OMNIBUS SOLICITATION OF THE
NATIONAL INSTITUTES OF HEALTH,
CENTERS FOR DISEASE CONTROL AND PREVENTION, AND
FOOD AND DRUG ADMINISTRATION FOR

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

NIH, CDC, and FDA Program Descriptions and Research Topics (Revision: January 31, 2025)

SUBMISSION DATES

SEPTEMBER 5, 2024, JANUARY 5, 2025, AND APRIL 5, 2025
National Institutes of Health (SBIR and STTR)
Centers for Disease Control and Prevention (SBIR)
Food and Drug Administration (SBIR)

Notices of Funding Opportunities, Application Instructions, and Appendices are contained in separate files. Follow the links below to view these documents.

NOTICES OF FUNDING OPPORTUNITIES

REMINDER: ALL APPLICATIONS MUST BE SUBMITTED IN RESPONSE TO A NOTICE OF FUNDING OPPORTUNITY THROUGH GRANTS.GOV

- PHS 2024-02 OMNIBUS SOLICITATION OF THE NIH, CDC, AND FDA FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS (PARENT SBIR [R43/R44] CLINICAL TRIAL NOT ALLOWED)
- PHS 2024-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS

 TECHNOLOGY TRANSFER GRANT APPLICATIONS (PARENT STTR [R41/R42]

 CLINICAL TRIAL NOT ALLOWED)
- PHS 2024-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS (PARENT SBIR [R43/R44] CLINICAL TRIAL REQUIRED)
- PHS 2024-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS
 TECHNOLOGY TRANSFER GRANT APPLICATIONS (PARENT STTR [R41/R42]
 CLINICAL TRIAL REQUIRED)
- ADDITIONAL SPECIAL ANNOUNCEMENTS FOR SMALL BUSINESS RESEARCH OPPORTUNITIES

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SF424 (R&R) APPLICATION INSTRUCTIONS AND ELECTRONIC SUBMISSION INFORMATION

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PROGRAM DESCRIPTIONS AND RESEARCH GRANT TOPICS

Grant applications will be accepted and considered in any area within the mission of the awarding components (i.e., Institutes and Centers (ICs)) identified in this solicitation. Information about the HHS SBIR and STTR programs for applicants and awardees, including resources and programs available to HHS SBIR and STTR awardees, can be found at https://seed.nih.gov/.

Applicants are strongly encouraged to subscribe to the <u>NIH Guide for Grants and Contracts LISTSERV</u> or query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, and FDA awarding components.

You may also subscribe to the <u>SBIR-STTR LISTSERV</u> to get timely information about the NIH SBIR and STTR Programs.

Additional information on each of the awarding components (ICs) and their research interests is available electronically on the home pages shown throughout the "Research Topics" section of the solicitation.

NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. Information about the NIH SBIR and STTR programs for applicants and awardees, including resources and programs available to NIH SBIR and STTR awardees, can be found at https://seed.nih.gov/.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes and Centers). Those components that have an extramural element, that is, those that provide funds for research and research training activities in organizations external to the NIH, are shown below. The NIH makes every effort to finance worthy applications, including the co-funding of such applications by one or more awarding components having relevance in the projects.

Total funding support (direct costs, indirect costs, fees) normally may not exceed \$314,363 for Phase I awards and \$2,095,748 for the duration of the Phase II awards. However, this amount is subject to change and the most current information can be found on the NIH SEED website. Awards exceeding these amounts may be made at the discretion of an Institute or Center for applications within one of the SBA-Approved Waiver Topics. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Center staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of Institute or Center priorities, constraints on the growth of average grant costs, and the availability of funds.

Before considering and/or preparing an application to the SBIR and STTR programs, all applicants are **strongly encouraged** to review the agencies' and NIH Institutes' and Centers' websites and to contact the SBIR and STTR program coordinators listed below. The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR and STTR program.

Contact Information

Questions of a general nature about the HHS SBIR and STTR program may be directed to: SEED (Small business Education and Entrepreneurial Development)

Email: SEEDinfo@nih.gov

For Agency, Institute and Center Scientific/Research (Program) and Financial/Grants Management contacts, please see the contact page.

NATIONAL INSTITUTE ON AGING (NIA)

https://www.nia.nih.gov/

For more information on the NIA SBIR and STTR programs:

https://www.nia.nih.gov/research/sbir

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website, unless the application fits an SBA-approved NIA waiver topic. For topics listed in the SBA-Approved Waiver Topics, the NIA generally will not fund Phase I applications to the Omnibus greater than \$400,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,250,000 total costs or project periods greater than 3 years.

However, if your application is AD/ADRD focused, you may come in at \$500,000 for Phase I and \$2,500,000 for Phase II (total costs). For budgetary, administrative, or programmatic reasons, the NIA may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIA welcomes submission of Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing a wide range of <u>aging-focused products</u>, including digital- mobile/cyber-health technology, pharmaceutical compounds, and medical devices. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to realize further progress in commercialization, including stimulating interest in and investment by third parties. NIA will generally not fund Phase IIBs greater than \$3M total costs.

Prospective Phase IIB Competing Renewal applicants are <u>strongly encouraged to contact NIA's SBIR-STTR program contact prior to consideration and preparation of a Phase IIB application and well in advance of the SBIR-STTR submission due dates.</u>

NIA also welcomes the submission of CRP applications to the 2 CRP NOFOs (and subsequent reissued NOFOs):

- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Not Allowed (PAR-23-219)
- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Required (PAR-23-220)

Contact Information

For more information on research topics and questions about potential NIA SBIR/STTR grant applications and NIA's participation in the Phase IIB or CRP programs, please contact:

Program Contacts, NIA Small Business R & D Programs:

Michael-David ("M-D") A.R.R.Kerns, M.M., M.S., Ph.D.

