## Transformative Research to Address Health Disparities and Advance Health Equity *Pre-Application Webinar*

#### **<u>RFA-RM-21-021</u>** and <u>**RFA-RM-21-022**</u>

The webinar will begin shortly. If you have any technical difficulties, please send an email to <u>CFHealthDisparities@mail.nih.gov</u>.

This webinar is being recorded





# Webinar Instructions



- All participants are muted
- We ask participants to save all questions for the end.
- NIH staff will address questions received in advance first
- If time allows, participants may use the Q&A box to submit questions
- Scientific inquiries and ideas for research projects will not be discussed

## Submit Questions via the Q&A panel





## Program Leadership





Janine A. Clayton, M.D., FARVO Director, Office of Research on Women's Health Office of the Director (OD)



Michael H. Sayre, Ph.D. Director, Integrative Biological and Behavioral Sciences National Institute on Minority Health and Health Disparities (NIMHD)



David R. Wilson, Ph.D. Director, Tribal Health Research Office Office of the Director (OD)



Shannon N. Zenk, Ph.D., M.P.H., RN, FAAN Director National Institute of Nursing Research (NINR)



**Elizabeth Wilder, Ph.D.** Director, Office of Strategic Coordination (NIH Common Fund) *Office of the Director (OD)* 

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## Working Group Panelists





#### Alison Brown, MS, Ph.D., RDN

Program Director National Heart, Lung, and Blood Institute (NHLBI)



Stephanie Courchesne-Schlink, Ph.D. Senior Advisor NIH Common Fund Office of the Director (OD)



#### Nathan Stinson Jr., Ph.D., M.D., M.P.H. Director, Community Health and Population Science National Institute on Minority Health and Health Disparities (NIMHD)



**April Oh, Ph.D., M.P.H.** Senior Advisor for Implementation Science and Health Equity *National Cancer Institute* (*NCI*)

## Grants Management and Review





Aruna Behera, Ph.D. Scientific Review Officer *Center for Scientific Review (CSR)* 



Shalanda Bynum, Ph.D. Scientific Review Officer Center for Scientific Review (CSR)



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Chief, Grants Management Branch National Institute of Dental and Craniofacial Research (NIDCR)

## Webinar Agenda



- Overview of the NIH Common Fund
- Overview of the Transformative Research to Address Health Disparities and Advance Health Equity Initiative (<u>RFA-RM-21-021</u> and <u>RFA-RM-21-022</u>)
- Cooperative Agreements U01 Mechanism
- Review Process and Criteria
- Q&A

## What is the NIH Common Fund?

- Supports a set of trans-NIH scientific programs
- Fosters innovative ideas with the potential for transformative impact
- Intended to benefit the broad biomedical research community
- Funded by the Office of the Director, managed in partnership with the NIH Institutes and Centers





## The Common Fund Moves the NIH Mission Forward – Faster



# Supporting bold scientific programs that catalyze discovery across

all biomedical and behavioral research

Advances areas of biomedical and behavioral research important to the missions of multiple NIH Institutes and Centers

Spurs subsequent biomedical advances that otherwise would not be possible without an initial strategic investment



## Part of the NIH UNITE initiative

NIH has launched the UNITE initiative to identify actions to end structural racism and racial inequities throughout the biomedical research enterprise.

As part of UNITE, the Common Fund is supporting transformative research to address health disparities and advance health equity.







nih.gov/ending-structural-racism



# Transformative Research to Address Health Disparities and Advance Health Equity



Transformative Research to Address Health Disparities and Advance Health Equity (<u>RFA-RM-21-021</u>)

Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions (<u>RFA-RM-21-022</u>)

#### Purpose:

- to develop, implement, and/or disseminate innovative and effective interventions and strategies that prevent, reduce, or eliminate health disparities and inequities (RFA-RM-21-021 and RFA-RM-21-022)
- to increase the competitiveness of investigators and expand the research base dedicated to health disparities research at minority serving institutions (RFA-RM-21-022)





<u>RFA-RM-21-021</u> – Open to all institutions/organizations that are typically allowed to apply for NIH awards (but not NIH intramural investigators)

<u>RFA-RM-21-022</u> – for Minority Serving Institutions

Eligibility requirements:

1) award undergraduate (B.S. or B.A.) and/or graduate degrees in biomedical sciences;

2) at the time of the application, have received no more than \$6 million dollars per year (total costs) from <u>NIH</u> <u>Research Project Grants</u> (RPGs) in each of the preceding two fiscal years, calculated using <u>NIH RePORTER</u>; and

3) enroll at least 25% of undergraduate students supported by Pell grants based on the most recent two years of data available from the <u>Integrated Postsecondary Education Data System (IPEDS) database</u> maintained by the National Center for Education Statistics, or are an accredited medical/health professional school with a historical mission statement that explicitly states that it was founded to educate students from nationally <u>underrepresented</u> backgrounds.

