

National Institute of Neurological Disorders and Stroke

NINDS Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative

> RFA-NS-24-006 & RFA-NS-24-007 Pre-Application Technical Assistance Webinar

Wednesday, September 13, 2023 | 1:00pm ET





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

Participants may ask questions using the Q&A feature. Questions will be answered during the Q&A session at the end of the webinar as time permits (feel free to submit questions prior to the Q&A session)

These slides and a recording of today's webinar will be available on the NINDS HERN website: https://www.ninds.nih.gov/HERN-initiative









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Acting Chief Scientific Review Branch, NINDS





1. HERN NOFO Background & Overview

- 2. Peer review of applications
- 3. Participant Q&A



National Institute of Neurological Disorders and Stroke

Part 1: HERN NOFOs Background & Overview

Cheryse A. Sankar, PhD Program Director Office of Global Health & Health Disparities, NINDS



NINDS Health Disparities Mission Statement & OGHHD



The NINDS is committed to reducing the <u>disproportionate impact</u> of neurological disease borne by underserved groups of society by funding a spectrum of research from basic science through clinical studies and training the next generation of health disparities investigators



The NINDS Office of Global Health and Health Disparities (OGHHD) leads the coordination, development, and reporting on programs and initiatives related to national and international research on disparities and inequities in neurological disease.



NINDS Director's Message





Neurological Health Equity: Research for All

Tuesday, August 15, 2023

Today, I am happy to announce that the findings and recommendations from our two-year strategic planning effort for health disparities and equity research are published in a special issue of Neurologys I extend my deepest thanks to the dozens of expert researchers and clinicians that served on a working group of the National Advisory Neurological Disorders and Stroke (NANDS) Council for Health Disparities and Inequities in Neurological Disorders. This working group of dedicated individuals went above and beyond, providing recommendations that were adopted by the NANDS Council, which the NANDS Council then provided to me. They have also produced a series of well-researched, in-depth articles addressing several interrelated topics, including social determinants of health (SDoH), community engaged research, diversifying the workforce, diversity, equity, inclusion, accessibility, and health equity research training, and public communication. The special issue serves as a guide for the neuroscience and neurological health community to identify and seize high impact opportunities to improve neurological health for all people, a core component of our mission statement. The priorities are an extension of the 2021-2026 NINDS Strategic Plan and are published with the expectation that future NINDS topical and disease-specific strategic plans will revisit these recommendations as applicable to different research areas. Most importantly, NINDS emphasizes the critical need to follow up data collection efforts with tests of interventions to enhance health equity.

The recommendations focus on several interrelated topics:

- · Social determinants of health (SDOH)
- · Community-engaged research approaches in clinical interventions
- · Neuroscience workforce diversity
- · Diversity, equity, inclusion, and accessibility (DEIA) and health inequities training
- · Communication and engagement with diverse communities

NINDS announces neurological health equity strategic plan

Monday, August 14, 2023 Detailed plan lays the groundwork to reduce neurologic health disparities and inequities

> "The national conscience has opened to a new appreciation for the **need for action to promote health equity and end the web of conditions that have perpetuated unhealthy disparities**." These collective efforts reflect our and NIH's broader commitment to end structural racism and racial inequities throughout the biomedical research enterprise.

References:

NINDS Director's Message (ninds.nih.gov)

Benson RT, Koroshetz WJ. Health Disparities: Research That Matters. Stroke. 2022 PMID: 35168369







The most widely read and highly cited peer-reviewed neurology journal



SUPPLEMENT

The National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH) Health Equity Research Strategic **Planning Process and Recommendations**



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Neurology.org/N

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K.C. Johnston and E. Trevathan

OPEN ACCESS

Mortality Calculation

The Lives Lost to Inequities: Avertable Deaths From S9 Neurologic Diseases in the Past Decade

S.H. Woolf, D.A. Chapman, J.H. Lee, K.C. Johnston, R.T. Benson, E. Trevathan, W.R. Smith, and D.J. Gaskin **OPEN ACCESS**