National Institute on Aging (NIA)

Email: niasmallbusiness@mail.nih.gov

Bio: https://www.nia.nih.gov/about/staff/kerns-michael-david

Rajesh Kumar, Ph.D.

National Institute on Aging (NIA)

Email: niasmallbusiness@mail.nih.gov

If there are specific questions pertaining to the interests or activities of the NIA scientific divisions, contact:

Division of Aging Biology:

Leonid Tsap, Ph.D.

National Institute on Aging (NIA) Email: Leonid.Tsap@nih.gov

Bio: https://www.nia.nih.gov/about/staff/tsap-leonid

Division of Behavioral and Social Research:

Dinesh John, Ph.D.

National Institute on Aging (NIA) Email: dinesh.john@nih.gov

Bio: https://www.nia.nih.gov/about/staff/john-dinesh

Division of Geriatrics and Clinical Gerontology:

Lyndon Joseph, Ph.D.

National Institute on Aging (NIA) Telephone: 301-496-6761 Email: lyndon.joseph@nih.gov

Bio: https://www.nia.nih.gov/about/staff/joseph-lyndon

Division of Neuroscience:

Zane Martin, Ph.D.
National Institute on Aging (NIA)
Email:zane.martin@nih.gov

Bio: https://www.nia.nih.gov/about/staff/martin-jones-zane

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

http://www.niaaa.nih.gov

For more information on the NIAAA SBIR and STTR programs:

https://www.niaaa.nih.gov/research/niaaa-sbir

Budget Guidance

NIAAA will make awards compliant with all statutory guidelines as outlined above. Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the Small Business Administration (SBA), which can be found on the NIH SEED website. With the exception of the topics indicated therein, NIAAA will generally not fund Phase I applications to the Omnibus greater than \$385K or Phase II awards over \$3M total costs even if topics are listed under the SBA-Approved Waiver Topics. Applicants considering a requested budget greater than the standard limits are strongly encouraged to contact the NIAAA SBIR/STTR Program Director before submitting an application. For budgetary, administrative, or programmatic reasons, NIAAA may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIAAA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to, medical implants, drugs, vaccines, biologicals, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. To be eligible for Phase IIB consideration, the project must retain high significance in the light of current market conditions.

Prospective applicants are strongly encouraged to contact NIH staff well in advance of submitting a Phase IIB Competing Renewal application by submitting to niaaasbirsttr@mail.nih.gov a letter of intent that includes the following information:

- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Grant number and title
- Progress of the Phase II award
- Goals and justification for the Phase IIB request

It is expected that only a portion of NIAAA SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

NIAAA will accept submission of CRP applications to the following NOFOs (and reissues):

SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late-Stage Development - Clinical Trial Not Allowed (PAR-23-219)

SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late-Stage Development - Clinical Trial Required (PAR-23-220)

Contact Information

Megan Ryan, M.B.A.
NIAAA SBIR/STTR Program Director
National Institute on Alcohol Abuse and Alcoholism
6700B Rockledge Dr.
Rockville, MD 20852-1705

Phone: 301-827-6166 Email: mryan1@nih.gov

For general inquiries: NIAAASBIRSTTR@mail.nih.gov

For administrative and business management questions, contact:

Jeff Thurston SBIR/STTR Grants Management Lead National Institute on Alcohol Abuse and Alcoholism Phone: 301-443-9801

Email: jeffrey.thurston@nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

http://www.niaid.nih.gov

For more information on the NIAID SBIR and STTR programs:

https://www.niaid.nih.gov/grants-contracts/small-businesses

Budget Guidance

Total funding support (direct costs, indirect costs, fee) normally may not exceed the dollar amounts specified by the SBA, which can be found on the <u>NIH SEED website</u>. Budget requests at or near these hard caps should be well justified. Phase II/IIB applicants should note that NIAID *will not* generally allow awards (of any duration) that exceed \$1,000,000 total costs per year.

NIH has received a waiver from SBA, as authorized by statute, to exceed total award amount hard caps for specific topics. The current list of approved NIAID topics is included in the <u>SBA-Approved Waiver Topics</u>. Topics that align with NIAID's priority research areas are listed for each Division; any listed NIAID topic is sufficient to consider budget requests that exceed the hard caps. Budget requests exceeding the hard caps must be very well justified in the "Budget Justification" attachment to the Research and Related Budget form and be clearly consistent with the scope of the proposal.

For proposals that address an approved topic, NIAID will allow Phase I applications with budgets of up to

\$300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to

\$1,000,000 total costs per year for up to 3 years. Requests for these budget levels must be very well-justified. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

NIAID staff cannot provide prior approval to exceed hard caps. Compliance with a pre-approved topic will be confirmed at time of award by the applicant's Grants Management Specialist and Program Officer.

NIAID will consider well justified Technical and Business Assistance (TABA) costs up to the limits specified on the NIH SEED Website. These costs can be requested *in addition* to the Phase I and II limits indicated above.

NIAID will generally not make SBIR or STTR awards with budgets that exceed these guidelines. For budgetary, administrative, or programmatic reasons, NIAID may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIAID welcomes Phase IIB Competing Renewal Applications (**SBIR only**) for Phase II grants and contracts via the Omnibus Solicitation for SBIR Grant Applications, and as indicated by other NIAID Notices of Funding Opportunities (NOFOs). Standard NIAID Phase II funding policy applies unless otherwise stated in the NOFO. STTR Phase II awardees may apply but must switch programs to SBIR. Non-NIAID Phase II awardees must contact NIAID prior to submission to confirm programmatic interest.

NIAID welcomes CRP applications from eligible NIAID Phase II/IB awardees through <u>PAR-20-129</u> (and subsequent reissued NOFOs) Please review this Notice of Funding Opportunity for details.

