Innovation for Healthy Living - Improving Minority Health and Eliminating Health Disparities (RFA-MD-22-004); and Technologies for Improving Minority Health and Eliminating Health Disparities (RFA-MD-22-003) Technical Assistance Webinar

LCDR Michael Banyas, USPHS, MPA, MA (candidate)
NIMHD SBIR/STTR Program Manager
Community and Scientific Programs
03/02/2022

National Institute on Minority Health and Health Disparities

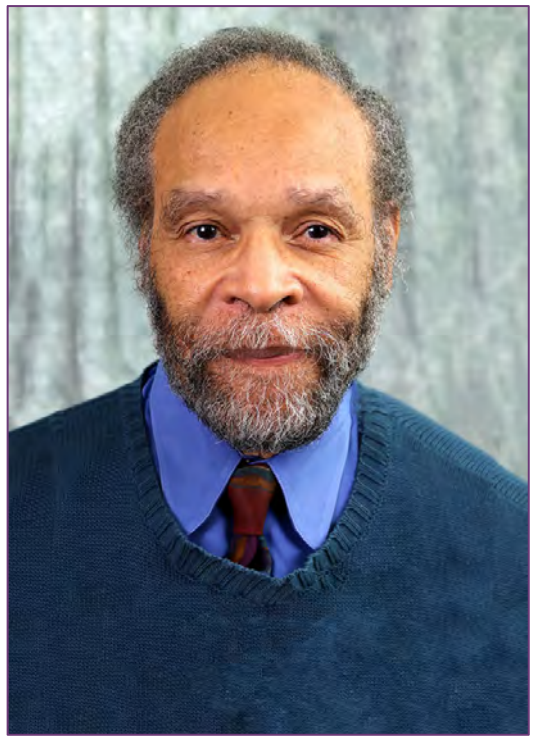
Agenda

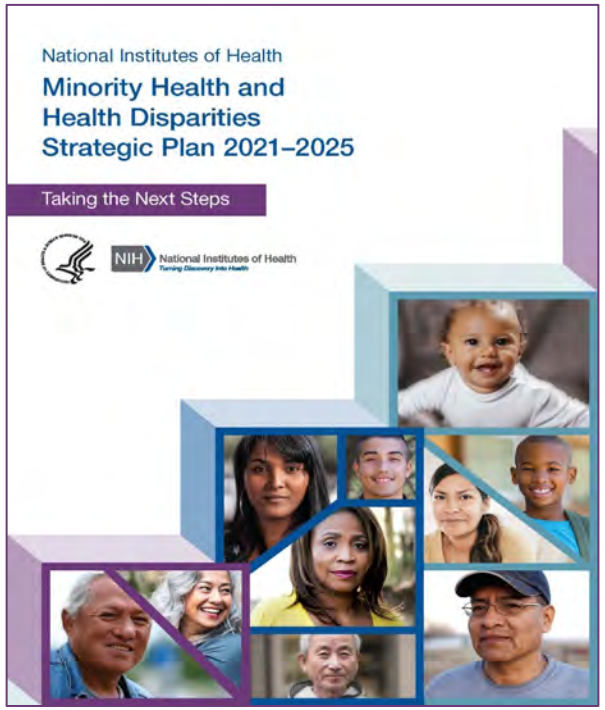
- Welcome from Nathanael Stinson Jr, PhD, M.D., M.P.H. Rear Admiral U.S. PHS ret, Division Director, Community Health and Population Science, National Institute of Minority Health Disparities
- Overview of NIH SEED Program and Requirements for SBIR and STTR Applicants
- RFAs:
  - SBIR: Healthy Living - Improving Minority Health and Eliminating Health Disparities (RFA-MD-22-004); and
  - STTR: Technologies for Improving Minority Health and Eliminating Health Disparities (RFA-MD-22-003)
- Application Requirements
- Partner NIH Institutes and Center Presentations
  - National Institute Drug Abuse
  - National Institute of Diabetes, Digestive and Kidney Diseases
  - National Heart Lung Blood Institute
  - National Institutes of Neurological Disease and Stroke
  - National Center for Advancing Translational Science
  - National Institute of Aging
- Application Review Process, Jingsheng Tuo, PhD, SRO, Scientific Review Branch
- Attendee Questions

Questions

- General RFA Questions: nimhdsbirsttr@mail.nih.gov
- Specific NIH Institute/Center Questions Can Be Found at the End of the RFA
- Webinar Questions Please Use the Chat

Welcome from Dr. Stinson
Division Director, Community Health and Population Science, National Institute of Minority Health Disparities (NIMHD)





"Charged with leading scientific research to improve minority health and reduce health disparities, NIMHD developed the 2021-2025 NIH Minority Health and Health Disparities Strategic Plan in collaboration with all NIH Institutes, Offices and Centers and externally with experts and communities impacted by health disparities. This strategic plan demonstrates the commitment of all of NIH to improving minority health and reducing health disparities."

