# Technical Assistance Webinar for RFA-MD-23-011, NIMHD Centers of Excellence in Investigator Development and Community Engagement (P50 - Clinical Trial Optional)

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Webinar starts at 2:00 PM EST



# **Webinar Tips**

Participants will be in <u>Listening Mode</u> 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: <a href="http://www.nimhd.nih.gov/">http://www.nimhd.nih.gov/</a>.



# **Agenda**

- I. RFA background and objectives
- II. Application information
- III. Peer review of applications
- IV. Timeline for submission, review, and selection of cooperative agreements
- V. Selected FAQs and participant questions



# Part I: RFA Background and Objectives

# **Background**

Established by Minority Health and Health Disparities Research and Education Act of 2000 (Public Law 106-525)

- Center grants to facilitate minority health and health disparities research education and training.
- Eligibility limited to academic institutions with a track record in enrolling, training, graduating students from health disparity populations.



# **Objective of FOA**

To support the research training and education of investigators from diverse backgrounds, including those underrepresented in biomedical research, particularly interested in diseases that disproportionately impact populations that experience health disparities (https://www.nimhd.nih.gov/about/overview/).



# Part II: Application Information

# **P50 Center Eligibility**

### Institution of Higher Education

- Had a significant number of members of health disparity populations enrolled as students in the institution.
- Current NIH-designated health disparity populations:
  - Blacks or African Americans
  - American Indians/Alaska Natives
  - Asian Americans
  - Hispanics/Latinos
  - Native Hawaiians/ other Pacific Islanders
  - Socioeconomically disadvantaged populations
  - Underserved rural populations
  - Sexual and gender minorities
  - Note: Health disparity populations not equivalent to groups underrepresented in the biomedical workforce

# **P50 Center Eligibility**

## Institution of Higher Education

- Been effective in assisting students from health disparity populations to complete a program of study or training and receive the advanced degree(s) offered.
- Made significant efforts to recruit and enroll health disparity population students into and graduate from the institution.
- Made significant recruitment efforts to increase the number of members of health disparity populations serving in full-time faculty or administrative positions at the institutions.



#### **Administrative Core**

- Provides overall scientific leadership and strategic direction for the Center of Excellence
- Provide administrative oversight and create mechanisms and procedures for ensuring interaction between the Center's Cores.
- Evaluate the quality, performance, and outcomes of the educational activities
- Core directed by the PD(s)/PI(s) of the Center



### **Investigator Development Core**

- Develop pilot project program for post-doctoral fellows, junior faculty, and other early-stage investigators.
- Solicit and select pilot projects, provide necessary guidance for the development of pilot projects as well as to support awardees to ensure successful completion of projects.
- Offer career enhancement activities for investigators at all faculty levels of the applicant and collaborating institutions.



### **Investigator Development Core**

- Annual funding for the pilot project program should be a minimum of \$300,000 total direct costs with at least three new pilot projects awarded each year.
- Eligibility to receive a pilot project award is limited to post-doctoral fellows, junior faculty and other early- stage investigators as defined by NIH (see <a href="https://grants.nih.gov/policy/new\_investigators/index.htm#definition">https://grants.nih.gov/policy/new\_investigators/index.htm#definition</a>).
- Recruitment of early career investigators from groups underrepresented in the biomedical research workforce encouraged.



### **Community Engagement and Dissemination Core**

- Facilitates equitable collaborative and sustainable relationships with community and other stakeholders.
- Coordinate dissemination activities with community members, partner organizations, and relevant service organizations or policymakers, as well as the scientific community.
  - Includes strategic planning about how to translate findings into sustainable community and system-level changes at the local level and beyond.



# Part III: Peer Review of Applications





# P50 Program Peer Review

- Applications will be assessed for completeness by the Center for Scientific Review (CSR);
- NIMHD program staff will assess the applications for responsiveness based on the eligibility criteria in the RFA; and
- NIMHD scientific Review Officer (SRO) will assemble a panel of experts from the extramural community to peer review the applications.