Contact Information

For more information on NIAID's SBIR/STTR research topics, program policy or to identify NIAID Subject Matter Experts for a specific topic, please contact:

Dr. Natalia Kruchinin SBIR/STTR Program Coordinator Division of Extramural Activities National Institute of Allergy and Infectious

Diseases Phone: 240-669-2919 Email: kruchininn@niaid.nih.gov

Division of AIDS

Director: Dr. Carl Dieffenbach Telephone: 301-496-0545 Email: CDieffenba@niaid.nih.gov

Division Small Business Representative:

Dr. Brigitte Sanders
Telephone: 240-627-3209

E-mail: sandersbe@niaid.nih.gov

Vaccine Research Program (VRP)
Director: Dr. James Lane (acting)
Telephone: 301-435-3727
Email: laneji@mail.nih.gov

Vaccine Clinical Research Branch (VCRB)

Contact: Dr. Patricia D'Souza Telephone: 240-627-3037 Email: pdsouza@niaid.nih.gov

Preclinical Research and Development Branch (PRDB)

Contact: Dr. Anjali Singh Telephone: 240-627-3030 Email: anjalisingh@niaid.nih.gov

Vaccine Translational Research Branch (VTRB)

Contact: Dr. Michael Pensiero Telephone: 301-435-3749 Email: mpensiero@niaid.nih.gov

Basic Sciences Program (BSP)

Director: Dr. Diana Finzi Telephone: 301-451-2598 Email: <u>Dfinzi@niaid.nih.gov</u>

Pathogenesis and Basic Research Branch (PBRB)

Contact: Dr. Karl Salzwedel Telephone: 301-496-5332

Email: salzwedelkd@niaid.nih.gov

Targeted Interventions Branch (TIB)

Contact: Dr. Brigitte Sanders Telephone: 240-627-3209 E-mail: sandersbe@niaid.nih.gov

Epidemiology Branch (EB) Contact: Lori Zimand Telephone: 240-627 3212 Email: Izimand@niaid.nih.gov

Therapeutics Research Program (TRP)

Director: Dr. Peter Kim Telephone: 301-451-2761 Email: peter.kim2@nih.gov

Drug Development and Preclinical Research Branch (DDPRB)

Contact: Roger Ptak
Telephone: 301-761-7424
Email: roger.ptak@nih.gov

Complications and Co-infections Research Branch (CCRB)

Contact: Dr. Beverly Alston Telephone: 301-435-3773 Email: balston@niaid.nih.gov

HIV Research Branch (HIVRB) Contact: Tia Morton, RN Telephone: 240-627-3073 Email: frazierti@niaid.nih.gov

TB Clinical Research Branch (TCRB)

Contact: Dr. Andrew Vernon Telephone: 301-761-5130 Email: andy.vernon@nih.gov

Laboratory and Clinical Sciences Branch (LCSB)

Contact: Dr. Fatima Jones Telephone: 240-550-7863 Email: maria.jones@nih.gov

Prevention Sciences Program (PSP)

Director: Dr. Sheryl Zwerski Telephone: 301-402-4032 Email: szwerski@niaid.nih.gov

Clinical Prevention Research Branch (CPRB)

Contact: Dr. Lydia Soto-Torres Telephone: 240-292-4807

Email: Isoto-torres@niaid.nih.gov

Preclinical Microbicide & Prevention Research Branch (PMPRB)

Contact: Dr. James Cummins Telephone: 240-292-4800 Email: cumminsje@niaid.nih.gov

Maternal, Adolescent and Pediatric Research Branch (MAPRB)

Contact: Judi Miller Telephone: 240-292-4801 Email: jmillera@niaid.nih.gov

Division of Allergy, Immunology and Transplantation (DAIT)

Director: Daniel Rotrosen, M.D. Telephone: 301-496-1886 Email: drotrosen@niaid.nih.gov

Division Small Business Representative:

Dr. Michael Minnicozzi Telephone: 240-627-3532

E-mail: minnicozzim@niaid.nih.gov

Allergy, Asthma, and Airway Biology Branch

Chief: Alkis Togias, M.D. Telephone: 301-496-8973 Email: togiasa@niaid.nih.gov

Basic Immunology Branch

Chief: Dr. Alison Deckhut-Augustine

Telephone: 301-496-7551, Fax: 301-480-2381

Email: augustine@niaid.nih.gov

Autoimmunity and Mucosal Immunology Branch

Chief: Dr. Ellen Goldmuntz Telephone: 240-627 3502

Fax: 301-480-1450

Email: egoldmuntz@niaid.nih.gov

Transplantation Branch Chief: To be announced

Telephone: TBD Email: TBD

Radiation and Nuclear Countermeasures Program

Director: Andrea L. DiCarlo, PhD

Telephone: 240-627-3492 Email: cohena@niaid.nih.gov

RNCP SBIR Contact: Carmen I. Rios, PhD Telephone: 240-627-3553 Email: carmen.rios@nih.gov

Division of Microbiology and Infectious Diseases (DMID)

Director: Emily Erbelding, M.D., M.P.H.

Telephone: 301-435-3384 Email: emily.erbelding@nih.gov

Division Small Business Representative:

Dr. Barbara Mulach Telephone: 240-627-3322 Email: bmulach@niaid.nih.gov

Division Small Business Representative:

Dr. Alyssa Werner

Telephone: 301-761-7525 Email: alyssa.werner@nih.gov

Office of Genomics and Advanced Technologies (OGAT)

Contact: Dr. Inka Sastalla Telephone: 301-761-6431 Email: <u>sastallai@mail.nih.gov</u>

Virology Branch (VB)
Contact: Dr. Julie Dyall
Telephone: 301-631-7296
Email: Julie.dyall@niaid.nih.gov

Bacteriology and Mycology Branch (BMB)

Contact: Dr. Alec Ritchie Telephone: 240-627-3356 Email: aritchie@niaid.nih.gov

Enteric and Sexually Transmitted Infections Branch (ESTIB)

Contact: Dr. Tom Hiltke Telephone: 240-627-3275 Email: thiltke@niaid.nih.gov

Parasitology and International Programs Branch (PIPB)

Contact: Dr. Annie Mo Telephone: 240-627-3320 Email: moa@niaid.nih.gov

Respiratory Diseases Branch (RDB)

Contact: Dr. Xin-Xing Gu Telephone: 240-627-3265 Email: guxx@niaid.nih.gov

Office of Biodefense Research and Surety (OBRS) Biodefense Research Countermeasures Branch (BRCB)

Contact: Dr. Dave Yeung Telephone: 301-761-7237 Email: <u>dy70v@nih.gov</u>

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

http://www.niams.nih.gov

For more information on the NIAMS SBIR and STTR programs:

https://www.niams.nih.gov/grants-funding/funding-opportunities/small-business-grants

Budget Guidance

For budgetary, administrative, or programmatic reasons, NIAMS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website.

