

Fogarty International Center

Pre-Application Technical Assistance Webinar

Global Alliance for Chronic Diseases (GACD)

Implementation Research on Noncommunicable Disease Risk Factors among Low- and Middle-Income Country and Tribal Populations Living in City Environments

PAR-23-042 (R01 Clinical Trial Optional) | PAR-23-043 (R61/R33 Clinical Trial Required)

Brad Newsome, PhD
Program Officer
Fogarty International Center (FIC)

Lindsey Martin, PhD
Program Officer
National Institute of Environmental Health Sciences (NIEHS)

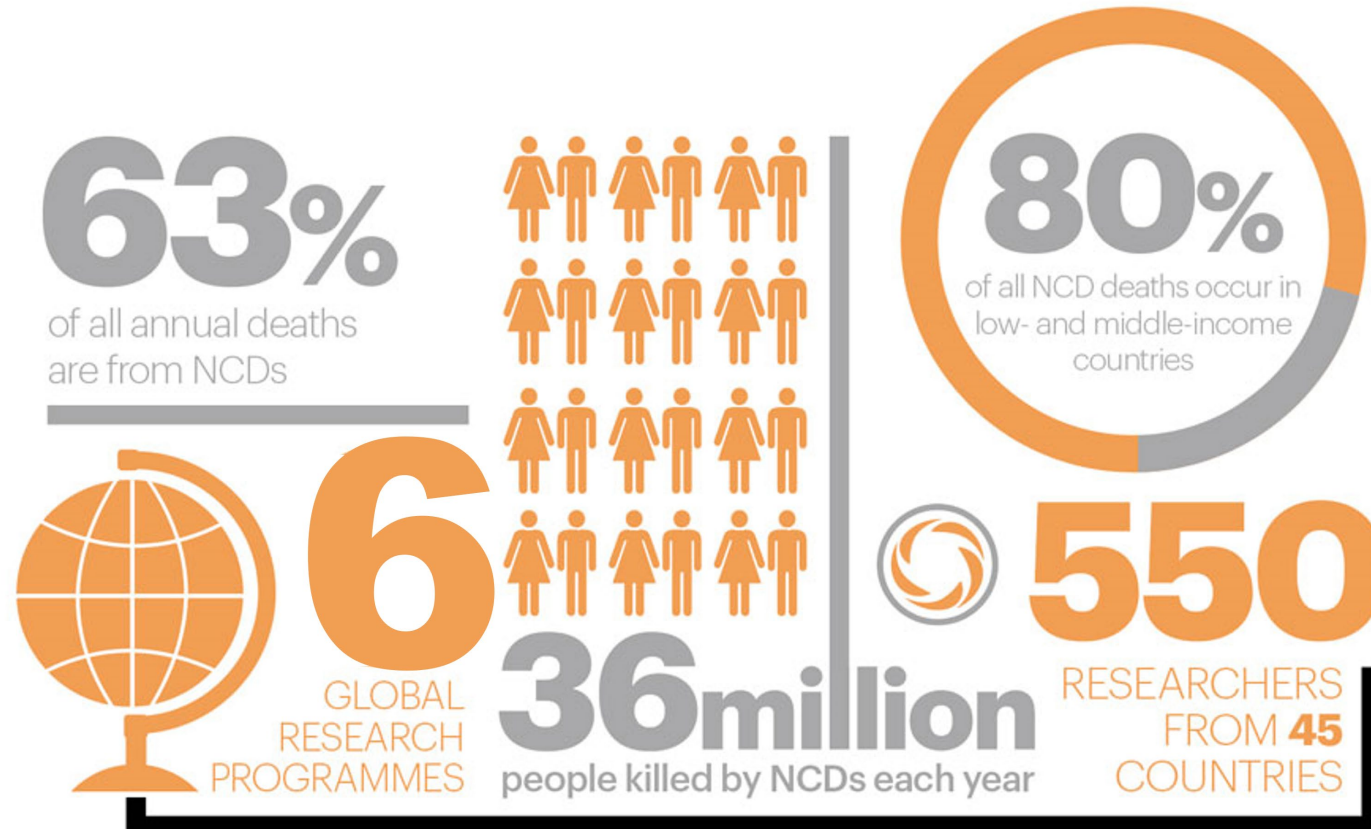


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Agenda

- **Overview of the Global Alliance for Chronic Diseases (GACD)**
- **Current Funding Opportunity Announcement Mechanistic Overview**
- **FOA Scientific Details and Expectations**
- **Q&A**