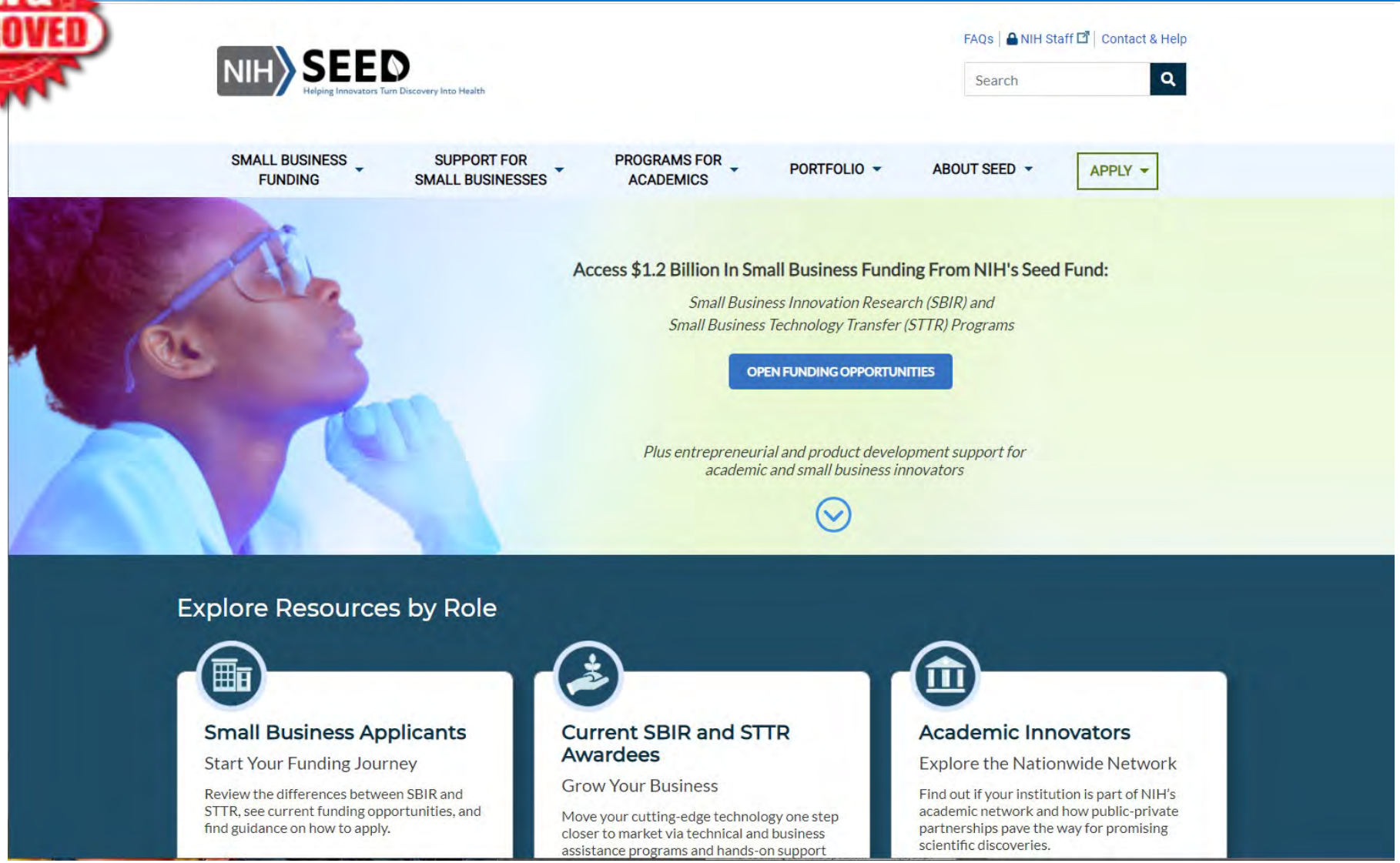
National Institute on Minority Health and Health Disparities

