations experience a disproportionate burden of kidney disease
- **Structural racism** is a key driver of health inequities for individuals living with kidney disease

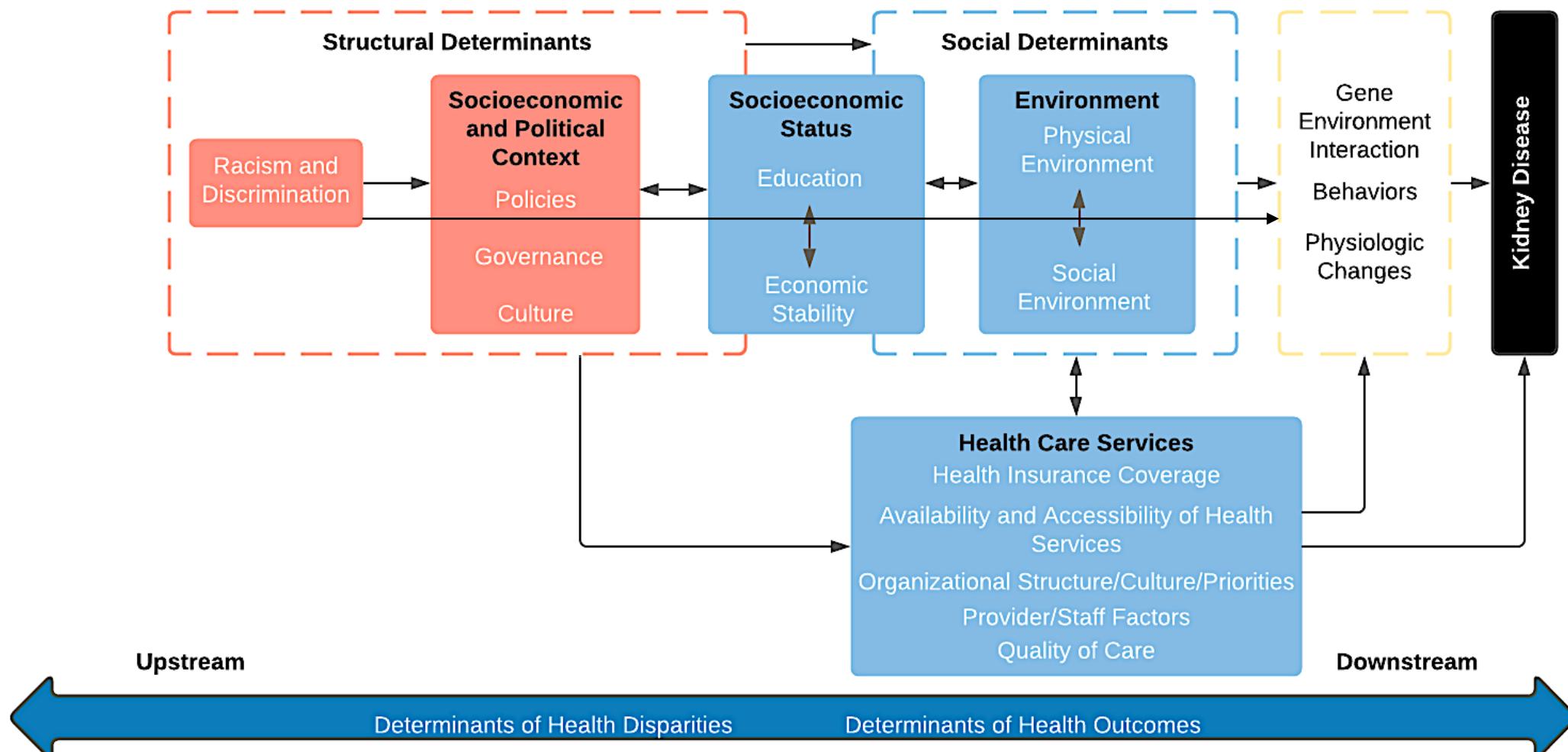
Structural Racism

“Totality of ways in which societies foster racial discrimination, through mutually reinforcing inequitable systems (in housing, education, employment, earnings, benefits, credit, media, health care, criminal justice, and so on) that in turn reinforce discriminatory beliefs, values, and distribution of resources, which together affect the risk of adverse health outcomes”