The need for NCD research in LMICs















Background: Global Alliance for Chronic Diseases (GACD)

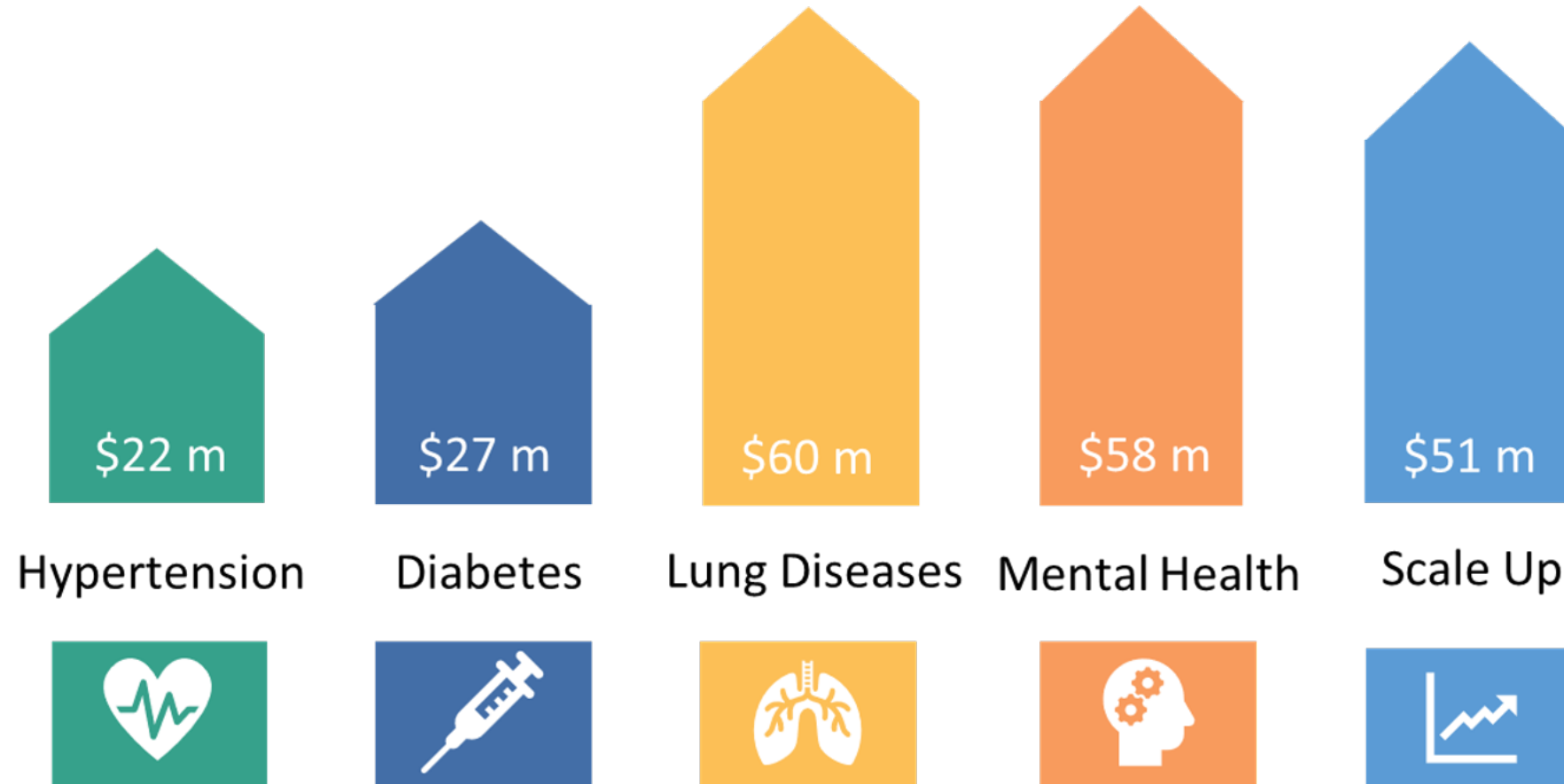
- **GACD Mission:** To reduce the burden of chronic non communicable diseases (NCDs) in low-and middle-income countries, and in indigenous populations facing conditions of vulnerability in high-income countries, by building evidence to inform national and international NCD policies and contribute to the achievement of the Sustainable Development Goals under section 3.4.
- 1st collaboration of major research funding agencies to specifically address chronic, non-communicable diseases
 - Together, the 15 members of the alliance represent 80% of glc funding for health research