Overview of NIH SEED Program and Requirements for SBIR and STTR Applicants

National Institute on Minority Health and Health Disparities

National Institute on Minority Health and Health Disparities

Small Business Program Website



National Institutes of Health
Office of Extramural Research

https://seed.nih.gov

National Institutes of Health
Turning Discovery Into Health

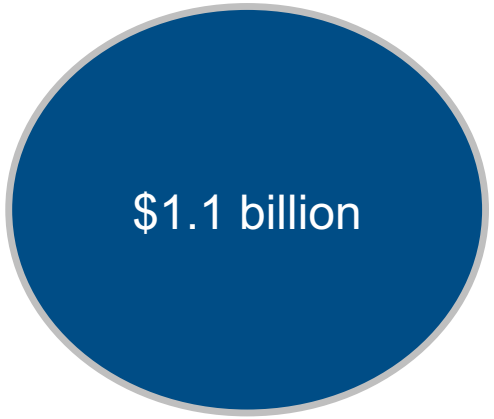
NIH Mission




To seek fundamental knowledge about the nature and behavior of living systems and the ***application of that knowledge to enhance health, lengthen life, and reduce illness and disability****.*

The Small Business Program helps NIH accelerate discoveries from bench to bedside

$1.2 Billion Dedicated Funding via Set-aside from NIH's R&D Budget



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

Eligibility Criteria

- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the US (with few exceptions)
- Individual Ownership:
  - Greater than 50% US-owned by individuals and independently operated <OR>
  - Greater than 50% owned and controlled by other business concerns that are greater than 50% owned and controlled by one or more individuals, an Indian tribe, ANC or NHO (or a wholly owned business entity of such tribe, ANC or NHO) <OR>
  - **SBIR ONLY**: Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

Determined at the Time of Award

SBIR and STTR Critical Differences

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business

Award always made to small business

Electronic Submission

Grant applications **and** SBIR contract proposals must be submitted **electronically**.

Two-Factor Authentication:

login.gov
will soon be required to access eRA Commons

Use the same login.gov account for eRA, Grants.gov, and SAM

REQUIRED REGISTRATIONS

- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

- Grants submit via **ASSIST** or Grants.gov Workspace
- For contracts, submit proposals with electronic Contract Proposal Submission (eCPS) website

Helpful NIH Grants Registration Infographic

SEED Support for Awardees

Technical and Business Assistance (TABA)

TABA Needs Assessment → TABA Funding (requested in grant application)

Education

- I-Corps at NIH
- Concept to Clinic: Commercializing Innovation (C3i) Program

Funding and Support

- Commercialization Readiness Program (CRP)
- Regulatory & Business Development Consultants

Partnering and Investment Opportunities

- Company Showcase

BIO International Convention · RESI Redefining Early Stage Investments · LifeSciences Summit · The MedTech Conference powered by AdvaMed · ACA Angel Capital Association

National Institutes of Health
Office of Extramural Research

https://sbir.nih.gov/support-for-awardees

SBIR: Overview Healthy Living - Improving Minority Health and Eliminating Health Disparities (RFA-MD-22-004)

	SBIR Criteria
Partnering Requirement	Permits partnering
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)
Principal Investigator	Primary employment (>50%) must be with the small business

NIH Designated Racial and Ethnic Minorities

	STTR
Partnering Requirement	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	PI may be employed by either the research institution partner or small business

National Institute on Minority Health and Health Disparities

Partner ICs

Institute and Center	Total Cost Ceiling	Number of Awards
National Institute on Minority Health and Health Disparities (NIMHD),	$1,000,000	3-4 awards
National Heart, Lung, and Blood Institute (NHLBI)	$2,900,000	3 Phase I and 1 Direct-to-Phase II awards
National Institute on Aging (NIA)	$1,000,000	3-4 awards
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	$1,000,000	3-4 awards
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	$1,000,000	1-3 awards
National Institute on Drug Abuse (NIDA)	$250,000	1 award
National Institute of Dental and Craniofacial Research (NIDCR	$250,000	1 award
National Institute of Neurological Disorders and Stroke (NINDS)	NOSI	NOSI
National Center for Advancing Translational Sciences (NCATS)	$1,000,000	1-3 Awards

Purpose of the RFAs

1) Engage small business concerns (SBC) in developing technologies and products that engage, empower, and motivate individuals, and communities, such as providers and healthcare institutions.