For topics listed in the <u>SBA-Approved Waiver Topics</u>, NIAMS does not apply these topics to the Omnibus Program Announcements. NIAMS only applies the waiver topics to special Notices of Funding Opportunities that specifically allow higher budgets than those in the Omnibus Program Announcements. When the waiver topics are applied, NIAMS generally will not fund Phase I applications greater than \$350,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,300,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

NIAMS provides Technical and Business Assistance (TABA) Funding. Small Businesses may request up to \$6,500 per year for a Phase I and up to \$50,000 per Phase II project (across all years) to support subcontracts or consultants above the budget cap. Small businesses should include this budget request as part of the application and provide a detailed budget justification.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIAMS does not accept Phase IIB renewal applications. NIAMS participates in the CRP program and sets its own budget limits for the CRP applications in the program announcements. NIAMS does not support clinical trials through the CRP program.

Contact Information

For general SBIR/STTR program information, contact: Dr. Xibin Wang, NIAMS SBIR/STTR Coordinator Telephone: 301-451-3884

- 004 400 4004

Fax: 301-480-1284

Email: wangx1@mail.nih.gov

For administrative and business management questions, contact:

Ms. Victoria Matthews Telephone: 301-594-3968 Fax: 301-480-5450

Email: victoria.matthews@nih.gov

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

http://www.nibib.nih.gov

For more information on the NIBIB SBIR and STTR programs:

https://www.nibib.nih.gov/programs/small-business-programs

Budget Guidance

Normally, total funding support (direct costs, indirect costs, fees) may **not** exceed the amounts defined by the Small Business Administration (SBA), which can be found on the NIH SEED website.

Applicants considering a requested budget greater than the current SBA guidelines should ensure that the project falls within a topic listed in the <u>SBA-Approved Waiver Topics</u>.

Generally, NIBIB will **not** support Phase I (R41/R43) project periods greater than 1 year, or Phase II (R42/R44) project periods greater than 2 years.

For budgetary, administrative, or programmatic reasons, NIBIB may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIBIB does not accept Phase IIB renewal application through the Omnibus Solicitations.

NIBIB participates in the **Commercialization Readiness Pilot (CRP)** program for **Phase II applications only**.

Contact Information

For additional information on research topics, contact:

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National Institute of Biomedical Imaging and Bioengineering

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Email: NIBIB-SBIR@mail.nih.gov

For administrative and business management questions, contact:

Mr. James Huff

National Institute of Biomedical Imaging and Bioengineering

Telephone: 301-451-4786, Fax: 301-451-5735

Email: huffj@mail.nih.gov

NATIONAL CANCER INSTITUTE (NCI)

https://www.cancer.gov/

For more information on the NCI SBIR and STTR programs:

http://sbir.cancer.gov

Budget Guidance

For budgetary, administrative, or programmatic reasons, NCI may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. However, for certain research topics, the U.S. Small Business Administration has approved a list of SBA-Approved Waiver Topics for which the NCI generally will fund Phase I applications with higher budgets up to \$400,000 total costs combined over all years, and project periods up to 2 years; similarly, for certain research topics, NCI will consider Phase II applications with higher budgets up to \$2,250,000 total costs combined over all years, and project periods up to 3 years.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

The National Cancer Institute (NCI) welcomes CRP applications from companies that have active or completed NCI SBIR (Phase II and Phase IIB) or STTR (Phase II) awards (PAR-20-128).

Please note that NCI will provide funding support up to a maximum of \$250,000 in total costs (direct costs, indirect costs, and fee). Potential applicants are strongly encouraged to contact NCI SBIR Program staff to discuss prior to submission the CRP activities for which support will be requested. The NCI may decline funding of any application for reasons of program balance or budget. NCI does not participate in the SBIR/STTR Commercialization Readiness Pilot Program Technical Assistance and Late-Stage Development (SB1) NOFOs (PAR-20-129 or PAR-20-130). For SBIR/STTR Phase II awardees in need of additional assistance for late-stage development and/or clinical trials, the NCI recommends its SBIR Phase IIB program.

Phase IIB

The NCI does not accept applications for Phase IIB SBIR competing renewal awards through this Omnibus Solicitation. However, the NCI offers Phase IIB opportunities in the form of the NCI SBIR Phase IIB Bridge Award, which is announced via a separate funding solicitation: https://sbir.cancer.gov/bridge. Please note that NCI will provide funding support up to a maximum of \$4,500,000 in total costs (direct costs, indirect costs, and fee). The NCI Phase IIB Bridge Award is designed to support the next stage of development for cancer-related technologies previously funded under SBIR or STTR Phase II awards from any Federal agency. The purpose of this award is to address the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization. To achieve this goal, the Bridge Award funding opportunity is specifically designed to incentivize partnerships between federally funded SBIR Phase II awardees and third- party investors and/or strategic partners. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds).

To ensure that you will be notified upon the release of the NCI SBIR Phase IIB Bridge Award solicitation, please sign up for the NCI SBIR mailing list: https://bit.ly/NciSbirEmailSignUp. If you have any questions regarding the NCI SBIR Phase IIB Bridge Award, please contact your Phase II program director.