See Notice <u>NOT-RM-21-026</u> for requested institutional information

### Multi-PI Applications

- Multi-PI applications are allowed for both <u>RFA-RM-21-021</u> and <u>RFA-RM-21-022</u>
- For <u>RFA-RM-21-022</u>, <u>ALL</u> PI(s)/PD(s) on a Multi-PI application must be from eligible institutions
- For <u>RFA-RM-21-022</u>, collaborations with a non-eligible institution are allowed on an application from an eligible institution, but the majority of the research should be directed by the PI of the awardee (eligible) institution.



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# Scientific requirements



- All projects must include an **intervention component** 
  - Development/testing of a novel intervention
  - New implementation/dissemination strategies for evidence-based interventions
  - Novel examination of program/policy interventions that provide innovative insight into their effectiveness
- All projects must be **transformative** projects should reflect ideas substantially different from mainstream concepts and have high potential to lead to major improvements in health
- All projects must include a focus on one or more NIH-designated populations that experience health disparities in the U.S. – Blacks/African Americans, Hispanics/Latinos, American Indians and Alaska Natives, Asian-Americans, Native Hawaiians and Other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities (SGM)
- All projects must document or demonstrate meaningful collaboration and partnership with local community-engaged leaders that represent the communities/populations of focus

This list is not exhaustive. Please read RFAs carefully for additional requirements and instructions

# Not required, but encouraged



- Community-prioritized research questions what are the health conditions/topics most important to the communities involved in the project?
- Cross-cutting issues, such as social determinants of health across sectors
- Priority areas of multiple NIH Institutes and Centers
- Multi-level interventions that address two or more levels of influence of health and behavioral outcomes (interventions that go beyond the level of the individual)
- Transdisciplinary and intersectoral collaborations (e.g. transportation, housing, food systems)

This list is not exhaustive. Please read RFAs carefully for additional areas/topics that are encouraged

# Application



#### Uses standard Research (R) application form (<u>SF424 (R&R) Application</u> <u>Guide</u>), but in an <u>unconventional way</u>

Research Strategy section• Not used to provide substantial preliminary data and experimental details • Instead, used to address items of programmatic importance to this RFA • Overview and importance of research project (set context for project) • Approach (describe underlying logic and will ensure robustness/rigor) • Innovation (explain why research should be considered innovative) • Appropriateness for this RFA (why not a more traditional research grant program) • Timeline (transformative impact within project period, include critical decision points and possible alternative paths)	Specific Aims page	<ul> <li>Not used to list specific objectives of project</li> <li>Instead, used as a one-page distillation of project and why it is well-aligned with the spirit of the RFA</li> <li>Two sections:         <ul> <li>Significance, Innovation, Impact</li> <li>Insight and Rationale</li> </ul> </li> </ul>
	•••	<ul> <li>Instead, used to address items of programmatic importance to this RFA         <ul> <li>Overview and importance of research project (set context for project)</li> <li>Approach (describe underlying logic and will ensure robustness/rigor)</li> <li>Innovation (explain why research should be considered innovative)</li> <li>Appropriateness for this RFA (why not a more traditional research grant program)</li> <li>Timeline (transformative impact within project period, include critical</li> </ul> </li> </ul>

## **Research Strategy considerations**



- While reviewers will have expertise in areas such as health disparities, health equity, social determinants of health, and/or intervention studies, they will not all have expertise in the specific disease, condition, or health topic your proposal addresses. Be sure your proposal makes it easy to understand the innovative nature of your project and potential for transformative impact.
- Though no detailed experimental plan is required, make it clear what you are proposing to do.
- Convince the reviewers that you have thought deeply about the project identify areas of scientific risk, how they will be mitigated, alternative approaches.
- Also, convince the reviewers that the research will be done in a robust and rigorous manner many types of study designs are possible, so make it clear why your design is appropriate for the intervention chosen.
- Ensure that the study design is culturally and contextually appropriate, and that findings can be translated into sustainable changes that promote health equity.
- Clearly describe meaningful collaboration and partnership with local community organizations and/or community-engaged leaders.