2) Emphasis in supporting sustainable health promoting activities and interventions leading to improved health, healthcare delivery, and the elimination of health disparities in one or more NIH-defined population groups who experience health disparities.

NIH Designated Racial and Ethnic Minorities

- Asians (Native Hawaiians and Other Pacific Islanders)
- African Americans/ Blacks
- Socio economically disadvantaged individuals
- Sexual/ gender minorities
- Rural areas
- American Indians/ Alaska Natives
- Hispanics/ Latinos

Technology Considerations

Considerations include:

- **Effectiveness in improving quality of care for racial/ethnic and health disparity population?**
- **Affordability for underserved population and providers?**
- **Acceptability and suitability for the population's culture, language, literacy level, and content?**
- **Does it assist in advancing the mission of the organization?**
- **Compatibility with the organizational culture of the customer?**
- **Can the proposal be combined with or embedded within other current services or programs within the organization?**
- **Accessibility and or deliverable to the desired populations and those who intended to use the technology?**

Organizations

- Does it assist in advancing the mission of the organization?
- Is it compatible with the organizational culture of the customer?
- Can the proposal be combined with or embedded within other current services or programs within the organization?
- Is the technology or product accessible and or deliverable to the desired populations and those who intended to use the technology?

Research Considerations

Physical Barriers

Knowledge Barriers

Infrastructure Barriers

Economic Barriers

Cultural Barriers

Budget

- **Total funding support (direct costs, indirect costs, fee) normally may not exceed $259,613 for Phase I awards and $1,730,751 for Phase II awards.**

- **Certain topic are authorized under by waiver for exceeding these total award amount hard caps for specific topics. The current list of approved topics by IC is found at https://sbir.nih.gov/funding#omni-sbir.**

- **Applicants are strongly encouraged to contact program officials prior to submitting any application in excess of limits listed above early in the application planning process.**

- **Applicants should propose a budget that is reasonable and appropriate for completion of the research project.**

Project Duration

- According to statutory guidelines, award periods normally may not exceed:
  - 1 year for Phase I; and
  - 2 years for Phase II.

- Applicants are encouraged to propose a reasonable and appropriate project duration period for completion of the research project.

NIH Institute and Center Presentations

Institute and Center	Presenter
National Institute on Drug Abuse (NIDA)	Julia Berzhanskaya PhD
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	Daniel Gossett, Ph.D.
National Heart, Lung, and Blood Institute (NHLBI)	Stephanie Davis, PhD
National Institute of Neurological Disorders and Stroke (NINDS)	Emily Caporello, PhD and Sarah Schwartz, PhD.
National Center for Advancing Translational Sciences (NCATS)	Lillianne M Portilla PhD . and Meena U. Rajagopal, Ph.D.
National Institute on Aging (NIA)	Joy Toliver, M.P.H

National Institute on Minority Health and Health Disparities

NIDA TOPICS OF INTEREST RFA-MD-22-004

JULIA BERZHANSKAYA, LEONARDO ANGELONE, ELENA KOUSTOVA

OFFICE OF TRANSLATIONAL INITIATIVES AND PROGRAM INNOVATIONS (OTIPI)

2/28/2022

NIDA TOPICS OF INTEREST RFA-MD-22-004

- NIDA is interested in the RFA-MD-22-004 topics related to prevention, management, monitoring, diagnosis, and treatment of Substance Use Disorders (e.g., Opioid Use Disorder, Stimulant Use Disorder) and supporting NIDA's mission
- For Fast-Track applications, NIDA encourages preliminary data that clearly support the technical and commercial feasibility. If repurposing already existing drug/ device/app for SUD diagnosis or treatment, provide preliminary data about existing drug/ device and scientific rationale for the feasibility in SUD space. For other requirements, see NIDA SBIR programmatic descriptions and contact Program Officer (https://seed.nih.gov/sites/default/files/2020-2_SBIR-STTR-topics.pdf)
- NIDA will only consider SBIR, not STTR applications to this topic
- NIDA-funded research on health disparities (SBIR or non- SBIR) and potential academic collaborators can be found in the NIH reporter (reporter.nih.gov)
- Example: R41DA048692-01"Culturally sensitive, evidence-based, Spanish language mobile app for smoking cessation for Latino cigarette smokers"