GACD Associate Members

 <p>Secretariat of Government of Health, Argentina*</p>	 <p>Chinese Academy of Medical Sciences*</p>	 <p>South African Medical Research Council</p>
 <p>National Health and Medical Research Council, Australia</p>	 <p>Directorate General – Research and Innovation, European Commission</p>	 <p>Health Systems Research Institute, Thailand</p>
 <p>Sao Paulo Research Foundation, Brazil</p> <ul style="list-style-type: none">National Council of Scientific and Technological Development, Brazil*	 <p>Indian Council of Medical Research</p>	 <p>UK Medical Research Council</p>
 <p>Canadian Institutes of Health Research</p>	 <p>Agency for Medical Research and Development, Japan</p>	 <p>UK Department of Health and Social Care</p>
	 <p>Health and Research Council, New Zealand</p>	 <p>US National Institutes of Health</p>

Past Investments: Investing in impactful implementation research, 2010-Present



GACD-wide funding (15 Member Orgs) to-date: US\$220 Million (110 projects)

NIH Funding to-date: ~US\$40 Million (11 projects)

NIH ICs Involved: FIC (Administrative Lead), NHLBI, NCI, NIMH, NIA, NIDA, NICHD, NIMHD, NIEHS, CSR

Recent and Current Solicitation Topics: Cross-NIH effort with global, cross-cutting impact

- **2020:** Primary and secondary prevention of cancer
 - Implementation science for the primary and/or secondary prevention of cancer in LMICs and/or in populations facing conditions of vulnerability in HICs. Research activities focus on the adaptation and scale-up of the implementation of intervention(s) in accessible, affordable and equitable ways in order to improve the prevention and early diagnosis of cancer in real-life settings
- **2022:** NCD prevention in adolescents, young adults and other vulnerable stages across the life course
 - Implementation science focused on addressing common NCD risk factors by adapting interventions that reduce health risk and/or enhance positive health and lifestyle behaviours in young people, and in other vulnerable life course stages (e.g., childhood, elderly)
- **2023:** Interventions in city environments to reduce NCD risk
 - Implementation science focused on individual and/or structural level interventions that can reduce NCD risk and/or maximise the health-promoting potential of cities. Transdisciplinary partnerships among health, urban planning and behavioral science experts are encouraged

NCDs in the Context of Cities

- More than half of the world's population currently live in cities and this number is projected to rise to 68% by 2050.
- Recent climate related disasters, such as major flooding events, fires, and droughts, highlight how cities are at the forefront of the climate change crisis.
- Urgent need to equip local authorities and policymakers with strategies for maximizing the health-promoting potential of cities, while minimizing or reversing environmental degradation and health inequities.
- Cities provide tremendous social, cultural, and economic opportunity, and have the potential to become engines of good health and support climate change adaptation.