Contact Information

For additional information about the NCI SBIR/STTR programs, please contact the NCI SBIR Development Center:

9609 Medical Center Drive Rockville, MD 20850

Website: http://sbir.cancer.gov Email: NCIsbir@mail.nih.gov Phone: 240-276-5300

For additional information on research topics, please contact a Program Officer with the relevant area of expertise:

Michael Weingarten, MA

Director, NCI SBIR Development Center Email: weingartenm@mail.nih.gov

Gregory Evans, PhD

Program Director and Team Leader

Email: evansgl@mail.nih.gov

Areas of Expertise: Therapeutics (Immunotherapy, Gene Therapy), Cancer Imaging, Cancer Control,

Tools for Cancer Biology Research, and Digital Health

Jonathan Franca-Koh PhD, MBA Program Director and Team Leader Email: jonathan.franca-koh@nih.gov

Areas of Expertise: Cancer Biology, Biologics, Small Molecules, and Cell-Based Therapies

Monique Pond, PhD

Program Director and Team Leader Email: monique.pond@nih.gov

Email. <u>monique.pond@nin.gov</u>

Areas of Expertise: Biologics, Small Molecules, Therapeutic Devices, Digital Health, Regulatory

Resources

Patricia Weber, DrPH Program Director

Email: weberpa@mail.nih.gov

Areas of Expertise: Digital Health and Therapeutics (Small Molecules, Biologics, Immunotherapy)

Xing-Jian Lou, PhD Program Director

Email: loux@mail.nih.gov

Areas of Expertise: In Vitro Diagnostics and Therapeutics (Gene Therapy, Biologics, Small Molecules)

Ming Zhao, PhD Program Director

Email: zhaoming3@mail.nih.gov

Areas of Expertise: In Vitro Diagnostics, Cancer Stem Cells, Molecular Imaging, Bioinformatics, Therapeutics (Small Molecules, Biologics, Immunotherapy), and Cancer Control (Community-Based Participatory Research)

William Bozza, PhD Program Director

Email: william.bozza@nih.gov

Areas of Expertise: Biologics, Protein Therapeutics, Regulatory (CMC)

Sarra Djemil, PhD Program Director

Email: sarra.djemil@nih.gov

Areas of Expertise: Therapeutics, Digital Health, Mentoring

Saroj Regmi, PhD Program Director

Email: saroj.regmi@nih.gov

Areas of Expertise: Therapeutics, Diagnostics, Imaging, Digital Health, Investor Initiatives, Small Business

Transition Grant, I-Corps

Swamy Tripurani, PhD Program Director

Email: swamy.tripurani@nih.gov

Areas of Expertise: Therapeutics, Biologics, Small Molecules, Diagnostics, Devices, and Regulatory

(CMC and Nonclinical)

Melissa Li, PhD Program Director

Email: melissa.li@nih.gov

Areas of Expertise: Biologics, Small Molecules, Digital Health

Linda Zane, PhD Program Director

Email: linda.zane@nih.gov

Areas of Expertise: Therapeutics, Diagnostics, Research Tools

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

http://www.nichd.nih.gov

For more information on the NICHD SBIR and STTR programs:

https://www.nichd.nih.gov/grants-contracts/SBIR STTR

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the <u>NIH SEED website</u>. It is strongly encouraged to contact program staff prior to applying.

The NICHD received a budgetary guideline waiver from the Small Business Administration for applications relating to a limited list of scientific topics in <u>SBA-Approved Waiver Topics</u>. For these the NICHD will accept applications up to \$400K total costs for Phase I and \$2.25M for Phase II. Applicants should propose a budget that is reasonable and appropriate for completion of the research project and requests for these budge levels must be very well justified. Applicants are encouraged to contact the listed NICHD Branch Contact Program Officer for scientific-related questions about a project's eligibility for a budgetary waiver.

For general budgetary questions, applicants should contact NICHD's SBIR/STTR Grants Management Coordinator. The NICHD may decrease the budget or length of an award or decide not to fund an application for budgetary, administrative, or programmatic reasons.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

The NICHD accepts Phase IIB SBIR Competing Renewal applications to support additional R&D necessary for approval of a federal regulatory agency (e.g., FDA, FCC). Such products may include medical implants, pediatric devices, drugs, vaccines, and new treatment or diagnostic tools Applicants who received NICHD SBIR Phase II support and who are currently Phase II awardees are eligible. If the project meets the criteria for a budgetary waiver (see SBA-Approved Waiver Topics), the Phase IIB should not exceed \$3M total costs for three years. The amount of award may vary year to year depending on the research proposed. Funding priority will be given to those small business concerns that show the ability to develop innovative products and demonstrate growth towards independence from the SBIR/STTR programs.

Prospective applicants are strongly encouraged to contact NICHD program staff well in advance of submitting a Phase IIB Competing Renewal application.

