

Technical Assistance Webinar for RFA-MD-23-004

Community Level Interventions to Improve Minority Health and Reduce Health Disparities (R01 Clinical Trial Optional)

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June 7, 2023

Webinar starts at 2:00 PM EST



NIH National Institute
on Minority Health
and Health Disparities

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Webinar Tips

Participants will be in Listen Mode and will not be able to ask questions verbally.

Participants may ask questions using the chat feature. Questions will be answered during the Q&A session at the end of the webinar as time permits.

These slides and a recording of today's webinar will be available on the NIMHD website: <http://www.nimhd.nih.gov/>.



Agenda

- I. RFA background, Objectives, and Expectations
- II. Peer Review of Applications
- III. Timeline for Submission, Review, and Selection of Applications
- IV. Participant Questions



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Part I:

RFA Background, Objectives, and Expectations



Key Definitions

Community: A social group of any size whose members reside in a specific locality, share government, and often have a common cultural and historical heritage ([Dictionary.com](https://www.dictionary.com)). Communities may be self-defined (e.g., the LGBTQ community in a city or county) or defined by the catchment area of local government or service providers.

Community-level intervention: An intervention that modifies community characteristics, including the physical or social environment; laws, policies, or practices of organizations or governmental agencies within the community; and/or norms or collective behaviors of community residents.

Community-engaged research (CER): CER is the process of working collaboratively with groups of people affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being (Centers for Disease Control and Prevention). CER emphasizes collaborative partnerships with key stakeholders such as community partners, leaders, and knowledge holders, and leverage community resources to achieve community benefit via the research process.

NIH-designated populations with health disparities: Racial and ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities in the U.S.



Background

- The NIMHD Community-Based Participatory Research (CBPR) program was established in 2005 to:
 - address need for improved transdisciplinary and intervention research addressing health disparities and
 - strengthen the science of community engagement in addressing health disparities in populations that experience disparities
- Next step is for research and interventions that use community-engaged approaches to assess/intervene beyond individual-level
- Need to shift from individual-level and researcher-derived interventions to community-derived structural multisectoral interventions to improve minority health and eliminate health disparities



Research Objective





This initiative will support research projects to develop and test prospective community-level interventions to improve minority health and decrease health disparities.



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Community-Level Interventions

		Levels of Influence*			
		Individual	Interpersonal	Community	Societal
Domains of Influence <i>(Over the Lifecourse)</i>	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

National Institute on Minority Health and Health Disparities, 2018

*Health Disparity Populations: Race/Ethnicity, Low SES, Rural, Sexual and Gender Minority

Other Fundamental Characteristics: Sex/Gender, Disability, Geographic Region

<https://www.nimhd.nih.gov/about/overview/research-framework/nimhd-framework.html>



Community-Level Interventions

A community-level intervention:

- Modifies community characteristics (individual characteristics may also be modified)
 - Physical or social environment; laws, policies, or practices of organizations or agencies within the community; and/or norms or collective behaviors of community residents.
- Targets community-level determinants of health
- Employs community-engaged research methods



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Community-Level Interventions

What does NOT constitute a community-level intervention?

- An intervention that helps individuals address, cope with, manage, or navigate community-level determinants
- An intervention that is community-based but does not target community-level determinants of health
- An intervention that includes community-wide elements, but intervention effects are tested only at the individual level



Research Expectations

- Led by or involve collaborations with relevant community organizations or stakeholders
- Improve health outcomes in one or more populations with health disparities
- Focused on entire population in communities OR specific population within communities
- Guided by a conceptual model identifying hypothesized pathways between community-level intervention, community-level determinants, and health outcomes
- Collect data on community-level SDoH beyond individual self-reported perceptions and experiences



Research Expectations (Cont'd)

- Prospectively test impact of intervention on health outcomes
- Include health outcomes at individual, interpersonal/organizational, or community level, or a combination
- Use appropriate measures and analytic methods for community-level mechanisms
- Test interventions that are sustainable in the community