NINDS Health Equity Recommendations

S17 Recommendations on Social Determinants of Health in Neurologic Disease

A. Towfighi, R.P. Berger, A.M.S. Corley, M.M. Glymour, J.J. Manly, and L.E. Skolarus

OPEN ACCESS

Use of Community-Engaged Research S27 Approaches in Clinical Interventions for Neurologic Disorders in the United States: A Scoping Review and Future Directions for Improving Health Equity Research

B. Boden-Albala, V. Rebello, E. Drum, D. Gutierrez, W.R. Smith, R.A. Whitmer, and D.M. Griffith **OPEN ACCESS**

Health Disparities Research Curricula and Training S47 Development: Recommendations From a National Institute of Neurological Disorders and Stroke Workgroup

B. Ovbiagele, L. Amezcua, S.C. Cruz-Flores, P. Griffith, G. Jean-Louis, C. Jenkins, V.J. Howard, and G. Smith-Byrd

OPEN ACCESS

- Diversity, Equity, Inclusion, and Health Inequities S59 Training in Neurologic Disorders and Stroke: Analysis and Recommendations From the NINDS Advisory **Council Working Group** D.L. Brody, R.F. Gottesman, G. Griffin, Z.M. Khalig, D.T. Lackland, G. Ling, and N. Mohile **OPEN ACCESS**
- The Communication of Scientific Information to Scientists, Clinicians, and the Public: Recommendations for Achieving Health Equity A.S. Ramírez, S.M. Mohl, C. Veasley, and S.A. Sheth **OPEN ACCESS**

NINDS Health Equity Framework

575 Determinants of Inequities in Neurologic Disease, Health, and Well-being: The NINDS Social Determinants of Health Framework D.M. Griffith, A. Towfighi, S.M. Manson, E.L. Littlejohn, and L.E. Skolarus **OPEN ACCESS**

NINDS Health Equity Portfolio Analysis

Analysis of NINDS Health Disparities and Health S82 Equity Research Portfolio, 2016-2020: Results and a Process for Transparency, Accuracy, and Reliability

S. Dodson, S. Spriggs, R. Calabrese, S. Chambers, M. Matthews, C. Sankar, A. Schaefer, C. Swanson-Fischer, D. Crawford, G. Umanah, and R.T. Benson **OPEN ACCESS**

NINDS Request for Information Analysis

Advancing Health Equity in Neurologic Disorders and S92 Stroke: Stakeholder Insights Into Health Disparities, Research Gaps, and Potential Interventions

E.L. Littlejohn, N.E. Booker, S. Chambers, J.A. Akinsanya, C.A. Sankar, and R.T. Benson

OPEN ACCESS

AMERICAN ACADEMY OF NEUROLOGY



Community-Engaged Health Equity Research in Neuroscience (HERN)





Understand specific drivers of health disparities and barriers to neurological health equity

Develop sustainable interventions to decrease disparities in neurological health among disadvantaged groups

NIH-designated populations that experience health disparities (HDPs)

American Indians/Alaska Natives Asian Americans Blacks/African Americans Hispanics/Latinos Native Hawaiians/Pacific Islanders Sexual and Gender Minorities Socioeconomically Disadvantaged populations Underserved Rural populations



Equity

HERN Element: Health Equity Research





Griffith DM, Towfighi A, Manson SM, Littlejohn EL, Skolarus LE. Determinants of Inequities in Neurologic Disease, Health, and Well-being: The NINDS Social Determinants of Health Framework. Neurology. 2023 Aug 15;101(7 Supplement 1):S75-S81. PMID: 37580154.



Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative



Current Funding Opportunities – Clinical Trial NOT Allowed





Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative R34: RFA-NS-24-007



Funding Opportunity Purpose

Assess feasibility and/or determine best practices to conduct community-engaged health equity research in neurological disorders with populations that experience health disparities (HDPs)

Support, enable and/or lay the groundwork for future clinical studies or trials

Fill a gap in 1) Engagement with one or more HDP communities; and/or 2) Multidisciplinary research team expertise in neurological disorders, health disparities research and/or community-engaged research

Expected Outcomes

Advance understanding of drivers of health disparities and barriers to neurological health equity

Establish collaborative research teams, including community partners, w/ expertise in community engagement with HDPs, health disparities research and neurological disorders



Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative R34: RFA-NS-24-007



Specific Areas of Interest (include but not limited to)

 Culturally-tailored approaches to identify barriers and determine effective strategies to build trust in communities that experience health disparities

 Identify and assess approaches to address disparities in neurological disorders due to stigma, bias and/or discrimination at the patient, provider, community and/or systems levels

 Strategies to address specific modifiable SDOH that contribute to disparities in neurological disorders

•Develop/Validate SDOH-informed instruments to promote detection and assessment of neurological disorder HD specific to populations that experience health disparities

 Strategies to address structural barriers, organizational practices, policies and other social, cultural, and contextual factors that impact disparate neurological health outcomes



Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative R01: RFA-NS-24-006



Funding Opportunity Purpose

Establish clinical trial readiness for community-driven research interventions to decrease disparities in neurological disorders in NIH-designated populations that experience health disparities (HDPs).

Utilize community-engaged research and collaborative, multidisciplinary teams to identify, develop, and evaluate strategies to improve outcomes related to neurological disorders in HDPs and fill gaps in clinical trial readiness

Expected Outcomes

Identify and understand drivers of health disparities and barriers for specific neurological disorders within HDP communities

Identify specific modifiable targets to prevent and/or decrease neurological morbidity/mortality and inequities among HDPs

Develop future community-driven research interventions to decrease disparities and gaps in neurological health among HDPs



Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative R01: RFA-NS-24-006



Specific Areas of Interest (include but not limited to)

Identify and validate approaches to examine the role of stigma, bias and/or discrimination as risk factors

Strategies to identify and measure specific modifiable social determinants of health

Elucidate the **biopsychosocial mechanisms** by which SDOH impact neurological disease

Develop and validate SDOH-informed instruments to promote detection and assessment of neurological disorder HD specific to populations that experience health disparities

Examine the role of Adverse Childhood Experiences in neurological health disparities

Identify strategies to address structural barriers, organizational practices, policies and other social, cultural, and contextual factors that impact disparate neurological health outcomes



Community-Engaged Health Equity Research in Neuroscience (HERN) Initiative R01: RFA-NS-24-006



Neurological Disorders

Clinical Trial Readiness: Applicants should describe the need to:

- Develop/validate specific targets, moderators and/or mediators (e.g., SDOH, etc) for future interventions
- Determine which HDP populations and/or subpopulations would be most appropriate ** as study participants
- Determine the optimal plan for ensuring robust and tailored outreach, recruitment and ** retention of the HDP(s) of interest
- Describe the potential impact of the proposed studies in addressing significant needs in the design and increasing the likelihood of success of upcoming clinical trials.



Community Engagement & Research Inclusion (CERI) Plan





Community Engagement

- Addresses barriers & facilitators of research participation
- Respectful, equitable and bi-directional knowledge transfer
- Builds trust

Community-Engaged Research

Is a process that broadly implements CE principles to meaningfully involve people with lived experience (PWLE), CPs, and caregivers from research planning to dissemination

CERI is Required as an Other Attachment – Under Section IV: Application and Submission Information

Limited to 2 pages

Will be Reviewed & Evaluated



Multidisciplinary Research Teams & Plan for Enhancing Diverse Perspectives



Multidisciplinary Research Teams



Research Expertise Health Equity

Neurological Disorders

Community-Engaged Research

Education & Training

Cultural competency, sensitivity & humility Community-Based Participatory Research

> Diverse Perspectives In Career Stage Representative of HDP(s)

URMs and non-URMs

Plan for Enhancing Diverse Perspectives (PEDP)

- Diverse collaborative research teams
- Multidisciplinary expertise
- Community-based orgs
- Health Equity & Community Engagement training

PEDP is Required as an Other Attachment – Under Section IV: Application and Submission Information

Limited to **1 page**

Will be Reviewed & Evaluated

Evaluated in the PEDP and Investigators section



HERN Initiative – Comprehensive strategy to ensure robust community engagement, recruitment/retention & workforce diversity centered on HDPs



National Institute of Neurological Disorders and Stroke





Non-Responsive Criteria



The following will be considered *non-responsive:

*Non-responsive applications <u>will</u> NOT be reviewed

•Projects <u>without a focus</u> on one or more NIH-designated populations that experience health disparities (NIH-HDPs)

•Applications that <u>do not include</u> a Community Engagement & Research Inclusion (CERI) plan

•Applications that <u>do not include</u> a Plan for Enhancing Diverse Perspectives (PEDP)

•Applications that **include** clinical trials (in any aims)

APPLICABLE TO BOTH R34: RFA-NS-24-007 & R01: RFA-NS-24-006



Focus on NIH-designated Populations that Experience Health Disparities



A focus on NIH-HDPs requires that one or more of the following groups are majority represented

NIH-designated populations that experience health disparities (HDPs)

American Indians/Alaska Natives Asian Americans Blacks/African Americans Hispanics/Latinos Native Hawaiians/Pacific Islanders Sexual and Gender Minorities Socioeconomically Disadvantaged populations Underserved Rural populations The inclusion of the following populations *among** NIH-HDPs are strongly encouraged, but not independently sufficient for the current funding opportunities

Examples of Populations not independently considered NIH-HDPs

Women Children Elderly People Living With Disabilities Incarcerated

*We strongly encourage intersectionality recognizing the greater impact of disparities in these populations

*Also see NIH guidance on inclusion of women (NOT-OD-18-014) and pops across the lifespan (NOT-OD-18-116)



Is this a clinical trial?



To determine if a proposed study is an NIH-defined Clinical Trial, answer the following Yes or No questions:

- i. Does the study involve **human participants**?
- ii. Are the participants **prospectively assigned to an intervention**?
- iii. Is the study designed to **evaluate the effect of the intervention** on the participants?
- iv. Is the effect being evaluated a **health-related biomedical or behavioral outcome**?

If the answer to all 4 questions is "Yes", then the study is an <u>NIH-defined</u> clinical trial.

A "No" answer to ANY question means it is NOT an <u>NIH-</u> <u>defined</u> clinical trial.

THIS CAN BE TRICKY!

Thoroughly review the information at the following websites to determine whether your proposed project is in fact a clinical trial:

NIH's Definition of a Clinical Trial

https://grants.nih.gov/policy/clinicaltrials/definition.htm

Clinical Trial Decision Tool

https://grants.nih.gov/ct-decision/index.htm



Award Information



RFA-NS-24-()	Maximum Project Period	Max Direct cost per year	*Total Direct cost over project period	**Anticipated # of awards
R34 (007)	3 yrs	\$225,000	Up to \$450,000	5-7
R01 (006)	5 yrs	\$500,000	Up to \$2.5M	5-7

*Budget must reflect the actual needs of the proposed project

**The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations

This is the anticipated budget over both funding cycles



Application to Award Cycle



First Cycle (For R34 and R01)



Second Cycle (For R34 and R01)



*Letters of intent are strongly encouraged but not required and not binding # Renewals/Resubmissions aren't allowed and those applying in the first cycle will not know if their application is awarded until after the second cycle application deadline



Who to Contact When?



Prior to submitting application

• Program Officer

NINDS HERN@nih.gov

After you submit

• Your SRO

After your review & summary statement

• Your Assigned PO



National Institute of Neurological Disorders and Stroke

Part 2: Review Process

Shantadurga Rajaram, Ph.D. Acting Chief Scientific Review Branch, NINDS



The NIH Grant Cycle







What SROs Look For When Recruiting Reviewers



- Demonstrated scientific expertise/research support
- Doctoral degree or equivalent
- Breadth of perspective
- Mature judgment
- Work effectively in a group context
- Integrity of the Review Process
- Impartiality
- Diversity
- Geographic distribution

and most importantly.....

• Lack of Conflicts





https://public.era.nih.gov/pubroster/rosterIndex.era



What Reviewers Look for in Applications



Reviewers need to be able to understand:

- WHAT you want to do...
- WHY it is important...
- That YOU can do it...

What they want to see:

- Impact
- Exciting ideas
- Clarity of thought
- Realistic Aims and Timelines
- Awareness of any Limitations of i) the Supporting Data and ii) the Study
- A well-organized, well-written application.





The Overall Impact score is an assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved.