Contact Information

Child Development and Behavior Branch

NICHD CDBB Small Business (SB) Program Director

Phone: 301-435-6855 OR 301-435-3602

Email: NICHDCDBB-SB-Program@mail.nih.gov

Contraception Research Branch

Steven C. Kaufman, MD, MS

Phone: 301-435-6989

Email: kaufmans@exchange.nih.gov

Developmental Biology and Congenital Anomalies Branch

Mahua Mukhopadhyay, PhD Phone: 301-435-6886

Email: mukhopam@mail.nih.gov

Fertility and Infertility Branch

Clara Cheng, PhD Phone: 301-435-6992 Email: clara.cheng@nih.gov

Gynecologic Health and Disease Branch

Candace M. Tingen, PhD Phone: 301-435-6971

Email: candace.tingen@nih.gov

Intellectual and Developmental Disease Branch

Sujata Bardhan, PhD Phone: 301-435-0471

Email: sujata.bardhan@nih.gov

Maternal and Pediatric Infection Disease Branch

Sai Majji, PhD

Phone: 301-402-8048 Email: sai.majji@nih.gov

Obstetric and Pediatric Pharmacology and Therapeutics Branch

Antonello Pileggi, MD, PhD, MSCTI

Phone:301-402-5019 Email: pileggia@nih.gov

Pediatric Growth and Nutrition Branch

Andrew A. Bremer, MD, PhD

Phone: 301-402-7886

Email: andrew.bremer@nih.gov

Pediatric Trauma and Critical Illness Branch

Tessie October, MD, MPH Phone: 301-827-6757

Email: tessie.october@nih.gov

Population Dynamics Branch

Ronna Popkin, PhD Phone: 301-827-5121

Email: ronna.popkin@nih.gov

Pregnancy and Perinatology Branch

Diane Gumina, PhD Phone: 301-827-7304

Email: diane.gumina@nih.gov

National Center for Medical Rehabilitation Research

Toyin Ajisafe, PhD Phone: 301-827-9242 Email: toyin.ajisafe@nih.gov For additional SBIR/STTR program administrative information and research topics contact:

Toyin Ajisafe, PhD Phone: 301-827-9242

Email: toyin.ajisafe@nih.gov

For additional financial/business management questions contact:

Mindy Bixby, Grants Management Specialist

Phone: 301-402-3204

Email: mindy.bixby@nih.gov

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

https://nida.nih.gov/

For more information on the NIDA SBIR and STTR programs:

https://nida.nih.gov/funding/small-business-innovation-research-sbir-technology-transfer-sttr-programs

Budget Guidance

Award budgets and project periods are listed in the Section II Award Information of the Omnibus/Parent Notices of Funding Opportunities for SBIR and STTR. Total award budgets include direct costs, indirect costs, and fees and are capped not to exceed the total award amounts listed.

NIDA also sets its budget limits for specific research topics that received a waiver from the U.S. Small Business Administration to exceed the hard budget caps. The current list of approved NIDA topics can be found in the SBA-Approved Waiver Topics. NIDA budget limit for Phase I on SBA-approved waiver topics is \$400,000 in total costs and a project period of up to 1 year. NIDA budget limit for Phase II on SBA-approved waiver topics is \$3,000,000 in total costs and a project period of up to 3 years.

In all cases, applicants should propose a budget and a project duration period that are reasonable and appropriate for the completion of the research project. Applicants are strongly encouraged to contact NIDA program officials early in the application process to receive assistance regarding the program.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIDA does not participate in the CRP program. NIDA will not accept Phase IIB applications through the Omnibus or specific program announcements.

Contact Information

Prior to Submission: Applicants are strongly encouraged to request a technical assistance meeting with NIDA SBIR/STTR staff prior to submitting any application. To schedule a meeting, please email:

Ernestine Lenteu
Program Specialist
NIDA Office of Translational Initiatives and Program Innovations
NIDASBIR@mail.nih.gov.

For additional information on research topics, please contact a Program Officer with the relevant area of expertise:

Leonardo Angelone, PhD

Program Officer

Email: leonardo.angelone@nih.gov

Areas of expertise: FDA-regulated therapeutic and diagnostic devices for substance use and addiction.

Morris Flood, DHSc Program Officer

Email: morris.flood@nih.gov

Areas of expertise: Consumer products and approaches that address the health-related social needs that impact substance use and addiction; and digital health technology translation to commercial substance use and addiction products that address the overall social determinants of health.

Stacie Gutowski, PhD

Program Officer Email: stacie.gutowski@nih.gov

Areas of expertise: FDA-regulated therapeutic and diagnostic devices for substance use and drug addiction, including neuromodulation.

Saravanan Karuppagounder, PhD

Program Officer

Email: saravanan.karuppagounder@nih.gov

Areas of expertise: Therapeutics for Stimulant Use Disorders and Marijuana or Cannabis Use Disorder, Biomarker Development and Validation.

Yordan Kostov, PhD Program Officer

Email: yordan.kostov@nih.gov

Areas of expertise: FDA-regulated monitoring and diagnostic devices for substance use and addiction, including target-agnostic detection.

Tam Nguyen, PhD Program Officer

Email: tam.nguyen@nih.gov

Areas of expertise: Pharmacotherapeutics for opioid use disorder, overdose reversal, and smoking

cessation.

Boris Sabirzhanov, PhD

Program Officer

Email: boris.sabirzhanov@nih.gov

Areas of expertise: Helping to End Addition Long-term (HEAL) initiative.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

http://www.nidcd.nih.gov

For more information on the NIDCD SBIR and STTR programs:

https://www.nidcd.nih.gov/funding/types/small-business-grants

Budget Guidance

Total funding (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting the application. The Small Business Administration has allowed NIDCD to make awards that exceed these amounts for the areas noted in the SBA-Approved Waiver Topics. For topics listed in the SBA-Approved Waiver Topics, the NIDCD generally will not fund Phase I applications greater than \$385,000 total costs or Phase II applications greater than \$3,000,000 total costs. All applications must contain sufficient detail to justify the requested budget, and NIDCD may decrease the length of an award and/or the budget as recommended by a review committee or administrative review.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIDCD does not accept applications for Phase IIB competing renewal awards.

NIDCD participates in the SBIR Commercialization Readiness Pilot program.

Contact Information

For administrative and business management questions, contact:

Ms. Samantha Tempchin Grants Management Officer National Institute on Deafness and Other Communication Disorders 301-435-0713, Fax: 301-451-5370

Email: tempchins@nidcd.nih.gov

For additional information on the following research topics, contact:

Hearing and Balance, BCI Communication Prostheses, Taste and Smell Programs

Roger L. Miller, Ph.D.

National Institute on Deafness and Other Communication

Disorders 301-402-3458 Email: roger.miller@nih.gov

Language Program

Holly L. Storkel, Ph.D.