National Institute of Diabetes and Digestive and Kidney Diseases

Research Mission of the NIDDK

- *Chronic*
- *Common*
- *Consequential*
- *Costly*

National Institute of Diabetes and Digestive and Kidney Diseases

https://www.niddk.nih.gov/research-funding/research-programs

Division of Diabetes, Endocrinology, and Metabolic Diseases	Division of Digestive Diseases and Nutrition	Division of Kidney, Urologic, and Hematologic Diseases
Type 1 Diabetes	Crohn's Disease	Chronic Kidney Disease
Type 2 Diabetes	Ulcerative Colitis	Polycystic Kidney Disease
Childhood Diabetes	Liver Disease	Kidney Injury & Failure
Diabetes Complications	Hepatitis	Vesicoureteral Reflux
Cystic Fibrosis	Drug Induced Liver Injury	Urinary Incontinence
Inborn Metabolic Errors	NASH	Urinary Tract Infections
Wasting Syndrome	Hemochromatosis	Benign Prostatic Hyperplasia
HAART Therapy	**Obesity**	Chronic Prostatitis
Molecular Therapies	Irritable Bowel Syndrome	Painful Bladder Syndrome
Endocrinology of Bone	Gastroparesis	Anemias & Iron Overload
Obesity	Barrett's Esophagus	Sickle Cell Disease

https://www.niddk.nih.gov/research-funding/research-programs

National Institute of Diabetes and Digestive and Kidney Diseases

Division of Diabetes, Endocrinology, and Metabolic Diseases

Guillermo A. Arreaza-Rubin, M.D.
Diabetic Technology, Type 1 Diabetes, and Endocrine Diseases

Teresa Jones, M.D.
Diabetic Wound Healing and Neuropathy and Type 2 Diabetes

Bradley M. Cooke, Ph.D.
Neuromodulation and Type 2 Diabetes Drug Discovery

Division of Digestive Diseases and Nutrition

Christine Densmore, M.S.

Division of Kidney, Urologic, and Hematologic Diseases

Daniel Gossett, Ph.D.

- NIDDK is participating in the SBIR funding opportunity: RFA-MD-22-004
- Innovations for Healthy Living - Improving Minority Health and Eliminating Health Disparities (R43/R44 - Clinical Trial Optional)

National Institute of Diabetes and Digestive and Kidney Diseases

https://www.niddk.nih.gov/

Diagnostics and Disease Management Tools for Use in Underserved Populations

NHLBI Workshop - Diagnostics and Disease Management Tools for Use in UP*:

Diagnostics have the power to deliver breakthroughs to promote screening & early detection and inform prevention & treatment. They can also help bridge the gap from discoveries to health and advance health equity.

Challenges:

To accelerate the development of transformative diagnostic and screening tools that are safe, affordable, and accessible to underserved communities. These tools should leverage social determinants of health to inform upstream prevention, screening, and treatment of major health priorities in underserved communities.

Geographic barriers	• Environmental racism • "Food deserts" • "Pharmacy deserts" • Lack of healthcare facilities in rural areas
Economic barriers	• UP less likely to be insured • Many disease mgmt. tools are unaffordable
Cultural barriers	• Healthcare providers require training on cultural sensitivity • Language barriers
Psychosocial Barriers	• Stress associated with poverty and structural racism increases HLBS disease risk • Decreased trust in healthcare system due to structural racism

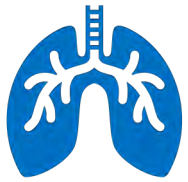
NIH National Heart, Lung, and Blood Institute

*Diagnostics and Disease Management Tools for Use in Underserved Populations: An NHLBI Research & Implementation Workshop, April 14-15, 2021

Innovations for Healthy Living and Heart, Lung, Blood, and Sleep (HLBS) Health

Heart
- Hypertension
- Coronary Artery Disease
- Myocardial Infarction
- Congestive Heart Failure
- Stroke/Cerebrovascular Disease
- CV Complications of Diabetes Mellitus
- CV Complications of HIV/AIDS

Lung
- Chronic Obstructive Pulmonary Disease
- Asthma
- Pulmonary Fibrosis
- Pulmonary Complications of HIV/AIDS



Blood
- Sickle Cell Disease
- HIV-Associated Thrombocytopenia

Sleep
- Obstructive Sleep Apnea
- Insomnia
- Other Sleep Disorders

The NHLBI is interested in funding tools, technologies, and devices to improve heart, lung, blood, and sleep (HLBS) health among **low-resource, historically-underserved,** and **remote communities**.