# **Preparations for Peer Review**

# RFA Specific Characteristics & Review Criteria

- Overall program goals
- Mechanism characteristics specific to this RFA
- Review Criteria: Specific to this NOFO in Section V
  - Additional Review Criteria/Considerations (e.g., Human Subjects/Clinical Trial/inclusion etc.)

# Administrative Review of Applications

- RFA requirements: whether the applications are complete as required by the RFA and have the appropriate sections to be able to be reviewed?
- Which personnel are involved in each application and their institution affiliation?
- The specific aims stated in each application and expertise needed.



### **Reviewer Selection**

#### Scientific Expertise

- as defined in FOA
- collective content of the applications

#### **Attention to Conflict of Interest**

#### Diverse representation

- gender
- demographics
- geography

### **Review Process**

- Pre-Meeting: Reviewers submit the written opinions/critiques
- During Meeting: Reviewers discuss the applications and vote for overall impact/final scores

Some applications may be "streamlined" not discussed (ND)

 Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.



### **Peer Review Criteria**

### Reviewers evaluate each applicant's potential to succeed Overall (Preliminary score)

- Significance
- Investigators
- Innovation
- Approach
- Environment



Administrative Core
Investigator Development Core
Community Engagement Core



#### **Peer Review Criteria**

https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-23-011.html

#### **Overall**

Criteria: Each receive a score

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Center to exert a sustained, powerful influence on the research field(s) involved, in consideration of the review criteria and additional review criteria

# Administrative Core; Investigator Development Core; Community Engagement Core;

Reviewers will provide an impact score to reflect their assessment of the likelihood for each of the Cores to exert a sustained, powerful influence on the research field(s) involved



## **Additional Review Criteria**

(included in the determination of the overall score)



**Study Timeline** (Specific to applications designated clinical trial on the electronic cover sheet)

#### **Human subjects**

Protection of Human Subjects against research risk

Five criteria

#### Inclusion

Sex/gender

Individuals of all ages

**Minorities** 

#### Other criteria

**Biohazards** 





#### **Additional Review Considerations**

(criteria not included in the determination of the overall score)

- Select Agent Research
- Resource Sharing Plans
  - The Data Sharing Plan and Genomic Data Sharing Plan (GDS) will not be evaluated at time of review.
  - Reviewers will comment on whether the Resource Sharing Plan(s) (i.e., <u>Sharing Model Organisms</u>) or the rationale for not sharing the resources, is reasonable.
  - https://oir.nih.gov/sourcebook/intramural-programoversight/intramural-data-sharing/2023-nih-datamanagement-sharing-policy
- Authentication of Key Biological and/or Chemical Resources <a href="https://grants.nih.gov/policy/reproducibility/guidance.htm">https://grants.nih.gov/policy/reproducibility/guidance.htm</a>
- Budget and Period of Support





# P50 Program Peer Review Meeting

Some applications may be "streamlined" -- not discussed (ND)

 Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Final Impact Score based on average of all voting reviewers x 10

Scores range from 10 (exceptional) to 90 (poor)

A summary statement for all applications would be available approximately 30 days after the review meeting

Do not contact the members of the review panel!



# **Videos on Peer Review Topics**

The Center for Scientific Review has produced videos with an inside look at peer review for scientific and technical merit and with tips for preparing applications.

https://era.nih.gov/era\_training/era\_videos.cfm

#### **Resources For Using ERA Commons**

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

#### **Problems with Submission Processing**

Always contact ERA Service Desk.

http://grants.nih.gov/support/

# In Doubt?

# Phone NIH

Peer Review, Program and Grant
 Administration Contacts are included on the last slide of this presentation and in the RFA.

### **Part IV:**

# Timeline for Submission, Review, and Selection of Applications



### **Timeline**

Letter of Intent Due Date: July 4, 2023

Application Due Date: Aug 4, 2023

(No late applications accepted!)