GACD City Environments Program Features

FOA Title: Implementation Research on Noncommunicable Disease Risk Factors among Low- and Middle-Income Country and Tribal Populations Living in City Environments

- Abbreviated “GACD City Environments”

Grant mechanisms: **PAR-23-042 (R01 Clinical Trial Optional)**

PAR-23-043 (Bi-Phasic R61/R33 Clinical Trial Required)

Eligibility: U.S. and World Bank-classified LMIC institutions as primary applicants

Duration: 5-year awards

Award Budget: ~\$500,000 per year per award (direct costs)

- FIC does not directly support any awards but leads the NIH efforts broadly; partner ICs fund and manage individual awards

Peer Review: CSR-led peer review through Special Emphasis Panel

Award Selection: ICs fund meritorious awards within their R01 or R61/R33 paylines or through select pay

PAR-23-042/-043: GACD City Environments

FOA Purpose:

- To support **implementation research** to reduce the risks of common noncommunicable diseases (NCDs) in World Bank-defined low- and middle-income countries (LMICs) and American Indian/Alaska Native (AI/AN) populations in the United States (US), with the potential to equip policymakers and practitioners with evidence-based strategies for prevention and/or management of NCDs among disadvantaged populations globally.
- Focus on **“cities”** given that air, water, and soil pollution; lack of greenspace; urban heat islands; lack of safe infrastructure for walking, cycling, and active living; lack of access to healthcare facilities, lack of health insurance, and cost of medications; housing conditions; and wide availability of tobacco, alcohol, and unhealthy foods and beverages contribute to the NCD epidemic in city environments.
- “Cities” include urban centers, informal settlements, slums, and periurban areas.

Implementation Research

Implementation research is central to this program

- This FOA is aligned with the overall GACD initiative to support implementation research, *defined as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health.*
- Implementation research examines which strategies work, for whom, and under what circumstances to promote the uptake, scale-up and spread of effective interventions.
- Projects may also address how interventions can be adapted and scaled up in ways that are feasible, acceptable, accessible, sustainable, and equitable in a given national context.
- Implementation research is especially relevant in LMICs, where it can help ensure that limited resources are invested in cost-effective interventions.

For more on Implementation Research:

<https://cancercontrol.cancer.gov/is>

<https://prevention.nih.gov/research-priorities/dissemination-implementation>

<https://www.niehs.nih.gov/research/supported/translational/implementation/index.cfm>

PAR-23-042/-043: GACD City Environments: Similarities

Both R01 CT Optional and R61/R33 CT Required:

- Address common NCD risk factors associated with city environments and related health inequities among populations in LMICs and AI/AN populations in the US.
- Describe study population and life course approach, evidence-based intervention(s), implementation research framework, efforts to address health equity, outcome measures, stakeholder and community engagement, implementation research capacity building, and equitable partnership and governance
- Requires LMIC institutional leadership or partnership
- Emphasis on multidisciplinary projects

PAR-23-042/-043: GACD City Environments: Differences

R01 - Clinical Trial (CT) Optional

- 5 years
- \$500K/yr Direct Cost (DC) (IC approval required >\$500K/year DC)
- Milestones required for CT but not for non-CT
- Participating ICOs: NCI, NHLBI, NIA, NIDA, NIEHS, NIMH, NINDS, NIMHD, ODP

R61/R33 CT Required

- Milestone-driven R61, 1 year, \$500K/yr (DC)
- Potential transition to R33, up to 4 years, \$500K/yr (DC)
- Milestones required for all years of R61/R33
- Potential transition to R33 contingent on meeting R61 milestones – Review R61/R33 structure carefully
- Participating ICOs: NHLBI, NIMH, ODP
 - Use R01 CT Optional for non-CT applications
 - Use R61/R33 CT Required for CT applications

R61/R33 Transition Milestones: Questions to Ask

PAR-23-043 (Bi-Phasic R61/R33 Clinical Trial Required)

Participating ICOs: NHLBI, NIMH, ODP

- Are the proposed transition milestones between the R61 and R33 phases well-defined with quantifiable measures that are appropriate for assessing the success of the R61 phase of the application?
- Do the milestones have specific quantifiable criteria that will enable clear decisions about their attainment?
- Is it clear how the R33 phase of the study will develop and expand once the R61 milestones are achieved?
- Given the potential benefits of the proposed research, do the milestones support the transition and will the overall project advance the intervention or tool?