We are also interested in funding technologies to address barriers related to the **implementation** and **dissemination** of evidence-based interventions for HLBS conditions in these communities.

National Institute for Neurological Disorders and Stroke (NINDS) Priority Areas

NINDS interests under RFA-MD-22-004:

R&D related to the development, validation, feasibility, and effectiveness of innovative digital health technologies such as:

- Mobile health
- Telemedicine/telehealth
- Health information technology
- Remote monitoring devices

Neurological indications such as:

- Stroke
- Vascular contributions to cognitive impairment and dementia (VCID)
- Dementia
- Epilepsy
- Parkinson's Disease
- Traumatic Brain Injury
- Pain

Applications should address access, reach, delivery, effectiveness, scalability or sustainability of interventions that target health inequity experienced by marginalized populations

NINDS awards ~$70M annually to small businesses

Phase I	Phase II
Hard Cap: $275,766	**Hard Cap:** $1,883,436
With Waiver: $700K (not more than $500K/yr)	**With Waiver:** $3M (not more than $1.5M/yr)
Duration: 6-24 months	**Duration:** 2-3 years

*NINDS highly encourages **inclusion of community-based participatory research** in applications to this RFA*

*NINDS encourages applications that can **demonstrate diverse representation in the core leadership team***

Innovations for Healthy Living - Improving Minority Health and Eliminating Health Disparities (R43/R44 - Clinical Trial Optional)- RFA-MD-22-004

- Mobile health (mHealth) and telehealth/telemedicine technologies and apps for improving communication among health care providers and between patients, families, and physicians and healthcare providers, medication adherence, diagnosis, monitoring, evaluation, medical management, screening, tracking, and treatment in underserved community settings and rural and remote locations

- Leveraging electronic health records and communication technologies to deliver and evaluate interventions that reduce health disparities by removing accessibility and health literacy barriers, facilitating population tailoring and personalization, and decreasing cost

- Using systems modeling, artificial intelligence, or other techniques to predict relationships between health disparities and health determinants and to assess health disparities interventions outcomes.

ncats-sbirsttr@mail.nih.gov

Connect with NCATS

Website: ncats.nih.gov

Facebook: facebook.com/ncats.nih.gov

LinkedIn: linkedin.com/company/nih-ncats/

Twitter: twitter.com/ncats_nih_gov

YouTube: youtube.com/user/ncatsmedia

E-Newsletter: ncats.nih.gov/enews

Listserv: bit.ly/1sdOI5w

ncats-sbirsttr@mail.nih.gov

National Center for Advancing Translational Sciences

National Institute on Aging

- NIA is interested in each of the RFA topics as they pertain to Alzheimer's Disease and Related Dementias.
- Applicants should reference the NIA Health Disparities Research Framework in identifying and proposing solutions.
- NIA intends to commit up to $1,000,000 total costs for 3-4 awards.
- For proposals that fit the approved waiver topics, the NIA will not fund applications above $500,000 total costs in Phase I and $2.5M in Phase II.

NIA Special Areas of Interest

Minority Health Disparities in Alzheimer's Disease and AD-Related Dementias	
	Monitor, evaluative, prevent, treat, or slow the progression of AD/ADRD.
Effective	Early detection and diagnosis of cognitive impairment, cognitive decline, and/or AD/ADRD in underdiagnosed aging minority populations.
Accessible	Prolong independence, support aging in place, combat social isolation, improve care coordination and management, and/or reduce the burden of caregiving associated with AD/ADRD.
Acceptable	Increase the inclusion of underrepresented populations in Alzheimer's research and clinical trials.