NIMHD Specific Areas of Research Interest

- Sample community-level intervention targets of interest for NIMHD include:
 - Increasing affordable healthy food options and opportunities for physical activity outside home
 - Changing community norms and structural barriers related to health promoting behaviors
 - Improving community attitudes toward sociodemographic groups or individuals with certain health conditions that are detrimental to the health and well-being of these populations
 - Promoting screening, detection, help-seeking, and self-management related to acute or chronic illnesses
 - Promoting community re-integration and health of individuals returning after incarceration or institutionalization
 - Preventing accidental injury, interpersonal violence, or suicide/STB especially with use of firearms



Research Resources

- PhenX Toolkit (<http://www.phenxtoolkit.org/>)
 - NIMHD encourages the use of standardized measures for conducting health disparities research. Investigators involved in human-subject studies are strongly encouraged to use common tools and resources that promote the collection of comparable data on SDOH across studies. Studies with human participants should incorporate SDOH measures from the Core and Specialty collections available in the Social Determinants of Health Collection of the PhenX Toolkit.
- Research Methods Resources - <https://researchmethodsresources.nih.gov/>
 - NIMHD encourages the use of appropriate, rigorous intervention study designs. This website provides information about study designs and statistical methods, including clinical trials. Special methods are required to determine sample size needed for specific analyses when assigning participants to study arms in groups or clusters or participant observations are analyzed for intervention effects. Methods consistent with plans for assignment of participants and delivery of interventions should be documented in the application. **Intervention designs that lack comparison conditions or sites are strongly discouraged.**



Application Resources

- NIH Online Application Help website:
<https://grants.nih.gov/grants/how-to-apply-application-guide.html>
- If new to the NIH grants process, this page may be of help as a starting point.
<https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply.htm>
- In addition to the SF424 (R&R) Application Guide, **review the RFA carefully, as applications that do not comply with RFA-specific instructions may be delayed or not accepted.** Use the R for “Research (R) Instructions” grant application guide: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/research-forms-h.pdf>.
- Applicant organizations must complete and maintain the following registrations to be eligible to apply for or receive an award, including System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390). All required registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible.
- **For this RFA, budgets are limited to \$1,000,000 in direct costs annually (not including Consortium F&A costs).** The scope of the proposed project should determine the project period, which can be a maximum of 5 years. This page may be helpful for preparing the budget.
<https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm>
- Include updated biosketches for all key personnel.
<https://grants.nih.gov/grants/forms/biosketch.htm>
- Contacting the scientific contacts listed in the RFA is highly recommended.



Part II:

Peer Review of Applications



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APPLICANT TELECONFERENCE: June 7, 2023 PEER REVIEW



Deborah Ismond, PhD, SRO



SUBMITTING AN APPLICATION

APPLICANT: Prior to submission, the applicant should conduct an internal review to ensure a well-organized document that contains all required components. The applicant organization must submit the application to NIH through [Grants.gov](https://www.grants.gov) by 5:00 pm local time July 7, 2023 (or August 9, 2023, for AIDS-related submissions). The applicant can check for errors/warnings and view the final image in [eRA Commons](#).

RECEIPT BY NIH: All applications are received and processed by the Division of Receipt and Referral (DRR) at the Center for Scientific Review (CSR). Once submitted, the application receives an ID number, is assessed for compliance and completeness of critical components, and then is assigned for peer review. Technical concerns about the submitted application should be sent to DRR.

PEER REVIEW PROCESS: After referral to an IC's Review Branch, the Scientific Review Officer (SRO) assembles a panel of expert reviewers to evaluate the scientific and technical merit of the applications received and sets up the peer review meeting.

PROGRAM OFFICERS: Program staff from the participating IC assess the responsiveness of applications submitted for specific initiatives/funding announcements. Non-responsive applications are withdrawn.