Social Determinants of Health



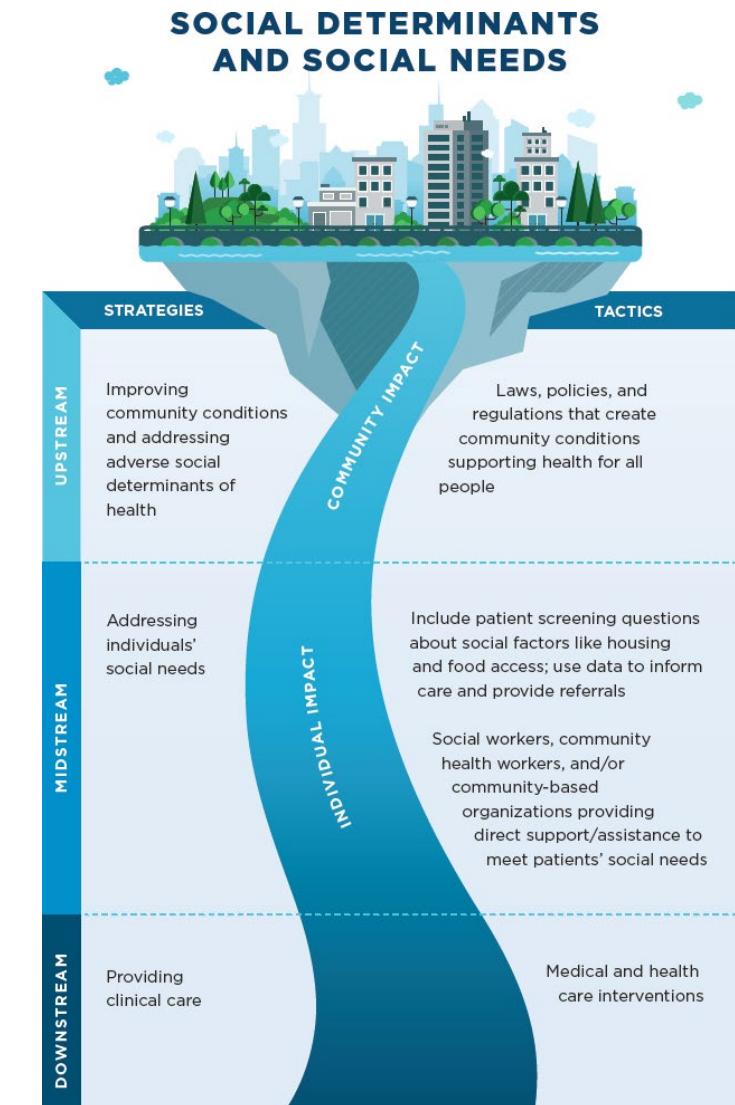
A conceptual framework for root causes of kidney health disparities



Adapted from AAFA conceptual framework for root causes of asthma disparities and the WHO framework for Action on the Social Determinants of Health (<https://www.aafa.org/media/2743/asthma-disparities-in-america-burden-on-racial-ethnic-minorities.pdf>)

The Need for Interventions to Address Structural Racism

- Substantial evidence describing kidney health disparities and potential contributors
- **Less research on interventions to mitigate kidney health disparities:**
 - Many focus on behavior change at the individual or interpersonal levels
 - **Few address structural drivers that perpetuate inequities** in health overall and among individuals living with kidney disease



NIDDK Workshop



Designing Interventions that Address Structural Racism to Reduce Kidney Health Disparities

February 24-25

[Meeting Summary](#)

Interventions to Address Structural Racism to Reduce Kidney Health Disparities FOAs

RFA-DK-22-014: Interventions that Address Structural Racism to Reduce Kidney Health Disparities – (U01-Clinical Trial Required)

RFA-DK-22-015: Interventions that Address Structural Racism to Reduce Kidney Health Disparities – Research Coordinating Center (U24 - Clinical Trial Not Allowed)

Application Due Date: November 17, 2022

Participating Organizations:

- National Institute of Diabetes and Digestive and Kidney Diseases ([NIDDK](#))
- National Institute on Minority Health and Health Disparities ([NIMHD](#))
- National Institute of Nursing Research ([NINR](#))
- Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention ([ODP](#))

THE GOAL

- To support a Consortium comprised of a **Research Coordinating Center (RCC)** and up to **6 Intervention Sites** working collaboratively to:
 - Design and conduct **community-engaged clinical trials** to test novel interventions that **dismantle or mitigate the effects of structural racism** that contribute to kidney health disparities
 - **Foster research collaborations** between investigators, people living with kidney disease, community-based organizations and other key stakeholders

RFA-DK-22-014

INTERVENTION SITES (U01)

Intervention Site Application (U01)

- Propose a **clinical trial** to test an intervention that aims to **dismantle structural racism or mitigate its effects:**
 - In one or more **NIH-designated Racial/Ethnic groups with health disparities, AND**
 - Aim to reduce disparities in health risks, care, and outcomes among **individuals living with kidney disease**

NIH-designated Racial/Ethnic Groups who experience Health Disparities:

American Indians/Alaska Natives

Asian Americans

Blacks/African Americans

Hispanics/Latinos

Native Hawaiians and Pacific Islanders

Studies proposed by successful applicants may be substantially revised, including potentially harmonizing intervention components and data collection measures across sites, or developing a unified study.