NIA Program Contact: Joy Toliver, joy.toliver@nih.gov

Review of STTR/SBIR at NIH/NIMHD

Jingsheng Tuo, PhD
SRO, Scientific Review Branch
National Institute on Minority Health
and Health Disparities
National Institutes of Health
Tel: 301-480-1290
E-Mail: Jingsheng.tuo@nih.gov

Review of STTR/SBIR at NIH/NIMHD

- Reviewers are recruited based on the expertise needed and the consideration of diverse representation
- Application assignment: expertise matching from various angles, avoid of conflict interests, 3 assigned reviewers/application
- Scores
  - An overall impact score and 5 criteria score (scale: 1-9). Overall impact score is not the average of 5 criteria scores. Reviewers weigh criteria differently.
  - Final overall impact score: average of all voting reviewers x 10 (range from 10 to 90)
  - Non-discussed applications will not receive final overall impacts core but criteria cores will show in the summary statement
- Summary statement
  - Containing a resume prepared by SRO based on the meeting discussion, 3 independent critiques (criteria scores) prepared by the assigned reviewers
  - Summary statement will be released within 30 days after the meeting.
  - SRO is not allowed to discuss the review results, funding, and summary statement with applicant/PIs after the meeting.

Evaluation of STTR/SBIR applications

- Does the project address an important problem or a critical barrier to progress in the field, leading to the change of concepts, technologies, treatments, or preventative interventions?
- Does the proposed project have commercial potential to lead to a marketable product, process or service?
- Five criteria
  - Significance: the rigor of prior work, literature or market need, Commercial potential (detailed commercialization plan is required for Phase 1)
  - Investigators, Biosketch, MPI
  - Innovation, focus on the product/service, not just the science
  - Approach: a rigorous developmental plan with clear, measurable milestones
  - Environment: equipment and other physical resources available, subject populations, or collaborative arrangement
- Proposals will be evaluated on a competitive basis. Reviewers are requested to differentiate applications

Scientific Premise and rigor

- Scientific Premise: the underlying scientific foundation--concepts, previous work, and data (when relevant)--of the project is sound, the major element attributing to the score of significant

- Rigor: scientific method that supports robust and unbiased design, analysis, interpretation, and reporting of results, and sufficient information for the study to be assessed and reproduced, the major element attributing to the score of approach

- Innovation: Something new or improved, having marketable potential
  - Development of new technologies
  - Refinement of existing technologies
  - Development of new applications for existing technologies

Additional Review Criteria

- Scoreable
  - Study timeline: for clinical trial, ensure that the recruitments of participants are in line with the project goal.
  - Human subjects
    - Protection of Human Subjects against research risk
    - Inclusion, Sex/gender, all age spans, minorities
    - Data monitoring (clinical trials)
  - Vertebrate Animal use: sex as a biological variable, If only one sex is being used, state whether and how this is scientifically justified
  - Biohazards
- Non scorable: Select Agents Research; Resource Sharing Plan; Budget and Period of Support; Authentication of key Biological and/or Chemical Resources

Specifies of the RFAs

- Technologies for Improving Minority Health and Eliminating Health Disparities (R41/R42-Clinical Trial Optional)

https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-22-003.html

- Innovations for Healthy Living - Improving Minority Health and Eliminating Health Disparities (R43/R44 - Clinical Trial Optional)

https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-22-004.html

- Reviewers are quidded to read section V of each FOA

    - Specifics

Key words: improve racial/ethnic minority health, reduce or eliminate health disparities

- Review guideline: https://grants.nih.gov/grants/policy/review-guidelines/R41-R42-R43-R44-guide-for-reviewers.htm

Grantsmanship

- Page limitation, font size
- Matched and updated biosketches
- Data presentation: legends, consistence, clear
- Matched supporting letter(s)
- Inclusion of required information: biohazard
- Clinical trial or nonclinical trial: NIH has clear definition. Miscategorized application could risk withdrawn
- A0 submission after A1 should not mention the previous review

Review integrity and others

- Do not contact reviewers. the meeting roster will be published 30 days before the meeting

- Acceptance of updates and corrections:
  - News of accepted publication(s)
  - Video
  - Supplementary preliminary data in one page (pandemic related policy)
  - Through your institution’s Authorized Organization Representative (Signing Official)

Understanding the coding

- Type 1: submitted for funding for the first time, application number starts as ‘1”
- Type 2: Competing for additional years of funding to continue original project, application number starts as “2”
- Fast Track (Direct phase II): Incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together as one application, is considered as type 1, application number starts as ‘1”, coded as “R42 or R44”
- Phase II, is considered as type 2, coded as ‘R42 or R44”
- Resubmission: application number ends up as “A1”, reviewers can read prior summary statement in the application folder.

Questions

- **General RFA Questions:** nimhdsbirsttr@mail.nih.gov
- **Webinar Questions Please Use the Chat**
- **Webinar Link will be sent to Registered**