- Determined by considering the 5 scored criteria (weighted based on reviewer judgment) and other criteria that count towards the score.
- The final score range is determined by the Overall Impact Scores from assigned reviewers.
- Panel members may vote outside this range although any intent to do so must be declared.
- Applications will NOT receive percentile rankings.

Significance ≠ Overall Impact

Minor Weakness:An easily addressable weakness that does not substantially lessen impactModerate Weakness:A weakness that lessens impactMajor Weakness:A weakness that severely limits impact

9-Point Scoring Scale

Impact	Score	Descriptor
	1	Exceptional
High Impact	2	Outstanding
	3	Excellent
	4	Very Good
Medium Impact	5	Good
	6	Satisfactory
	7	Fair
Low Impact	8	Marginal
	9	Poor



Review Criteria



- Overall Impact
- "Core" Review Criteria (***<u>Specific to this NOFO, CERI, PEDP</u>):
 - Significance (Rigor of the prior research)
 - Investigators
 - Innovation
 - Approach (Rigor of the proposed research, SABV)
 - Environment
- Other score influencing criteria (e.g. Human Subjects' Protections, Inclusion Policies)
- Non score influencing considerations (e.g., Resource Sharing Plans, Authentication Plans and Budget (including costs requested for data sharing.)



When Preparing Your Application



- Read instructions in the RFA(s). Make sure your application addresses ALL of the review criteria.
- **Clarify** how research /analyses plans proposed address the aims.
- Address rigor in both, prior & proposed research. Acknowledge any weaknesses in the former and state how the proposed work will address those. Factor in relevant variables.
- Discuss anticipated outcomes, interpretation of expected data, and potential pitfalls/back-up strategies.
- Help reviewers do their job. **Provide sufficient detail**. Do not overstuff but also do not assume that reviewers will "know what you mean."
- Make the application **reader-friendly.** Present an organized, lucid write-up.
- Include well-designed, correctly labeled tables and figures.
- Refer to/clearly cite relevant literature.
- Do not be overly ambitious.
- Include bio-sketches from all key personnel & letters of support from all key advisors and collaborators (make sure personal statement matches the specific application).
- Do not appear sneaky or sloppy. Spelling, Grammar matter.
- Solicit criticism from advisors EARLY; You need time to make improvements!



Peer Review Meeting Phases



Pre-Meeting:

- Each Application is assigned to 4 or more reviewers for review.
- Reviewers get access to Assignments and Instructions via a secure web interface ~ 4 -6 weeks before the meeting
- Reviewer Orientation Call
- Reviewers upload preliminary scores & critiques by a deadline and read critiques posted by others

At The Meeting:

- Each review group has a chairperson who facilitates the discussions
- Discussions focus on the strongest applications
- Assigned Reviewers state their preliminary scores & take turns presenting their critiques
- All non-conflicted members join the discussion
- Chair asks for comments/concerns on Additional Review Criteria (score influencing)
- Assigned Reviewers provide Final Scores that set the Score Range.
- Final Scores are recorded by assigned and unassigned reviewers (include any out of range scores).
- Lastly, the chair asks for comments/concerns on non score influencing Review Considerations.



Post-Meeting



The SRO Releases the Scores & Prepares Summary Statements.

All Applications Receive

- Scores for each core review criterion
- Critiques from assigned reviewers
- Administrative notes (if any) •

Only Discussed Applications Receive

- A Resume/summary of the discussion ٠
- A numerical overall impact/priority score

Review		
Application	Study Section	
Award Document Number:	Scientific Review Group: ZNS1 SRB-G	
FSR Accepted Code: N	Council Meeting Date (YYYY/MM): 2019/05	
Snap Indicator Code:	Meeting Date:	
Impact Score	Meeting Time Study Roster: <u>View Meeting Roster</u>	
Percentile:		
For information about next steps:	https://public.era.nih.gov/commons	

Early Stage Investigator Eligible: N



National Institute of Neurological Disorders and Stroke

Part 3: Questions & Answers



Thank You



https://www.ninds.nih.gov/HERN-initiative

Scan the following QR codes to browse our website for funding opportunities, contact information, and more!

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