Intervention Sites Application (U01)

National Institute on Minority Health and Health Disparities Research Framework

Domains of Influence <i>(Over the Lifecourse)</i>	Levels of Influence*				
	Individual	Interpersonal	Community	Societal	
Biological	Biological Vulnerability and Mechanisms	Caregiver–Child Interaction Family Microbiome	Community Illness Exposure Herd Immunity	Sanitation Immunization Pathogen Exposure	
Behavioral	Health Behaviors Coping Strategies	Family Functioning School/Work Functioning	Community Functioning	Policies and Laws	
Physical/Built Environment	Personal Environment	Household Environment School/Work Environment	Community Environment Community Resources	Societal Structure	
Sociocultural Environment	Sociodemographics Limited English Cultural Identity Response to Discrimination	Social Networks Family/Peer Norms Interpersonal Discrimination	Community Norms Local Structural Discrimination	Social Norms Societal Structural Discrimination	
Health Care System	Insurance Coverage Health Literacy Treatment Preferences	Patient–Clinician Relationship Medical Decision-Making	Availability of Services Safety Net Services	Quality of Care Health Care Policies	
Health Outcomes	 Individual Health	 Family/ Organizational Health	 Community Health	 Population Health	

Intervention Sites Application (U01)

- Applicants are strongly encouraged to:
 - Propose **multi-level, multicomponent interventions** that address multiple levels and domains of influence
 - Apply **anti-racism lens** to guide their intervention development and implementation
 - Use the [PhenX SDoH Assessment Collection](#) and the [NIH Common Data Elements \(CDE\) repository](#)

Intervention Site Application (U01)

- Use **community engagement strategies** that facilitate authentic engagement and partnership with people living with kidney disease, caregivers, community members, and other key stakeholders throughout the research process
- Applicants should:
 - Propose interventions that address issues considered to be a **high priority for the community**
 - Propose effective **communication and dissemination activities** to inform the community of the studies findings
 - **Budget for community-engagement** activities, as appropriate

Intervention Site Application (U01)

- Include a **multi-disciplinary research team** with diverse perspectives and backgrounds
 - At least one **principal investigator** with **experience in community-engaged health equity research**
 - A history of successful recruitment and retention of participants within their target population

Plan for Enhancing Diverse Perspectives (PEDP)

- A PEDP **must** be included in applications for the Intervention Sites and the RCC
- **2-page summary**
- **Key elements include:**
 - Summary of strategies that advance the scientific and technical merit through expanded inclusivity
 - Timeline and milestones for PEDP
 - 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
 - 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

Intervention Site Application (U01)

- Studies proposed by successful applicants **may be substantially revised**, including potentially:
 - Harmonizing intervention components and data collection measures across sites
 - Developing one (or more) unified study/ies to be conducted collaboratively by the consortium across multiple sites
- Applications will be evaluated individually on the merits of the proposed study. Applicants should propose a discrete study that is feasible at their own site(s) and **should not** attempt to account for potential harmonization.

Intervention Site Application (U01)

- **Award Budget:**

- Budgets limited to \$500,000 in direct costs per year
- Should reflect the actual needs of the project

- **Award Project Period:**

- The maximum project period is 5 years

Section of Application	Page Limit
Specific Aims	1
Research Strategy	12
Plan to Enhance Diverse Perspectives (PEDP)	2
Biosketch	5

[SF424 \(R&R\) Application Guide](#)

Application Due Date: November 17, 2022

RFA-22-015

RESEARCH COORDINATING CENTER (U24)

Research Coordination Center (U24)

- The Research Coordinating Center (RCC) will lead, manage, and harmonize efforts for the Consortium
- Responsibilities include, but are not limited:

Organization, Management, & Administrative Support	Research Coordination, Data Management & Data Analyses	Foster Research Collaborations & Community Engagement
<ul style="list-style-type: none">• Facilitate collaboration, communication, and resource sharing• Plan and support scientific and administrative meetings• Create and administer an Opportunity Pool of funds• Coordinate dissemination of study findings	<ul style="list-style-type: none">• Lead collaborative efforts to develop and refine final study protocols• Establish common data elements and common data collection process• Provide biostatistical, data management, and analytic expertise for Consortium-wide data analyses• Facilitate participant recruitment/retention and track study progress	<ul style="list-style-type: none">• Establish and convene meetings with a Community Advisory Board• Coordinate collaborative opportunities• Facilitate sharing of best practices, strategies, and lessons learned• Monitor community engagement activities at Intervention Sites

Please refer to the [RFA](#) for the full list of responsibilities

Research Coordinating Center (U24)