- Application budgets are not limited, but need to reflect the actual needs of the proposed project. Large budgets must be well-justified.
- This is intended to provide flexibility for researchers there is no requirement/expectation to have a large budget. Base your budget on the research needs.
- Requests in excess of \$250,000 direct costs in any year require detailed (non-modular) budgets
- Prior approval from NIH is NOT required before submitting a budget exceeding \$500,000 in annual direct costs
- The maximum project period is 5 years

## Cooperative Agreement (U01) Mechanism





- A **Cooperative Agreement** is used when there will be substantial Federal scientific or programmatic involvement.
- Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities.
- The NIH purpose is to support and stimulate the awardees' activities; it is NOT to assume direction, prime responsibility, or adopt a dominant role.

## Terms and Conditions of Award



#### See Section VI.2 in the RFAs for the complete list of Terms and Conditions of Award

PI(s)/PD(s)	Project Scientist (PS)	Program Official (PO)
<ul> <li>Provide scientific leadership for all aspects of the study</li> <li>Finalize study design milestones, including a robust statistical plan for analysis, with NIH staff by Nov. 30, 2021</li> <li>Provide summaries of progress towards goals and milestones</li> <li>Milestones will be reviewed at least annually; negotiate new milestones as appropriate, working with NIH staff</li> </ul>	<ul> <li>Consult with the PI(s)/PD(s) regarding study design milestones prior to finalizing study design and as needed thereafter</li> <li>Provide scientific and programmatic support (e.g. input on experimental/clinical approaches, study protocol, data analysis, etc.)</li> <li>Review the progress of the study</li> <li>The PS will not make decisions about the funding of this project</li> </ul>	<ul> <li>Review activities to ensure objectives are being met and NIH guidelines are followed</li> <li>Have the option to withhold support if technical performance requirements/milestones are not met</li> <li>Conduct special reviews of the project as the PO deems necessary</li> </ul>

## **Review Process**



- NIH's Center for Scientific Review (CSR) will convene a Special Emphasis Panel to review applications. Applicants do not need to provide recommended study section assignment.
- Applications for <u>RFA-RM-21-021</u> and <u>RFA-RM-21-022</u> will be reviewed separately.
- Reviews will take place in July.
- You may identify three to four broad expertise areas in your application either in the cover letter or using the assignment request form while submitting your application.
- All applications will receive a written critique. Only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score.
- Summary statements will be provided for discussed applications in August.





These RFAs include unique review criteria. Please read *Section V. Application Review Information* carefully!

- Reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge, understanding, or capability
- Reviewers will be looking for the potential for transformative impact, not preliminary data or detailed experimental plans
- Reviewers will evaluate five scored review criteria (Significance, Investigators, Innovation, Approach, and Environment) in the determination of scientific merit and give a score on a scale of 1-9.

### **Review Criteria**



**Significance:** Does the study have <u>clear transformative potential</u>? Is the prior research that serves as the key support for the proposed project rigorous? Does the project address issues related to sustainability and/or implications for implementing and/or disseminating the intervention, if successful, to other health disparity populations?

**Investigators:** Because of the unique nature of conducting research in populations experiencing health disparities and inequities, research productivity may not be reflected by research publications but can include contributions to public health such as dissemination of findings to community partners, community outcomes of previous research, and efforts to build relationships and trust with community leaders.

**Innovation:** Does the application provide novel or innovative insights into improving the health of one or more populations experiencing health disparities?

**Approach:** Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects? Does the research use a community engaged approach or cultural constructs that reflect the desires of the community and engage the community in research design and conduct?

**Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Does the project provide evidence of community engagement and support, as appropriate?

## After Review



Applications will receive second level review by the NIH Council of Councils.

NIH will consider the following in making funding decisions:

- Scientific and technical merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of the proposed project to program priorities
  - Despite inherent scientific/technical risk, the potential for the research to result in scientific breakthroughs of high significance to one or more health disparity populations
  - Unusually cross-cutting science
  - Scientific balance in the portfolio of research supported by the Transformative Research to Address Health Disparities and Advance Health Equity initiative

The earliest start date for awards is September 2021





# **Question and Answer**

Questions submitted in advance will be answered first If time allows, questions submitted in the Q&A box will be addressed If your question is not answered today, please send it to <u>CFHealthDisparities@mail.nih.gov</u>

Please remember that scientific inquiries and plans for individual research projects will not be addressed

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