COMPONENTS OF PEER REVIEW

- **Reviewers and Chairperson:** Recruited by SRO create a **Review Panel** with the combined expertise needed to assess submitted applications.
- **Section V of Request for Applications (RFA):** Specifies the **Review Criteria** used to evaluate scientific and technical merit.
- **Critique Template:** A fillable Word document that is used by Assigned Reviewers to evaluate scientific and technical merit by addressing the strengths and weaknesses of each application in relation to Review Criteria outlined in Section V and provide the content of Summary Statements.
- **NIH 9-Point Likert Scoring Scale:** Provides a metric for calibration of scoring and is used to evaluate Review Criteria and Overall Impact.
- **Peer Review Meeting:** Face-to-face, telephone, or virtual formats allow for the discussion of Review Criteria and final Overall Impact scoring of applications by Assigned Reviewers and the Review Panel as a whole.
- **Overall Impact Score:** Reviewers enter a Final Score for each application discussed. Composite scores are released following the Review Meeting.
- **Summary Statement:** Issued within ~30 business days, it provides feedback to applicants and program officials regarding the review panel's assessment of scientific and technical merit in relation to Review Criteria.



WHAT TO EXPECT OF PEER REVIEW

The goal of Peer Review is to provide a thorough and fair evaluation that is free from bias for each application and to assess the Scientific and Technical Merit based on the Review Criteria specified in the RFA.

- The first level of review involves recruitment of a panel of experienced scientists/clinicians to review submitted applications. They are selected for their expertise in relevant disciplines, methodologies, and/or populations based on the research proposed.
- Applications and potential reviewers are screened for potential conflict of interest (COI). Reviewers must certify that they have no conflicts and will maintain confidentiality.
- All applications and related materials are considered privileged communication.
- Peer Review is conducted as a closed meeting. All aspects are considered **confidential**, including assignments, discussion, and scoring. Applications and related review information are not to be shared or discussed.
- Reviewers should never be identified or contacted, including after the meeting has concluded.
- There is no disclosure of information regarding the outcome of review, except via the official Summary Statement and communication with the assigned Program Officer.



WHAT PEER REVIEWERS LOOK FOR...

[Careful preparation](#) and an understanding of how your application will be reviewed can help you build a solid application.

Applicants should study the funding opportunity announcement to which they are applying. Pay close attention to the specific **Review Criteria in Section V** by which applications will be evaluated.

- Reviewers evaluate each of the **Five NIH Review Criteria** using the points outlined in Section V of the funding opportunity announcement.
- For each Review Criterion, reviewers identify **score-driving issues** in terms of *strengths* and *weaknesses*.
- After considering all the Review Criteria in terms of strengths and weaknesses, reviewers prepare an **Overall Impact** statement to summarize their overall assessment of the project in relation to its potential for creating a powerful and sustained influence on the field.
- Reviewers evaluate other additional application requirements for completeness, so ensure that the application address all elements.



THE NIH R01 REVIEW CRITERIA

OVERALL IMPACT: The likelihood for the proposed project to exert a sustained, powerful influence on the research field(s) involved.

SPECIFIC REVIEW CRITERIA: Reviewers consider each of these R01 review criteria in determining scientific and technical merit and provide a separate score for each.

- 1) Significance:
- 2) Investigator(s):
- 3) Innovation:
- 4) Approach:
- 5) Environment:

Ensure that all additional aspects are addressed for the following aspects:

Additional Review Criteria: Scoreable.

Additional Review Considerations: Non-scoreable.

Optional Clinical Trial: *Pay attention to additional specified review criteria for applications involving clinical trials.*



NIH R01 REVIEW CRITERIA

SIGNIFICANCE

Addresses an important problem or a critical barrier to progress in the field? Has a strong scientific premise for the project? Achievement of project aims will improve scientific knowledge, technical capability, and/or clinical practice? Successful completion of these aims will change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

INVESTIGATOR(S)

The PD/PIs, collaborators, and other researchers are well suited for the project? They have appropriate experience and training and have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Collaborative projects or multi-PD/PI investigators have complementary and integrated expertise? Leadership approaches, governance, and organizational structure are appropriate for the project?

INNOVATION

The application seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Concepts, approaches or methodologies, instrumentation, or interventions are novel to one field of research or novel in a broad sense? Proposes refinement, improvement, or new application of theoretical concepts, approaches/methodologies, instrumentation, or interventions?