RCC proposals should propose a multi-PD/PI structure and a **multi-disciplinary team with diverse perspectives** and backgrounds

- At least one **PI should have experience in community-engaged health equity research**
- Well-documented experience leading large multi-disciplinary and multi-site clinical trial research teams (**Clinical Trials Research Experience Table**)
- Include expertise in health equity research, community-engagement, kidney research, interventional research, and implementation science

Research Coordinating Center (U24)

- RCC proposals should:
 - Describe the **leadership and organizational structure** of the RCC
 - Provide a detailed **plan for day-to-day operations** and activities to be overseen by the RCC
 - Describe **plans for addressing potential challenges** in the development, implementation, and execution of the intervention studies

Plan for Enhancing Diverse Perspectives (PEDP)

- A PEDP **must** be included in applications for the Intervention Sites and the RCC
- **2-page summary**
- **Key elements include:**
 - Summary of strategies that advance the scientific and technical merit through expanded inclusivity
 - Timeline and milestones for PEDP
 - Approaches to assess progress towards meeting PEDP defined goals

Examples of Potential Strategies

- Inclusion of personnel
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- 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

Research Coordinating Center (U24)

- **Award Budget:**

- Limited to \$500,000 in directs costs per year (excluding the opportunity pool)
- Should reflect the actual needs of the RCC

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- **Award Project Period:**

- The maximum project period is 5 years

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Application Due Date: November 17, 2022

CONSORTIUM STRUCTURE AND GOVERNANCE

Steering Committee (SC)

- Serves as the governing body of the Consortium
- Comprised of PD/PIs from the RCC and Intervention Sites, NIH Project Scientists, and individuals living with kidney disease and community representatives
- Primarily responsible for overseeing the design, plan, execution and analyses of Consortium studies
- Regularly meet as a full committee and in workgroups to develop and implement the final study protocols

Possible Study Harmonization

Studies proposed by successful applicants may be substantially revised, including the potential harmonizing intervention components and data collection measures across sites or developing a unifying study

Other Committees and Meetings

- **Executive Committee:**
 - Makes operational decisions for the Consortium between Steering Committee Meetings
 - Comprised of the Steering Committee Chair, RCC PDs/PIs, NIH Program Staff, and an individual living with kidney disease
- **Community Advisory Committee:**
 - Provide feedback regarding design and conduct of studies
 - Intervention Sites and RCC will identify potential participants
- **Data Safety Monitoring Board (Appointed by NIDDK and serve in consultative capacity):**
 - Provide input on the study designs and protocols prior to implementation
 - Monitor research efforts and the safety and progress of studies

Key Dates

- **Letter of Intent:** October 17, 2022
- **Application Due Date:** November 17, 2022
- **Peer Review:** February/March 2023
- **Council Review:** May 2023
- **Approximate Start Date:** July-Sept 2023

Intervention Site and RCC awardees should be prepared to meet virtually or in-person immediately after funding in July-September 2023

Frequently Asked Questions

- Do I propose a trial for my own site or for 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.
 - AFTER applications are selected for funding, the Steering Committee will meet to determine how they will move forward as a Consortium, including considering harmonization of interventions or intervention components across Intervention Sites *depending on the research question/populations proposed in funded applications.*

Frequently Asked Questions

- What is the advantage of applying to this RFA versus the Parent Announcement for investigator-initiated trials?

The RFA provides:

- An opportunity to collaborate with other investigators and with the NIH
- Set aside funds to support these projects
- 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

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.
- 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.
 - Please call us prior to submitting the applications

Frequently Asked Questions

- 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?
 - Propose outcomes that are scientifically justified and achievable during the funding period. Please refer to [Designing Interventions that Address Structural Racism to Reduce Kidney Health Disparities Workshop Summary](#).
 - We may have opportunities to continue to fund studies beyond the 5-year period to achieve sufficient power if studies show sufficient progress and promise.

Frequently Asked Questions

- Can applicants propose non-kidney outcomes?
 - Yes, as long as applicants also propose kidney-relevant outcomes and have sufficient funds to do both.
- Does the Research Coordinating Center (RCC) need to propose a trial?
 - No; however, the study team must have substantial clinical trial experience
 - The RCC applications **must** include a detailed table listing the characteristics of trials they have been involved in (**“Clinical Trial Research Experience.pdf”**)

Frequently Asked Questions

- How does this relate to the Common Fund Initiative - Community Partnerships to Advance Science for Society (ComPASS)?
 - ComPASS is a **NIH-wide** initiative
 - Goal: to develop a *new health equity research model* for **community-led, multisectoral structural intervention research** across NIH and other federal agencies

Frequently Asked Questions

If you have application specific
questions,

PLEASE CALL US

Please Contact Us!

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Participant Questions

