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
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: nimhdsbirstttr@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.”
Overview of NIH SEED Program and Requirements for SBIR and STTR Applicants
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
## SBIR and STTR Critical Differences

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<thead>
<tr>
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<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g., university)</td>
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<td><strong>Work Requirement</strong></td>
<td>Guidelines: May outsource 33% (Phase I) 50% (Phase II)</td>
<td>Minimum Work Requirements: 40% small business 30% research institution partner</td>
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<td><strong>Principal Investigator</strong></td>
<td>Primary employment (&gt;50%) must be with the small business</td>
<td>PI may be employed by either the research institution partner or small business</td>
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Award always made to small business
Grant applications and SBIR contract proposals must be submitted **electronically**.

### 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

**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

**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

https://sbir.nih.gov/support-for-awardees
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NIH Designated Racial and Ethnic Minorities

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<tr>
<td>National Institute on Minority Health and Health Disparities (NIMHD,)</td>
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<tr>
<td>National Heart, Lung, and Blood Institute (NHLBI)</td>
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<td>National Institute on Aging (NIA)</td>
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<td>National Institute of Biomedical Imaging and Bioengineering (NIBIB)</td>
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<td>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</td>
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<td>National Institute of Neurological Disorders and Stroke (NINDS)</td>
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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](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.
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.
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<th>Presenter</th>
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<tr>
<td>National Institute on Drug Abuse (NIDA)</td>
<td>Julia Berzhanskaya PhD</td>
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<tr>
<td>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</td>
<td>Daniel Gossett, Ph.D.</td>
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<td>National Heart, Lung, and Blood Institute (NHLBI)</td>
<td>Stephanie Davis, PhD</td>
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<tr>
<td>National Institute of Neurological Disorders and Stroke (NINDS)</td>
<td>Emily Caporello, PhD and Sarah Schwartz, PhD.</td>
</tr>
<tr>
<td>National Center for Advancing Translational Sciences (NCATS)</td>
<td>Lillianne M Portilla PhD. and Meena U. Rajagopal, Ph.D.</td>
</tr>
<tr>
<td>National Institute on Aging (NIA)</td>
<td>Joy Toliver, M.P.H</td>
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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.”
Research Mission of the NIDDK

- Chronic
- Common
- Consequential
- Costly

https://www.niddk.nih.gov/research-funding/research-programs
Division of Kidney, Urologic, and Hematologic 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 Diabetes, Endocrinology, and Metabolic Diseases

Christine Densmore, M.S.

Division of Digestive Diseases and Nutrition

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)

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.

*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

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**
- Hard Cap: $275,766
- With Waiver: $700K (not more than $500K/yr)
- Duration: 6-24 months

**Phase II**
- Hard Cap: $1,883,436
- With Waiver: $3M (not more than $1.5M/yr)
- 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.

NIH
National Heart, Lung, and Blood Institute

Twitter: @NINDSTranslate
ListServ: ninds-OTR@list.nih.gov and ninds-OGHHD@lists.nih.gov
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.
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/1sdOl5w

ncats-sbirsttr@mail.nih.gov
• 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**

**Effective**
- Monitor, evaluative, prevent, treat, or slow the progression of AD/ADRd.

**Accessible**
- Early detection and diagnosis of cognitive impairment, cognitive decline, and/or AD/ADRd in underdiagnosed aging minority populations.

**Acceptable**
- 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.
- 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 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)

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

• Reviewers are quidded to read section V of each FOA
  • Specifics
    Key words: improve racial/ethnic minority health, reduce or eliminate health disparities

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