Peer Review Meeting: November 2023

Council Review: January 2024

Earliest Start Date: April 2024





#### **NIMHD Contacts**

#### **Program**

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# Part V: Selected FAQs and Participant Questions

Send questions via webinar chat.



# Selected FAQs: Eligibility

Question: What does "significant" mean in relation to the eligibility criteria outlined in the Special Eligibility Requirements in the RFA?

Answer: There are not specific benchmarks such as percentages for the special eligibility criteria. It is subjective and the PI needs to "make the case" that they meet the criteria.

Question: Can you clarify the Institutional Special Maintenance of Effort Attestations?

Answer: This requirement is an assurance that an award under the Centers of Excellence program won't supplant funds supporting existing similar activities.



### Selected FAQs: Administrative Core

Question: Is there a minimal level of effort for the PI or Core leads?

Answer: No.

Question: If we have an advisory board, is it OK or preferable to state names of members with letters of support?

Answer: Advisory board members should not be named, but can be described as to the type of individuals such as expertise, etc.



Question: Should individual pilot projects be described in the application?

<u>Answer:</u> No. The application should describe the Pilot Project Program (soliciting, selecting, supporting, and monitoring pilot projects), not individual projects, which should be selected <u>after</u> the Center is awarded. Vertebrate animal studies are not a priority.

Question: Are graduate students eligible to receive a pilot project award?

<u>Answer</u>: No. Awards are limited to post-doctoral fellows, junior faculty and other early-stage investigators as defined by NIH.



Question: We understand that the annual funding for the pilot project program must be a minimum of \$300,000 total direct cost with at least 3 pilot projects per year, but are there requirements for the minimum amount awarded for each pilot project?

Answer: There is not a minimum amount for a pilot project.

Question: Is it possible to fund two-year pilot studies, rather than one-year pilot studies?

Answer: Yes.

Question: Is the center expected to provide trainings (seminars, workshops, short courses, etc.) only to pilot Project PIs or other researchers?

Answer: No. These activities can be open to all career level faculty.



Question: Can pilot projects be aligned to existing research projects?

Answer: Yes.

Question: Can salary support for post-docs be included in pilot projects? Other cores?

Answer: Salary support for post-docs is an allowable cost within any Center component for those engaged as personnel.

Question: Is the Center expected to provide trainings (seminars, workshops, short courses, etc.) only to pilot Project PIs or other researchers?

Answer: No. These activities can be open to all career level faculty.



Question: Should pilot investigators be limited to the groups identified by NSF (AA, Latinx, AIAN) rather than also including other groups which some consider underrepresented (e.g., Filipino, Vietnamese, etc.)?

Answer: No

Question: Our pilot programs are designed to provide both funding and help develop research skills, can the pilot project funding include funding for project-specific mentorship/services such as statistics, survey design, qualitative data analysis, and community engagement assistance?

Answer: Yes, these are allowable costs.



Question: If pilot projects are not awarded until a few months after the Center grant award, can investigators use the funds over a 12-month period (which would require funds be used in the 2nd project year)?

Answer: Yes. It is understood that there may be a lag in implementation and administratively NIMHD may adjust the timeline for the 1<sup>st</sup> year.

Question: Is funding for the pilot projects limited to research only or can it be used for non-research activities (e.g., workshops, technical training, publication costs, travel to conferences etc.)?

Answer: No. Appropriate cost related to the conduct of the pilot project is allowable.



Question: Can investigators from other institutions be awarded pilot projects?

Answer: Investigators from "collaborating" institutions that meet the special eligibility criteria are eligible for pilot projects.

Question: What is the best way to approach Human Subjects documentations (delayed onset)?

Answer: The pilot projects are delayed onset human subjects research. The answer should be "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form and follow the application instructions for delayed onset studies.



#### NIMHD Contacts

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# **Participant Questions**