APPROACH

The overall strategy, methodology, and analyses are well-reasoned and appropriate for accomplishing specific project aims? The investigators present appropriate strategies to ensure a robust and unbiased approach? Addresses potential problems, alternative strategies, and benchmarks for success? Includes strategies to establish feasibility and to manage particularly risky aspects? Presents adequate plans to address relevant biological variables for studies with human subjects or in vertebrate animals? For projects that involve clinical research, plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, are justified in terms of the scientific goals and research strategy proposed?

ENVIRONMENT

The scientific environment contributes to the probability of success? Available institutional support, equipment, and other physical resources are adequate for the proposed project? The project will benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?



SCORING AND OVERALL IMPACT SCORE

After assessing strengths and weaknesses of the Review Criteria and completing the section on Additional Review Criteria and Considerations, reviewers provide an overall assessment of the likelihood that the project will exert a sustained, powerful influence on the research field(s) involved. This is summarized in the written Overall Impact statement and involves assignment of an Overall Impact score.

The NIH utilizes a **9-point Likert rating scale** that ranges from 1 to 9 (Exceptional =1 and Poor =9) for the assessment of both **Review Criteria** and **Overall Impact** scores.

1. **Review Criteria scores** inform the evaluation of scientific/technical merit.
2. **Overall Impact scores** reflect the potential for exerting a sustained and powerful IMPACT or INFLUENCE on the research field involved.
3. **Final Composite scores** are released immediately following the peer review meeting. These scores are based on the mean Overall Impact scores of the discussed applications. This **Final Composite** score is recorded on the Summary Statement.



SUMMARY STATEMENT

Summary Statements provide official documentation of the review process and are typically released by the SRO in approximately 30 business days following the Peer Review Meeting. The front page will indicate (in upper left) the assigned Project Officer, who then becomes the applicant's primary point of contact going forward.

For discussed applications, the Summary Statement represents the review panel's overall recommendations. It includes the final overall composite score, the SRO writeup of discussion during the peer review meeting, as well as written comments and scoring from assigned reviewers based on the review criteria. It also may include comments regarding scorable and/or non-scorable aspects such as human subject concerns or administrative notes.

Applications that are not discussed (ND) are given an ND designation instead of a composite score, which may be indicated by an “++” on the face page. The ND summary statement includes written comments from assigned reviewers and scoring for the five review criteria as feedback for the applicant and program staff.



WHAT FOLLOWS PEER REVIEW?

NIH Program Officials consider the Overall Impact scores and Summary Statements resulting from the peer review process and examine which applications are best aligned with the Institute's priorities.

The second level of review occurs when the IC's Advisory Council is convened, which is composed of both scientific and public representatives chosen for their expertise, interest, or activity in matters related to health and disease.

Advisory Council members also consider the Institute's goals and needs and advise the Institute Director concerning funding decisions.

Final funding decisions based on Advisory Council advice are made by the Institute Director in consultation with Program Officials.

If an application is under consideration for funding, NIH will request "just-in-time" information from the applicant.



RESOURCES: Grant Submission or Peer Review

RESOURCES FOR APPLICANTS USING ERA COMMONS:

<https://www.era.nih.gov/applicants>

<https://era.nih.gov/sites/default/files/eRA-Commons-Resources.pdf>

PROBLEMS WITH SUBMISSION PROCESSING:

Always contact ERA Service Desk at: <http://grants.nih.gov/support/>

PEER REVIEW: The Center for Scientific Review (CSR) has produced several videos that provide an inside look at peer review process, on evaluating applications for scientific and technical merit and with tips for preparing applications.

https://era.nih.gov/era_training/era_videos.cfm

NIH GRANTS POLICY STATEMENT: On 2.5.1 Just-in-Time Procedures

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm



Part III:

Timeline for Submission, Review, and Selection of Applications



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Timeline

- Letter of Intent Due Date: 30 days prior to due date
- Application Due Date: July 7, 2023
- Peer Review Meeting: November 2023
- Council Review: January 2024
- Earliest Start Date: April 2024



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Part IV: Participant Questions

Submit questions via chat.



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