Non-Responsiveness Criteria

Review Non-Responsiveness criteria very carefully to ensure alignment of your application with program expectations

Some ***BUT NOT ALL*** Non-Responsiveness Criteria

- Applications which are not focused on evidence-based interventions known to reduce NCD risk factor(s) associated with city environments, do not justify the choice of intervention(s), and do not provide evidence of the intervention's effectiveness, acceptability, feasibility, and potential for long-term health and other impacts;
- Applications that do not focus on implementation research or hybrid effectiveness-implementation studies (i.e., ones that do not have the primary aim of informing the selection of an intervention or evaluating the effectiveness of an already proven intervention to be implemented in a given city context). All proposals must contain a plan to implement and/or scale up an intervention already proven to directly impact human health or address the social determinants of health;
- Applications that do not propose implementation research capacity building for LMIC and/or AI/AN Tribal Nation researchers;
- Applications that do not demonstrate equitable partnerships and shared leadership between high-income country (HIC)/LMIC and/or non-Tribal Nation/Tribal Nation members of the project team, and between the project team and external stakeholders, including written letters of support from these groups;

For more information: SEE FOA Part 2, Section 1. Funding Opportunity Description

Data Management and Sharing Policy

- NIH has issued the [Data Management and Sharing \(DMS\) policy](#) (effective January 25, 2023) to promote the sharing of scientific data. Sharing scientific data accelerates biomedical research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies.
- Under the DMS policy, NIH expects that investigators and institutions:
 - Plan and budget for the managing and sharing of data
 - Submit a DMS plan for review when applying for funding
 - Comply with the approved DMS plan
- Individual NIH Institutes, Centers, or Offices may have additional policies and expectations (see [NIH Institute and Center Data Sharing Policies](#)).
- [Download a simplified version of the Data Management and Sharing Policy Overview Page](#)

NIH Clinical Trials Policy

- PAR-23-042 (R01 Clinical Trial Optional)
- Please be sure to review the [NIH Clinical Trials Policy](#)
- Misclassified applications may be withdrawn
- **Use the following four questions to determine if your study meets the clinical trials policy:**
 - Does the study involve human participants?
 - Are the participants prospectively assigned to an intervention? (can involve randomization, but not always)
 - Is the study designed to evaluate the effect of the intervention on the participants?
 - Is the effect being evaluated a health-related biomedical or behavioral outcome?

Application Review

5 Core Review Criteria

Each scored from 1 (exceptional) - 9 (poor)

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Overall Impact

Scored from 1 (exceptional) – 9 (poor)

Assessment of the likelihood for the project to exert a sustained, powerful influence on the research involved, in consideration of the following review criteria and additional review criteria

Other score driving considerations: Milestones, study timeline, human subjects/inclusion, vertebrate animals, biohazard, resubmission

SEE FOA Section V. Application Review Information

Your Questions?

- Please use the chat feature in Zoom to submit questions and we will answer as many as possible
- Frequently Asked Questions and this Webinar Recording can be found at: <https://www.fic.nih.gov/Funding/Pages/collaborations-gacd.aspx>

Thank You!

- Contacts
 - Brad Newsome, PhD, GACD Lead Program Official, FIC
brad.newsome@nih.gov
 - Lindsey Martin, PhD, Program Official, NIEHS
lindsey.martin@nih.gov
 - Austin Downs, GACD Program Manager, FIC
austin.downs@nih.gov

Please contact contacts listed in the FOAs for questions related to IC-specific scientific alignment