National Institute on Deafness and Other Communication

Disorders 301-451-6842, Fax: 301-402-0390

Email: holly.storkel@nih.gov

Voice & Speech Program

Lisa M. Kopf, Ph.D.

National Institute on Deafness and Other Communication

Disorders 240-678-2544, Fax: 301-402-0390

Email: lisa.kopf@nih.gov

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

https://www.nidcr.nih.gov/

For more information on the NIDCR SBIR and STTR programs:

https://sbir.nih.gov/nidcr

Budget Guidance

Total funding (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting the application. The Small Business Administration has allowed NIDCD to make awards that exceed these amounts for the areas noted in the SBA-Approved Waiver Topics. All applications must contain sufficient detail to justify the requested budget, and NIDCR may decrease the length of an award and/or the budget as recommended by a review committee or administrative review.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIDCR does not accept Phase IIB renewal applications. NIDCR participates in the CRP program but does not support clinical trials through the CRP program.

Contact Information

For additional information on research topics, contact: Orlando Lopez, Ph.D.
Dental and Craniofacial Small Business Coordinator Division of Extramural Research
National Institute of Dental and Craniofacial Research
6701 Democracy Blvd., Rm. 612
Bethesda, MD 20892-4878
(301) 402-4243

Email: orlando.lopez@nih.gov

For administrative and business management questions, contact: Gabriel Hidalgo, MBA
Acting Chief Grants Management Officer
National Institute of Dental and Craniofacial Research
6701 Democracy Blvd., Rm. 656
Bethesda, MD 20892-4878
(301) 827-4630

Email: gabriel.hidalgo@nih.gov

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

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

For more information on the NIDDK SBIR and STTR programs:

https://seed.nih.gov/NIDDK small business programs

Budget Guidance

For budgetary, administrative, or programmatic reasons, the NIDDK may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found in the "Award Budget" section of the current Omnibus Solicitations. With appropriate justification from the applicant, the NIDDK may consider budgets that exceed these amounts to support research that aligns with an approved waiver topic (see SBA-Approved Waiver Topics).

The NIDDK generally considers:

- Phase I budgets up to \$350,000 total costs or project periods up to 2 years.
- Phase II applications up to \$2,200,000 total costs or project periods up to 3 years (Phase II budgets generally should not exceed \$1,100,000 total costs in any year).
- Phase IIB (see below) applications up to \$3,000,000 total costs or project periods up to 3 years (Phase IIB budgets generally should not exceed \$1,100,000 total costs in any year).

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff with a draft of their Specific Aims page before submitting an application. The NIDDK also participates in the SBIR/STTR Commercialization Readiness Pilot (CRP) Program. Applicants should review the Award Budget section of relevant Notices of Funding Opportunities. For Phase II awardees, especially those developing products that require clinical evaluation or approval by a Federal regulatory agency, the NIDDK strongly encourages potential applicants to apply to NIDDK's Phase IIB program.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIDDK will accept Phase IIB SBIR/STTR Competing Renewal grant applications (only) from NIDDK-supported Phase II awardees that propose to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, and 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Such products include, but are not limited to biological products, devices, drugs, medical implants, etc. related to the mission of the NIDDK. These awards are intended to support completion of research needed for an Investigational New Drug (IND) application or Investigational Device Exemption (IDE). Applicants must provide evidence that they have consulted formally with the U.S. the Food and Drug Administration (FDA) concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a

timeline related to Federal regulatory approval processes. Applicants should describe these consultations and the outcomes in the Progress Report section of the Research Strategy and provide FDA correspondence or meeting minutes as part of Just-in-Time procedures.

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities.

- Completion of studies as required by the FDA for an IND or Radioactive Drug Research Committee (RDRC) application.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Clinical studies in support of an application for clearance or approval by the FDA. See the table below and review NIDDK's Policies for Clinical Researchers (https://www.niddk.nih.gov/research-funding/human-subjects-research/policies-clinical-researchers) when considering an application involving human subjects.

The NIDDK also participates in the SBIR/STTR Commercialization Readiness Pilot (CRP) Program. Please review CRP NOFOs for NIDDK's participation. For Phase II awardees, especially those developing products that require clinical evaluation or approval by a Federal regulatory agency, the NIDDK strongly encourages potential applicants to apply to NIDDK's Phase IIB program.

Contact Information

For additional information on research topics, contact:

Diabetic Technology, Type 1 Diabetes and Endocrine Diseases

Dr. Guillermo Arreaza-Rubín

National Institute of Diabetes and Digestive and Kidney Diseases

Phone: 301-594-4724

Email: arreaza-rubing@niddk.nih.gov

Diabetic Wound Healing and Type 2 Diabetes

Dr. Yan Li

National Institute of Diabetes and Digestive and Kidney

Diseases Phone: 301-435-3721

Email: yan.li5@nih.gov

Neuromodulation, Diabetic Neuropathy, and Type 2 Diabetes Drug Discovery

Dr. Bradley M. Cooke

National Institute of Diabetes and Digestive and Kidney

Diseases Phone: 301-480-9896 Email: brad.cooke@nih.gov

Gastrointestinal, Obesity, and Nutrition Disorders and Diseases

Dr. Robert Lunsford

National Institute of Diabetes and Digestive and Kidney

Diseases Phone: 301-402-1397 Email: robert.lunsford@nih.gov

Liver, Pancreatic, and Neurobiological Disorders and Diseases

Ms. Christine Densmore

National Institute of Diabetes and Digestive and Kidney

Diseases Phone: 301-402-8714 Email: christine.densmorec@nih.gov

Kidney, Urologic and Hematologic Diseases

Dr. Daniel R. Gossett

National Institute of Diabetes and Digestive and Kidney

Diseases Phone: 301-594-7723 Email: daniel.gossett@nih.gov

For administrative and business management questions, contact:

Ms. Christina Coriz

National Institute of Diabetes and Digestive and Kidney Diseases

Phone: 301-594-8848

Email: christina.coriz@nih.gov

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

http://www.niehs.nih.gov

For more information on the NIEHS SBIR and STTR programs:

https://www.niehs.nih.gov/funding/grants/mechanisms/sbir

Budget Guidance

For all NIEHS research interest topic areas other than Hazardous Substances Remediation and Site Characterization SBIR Program included in this PHS 2024 Omnibus SBIR/STTR Solicitation, NIEHS will accept SBIR/STTR application total funding support (direct costs, indirect costs, and fee) requests up to \$306,872 for Phase I and \$2,045,816 for Phase II. NIEHS will not fund applications at budget levels exceeding these hard cap budget guidelines, except through specific RFAs. For budgetary, administrative, or programmatic reasons, NIEHS may decide not to fund an application or may decrease the length of an award and/or the budget. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project, and the budget request must be well justified. The Hazardous Substances Remediation and Site Characterization SBIR Program has different limits on budget requests and the applicants are strongly encouraged to stay within total allowed funding support request (direct costs, indirect costs, and fees) of \$183,460 for Phase I and \$1,223,064 for Phase II awards.

NIEHS will consider well justified Technical and Business Assistance (TABA) costs up to the limits specified on the NIH SEED website. These costs can be requested in addition to the Phase I and II limits indicated above.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIEHS does not intend to support any new Phase II B grants in this funding period. NIEHS currently participates in <u>PAR-23-219</u>: SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development (SB1, Clinical Trial Not Allowed).

Contact Information

For additional information on research topics, contact:

Dr. Daniel Shaughnessy National Institute of Environmental Health Sciences Division of Extramural Research and Training POB 12233 (K3-12) Research Triangle Park, NC 27709 (984) 287-3321

Email: shaughn1@niehs.nih.gov

Dr. Lingamanaidu V. Ravichandran National Institute of Environmental Health Sciences Division of Extramural Research and Training POB 12233 (K3-05) Research Triangle Park, NC 27709 (984)-287-3309

Email: lingamanaidu.ravichandran@nih.gov

For information on the NIEHS Superfund Research Program - Hazardous Substances Remediation and Site Characterization SBIR Program, contact:

Dr. Heather Henry National Institute of Environmental Health Sciences Division of Extramural Research and Training POB 12233 (K3-12) Research Triangle Park, NC 27709 (984) 287-3268

Email: henryh@niehs.nih.gov

For administrative and business management questions contact:

Mr. Clark A. Phillips National Institute of Environmental Health Sciences Division of Extramural Research and Training Grants Management Branch (984) 287-4037

Email: clark.phillips@nih.gov

NATIONAL EYE INSTITUTE (NEI)

http://www.nei.nih.gov

For more information on the NEI SBIR and STTR programs:

https://www.nei.nih.gov/grants-and-training/funding-opportunities/programs-and-research-priorities/small-business

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. For budgetary, administrative, or programmatic reasons, NEI may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. For topics listed in SBA-Approved Waiver Topics, NEI does not generally fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. Applicants are strongly encouraged to contact program officials prior to submitting any application in excess of the hard caps listed above and early in the application planning process.

Phase IIB Competing Renewal Awards and Commercial Readiness Pilot (CRP)

The NEI will only accept SBIR Phase IIB Competing Renewal grant applications from Phase II SBIR awardees to continue the process of developing technologies that ultimately require federal regulatory approval or require extraordinary time and effort in the Research and Development phase. Such technologies include, but are not limited to, pharmacologic agents, biological products, and devices. These technologies should be clearly related to the mission of the NEI. This renewal grant should allow small businesses to reach a stage in the project where interest and investment by third parties is more likely. The NEI expects that the Phase IIB grant will accelerate the transition of SBIR Phase II projects to the commercialization stage. The NEI encourages applicants to establish business relationships with third-party investors and/or strategic partners who can provide substantial financing to help accelerate the commercialization of promising new products and technologies that were initiated with SBIR funding.

The Competing Renewal application must be a logical extension of a previously completed Phase II (R44) SBIR grant. NEI grantees seeking SBIR Phase IIB Competing Renewal funding must submit an application within a period no later than the first six receipt dates following expiration of the previous Phase II budget period. Cumulative budgets should not exceed \$1,800,000 total costs, or time periods beyond three (3) years.

Although matching funds are not required, the NEI strongly encourages that applicants obtain significant private investment. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds.

Applicants are strongly encouraged to contact the NEI Program Officer, Dr. Paek Lee (contact information provided below) prior to submitting any application in excess of the hard caps listed above and early in the application planning process.

Contact Information

For more information on research topics, contact:

Paek Lee, Ph.D.

Program Director, Small Business SBIR/STTR Division of Extramural Science Programs National Eye Institute 6700B Rockledge Drive Bethesda, MD 20817 301-435-8164

Email: paek.lee@nih.gov

Tony D. Gover, Ph.D.

Program Director, Small Business SBIR/STTR (Anterior Segment) Division of Extramural Science Programs National Eye Institute 6700B Rockledge Drive Bethesda, MD 20817 301-529-7370

Email: tony.gover@nih.gov

For administrative and business management questions, contact:

Ms. Karen Robinson Smith

Chief Grants Management Officer **Grants Management Branch Division of Extramural Activities** National Eve Institute, NIH, DHHS 6700B Rockledge Drive, Suite 3400 Bethesda, MD 20892 301-451-2020, Fax: 301-496-9997

Email: kyr@nei.nih.gov

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

http://www.nigms.nih.gov

For more information on the NIGMS SBIR and STTR programs:

https://www.nigms.nih.gov/grants-and-funding/research-funding/small-business-research

Budget Guidance

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. NIGMS will not accept applications with budget requests exceeding this hard cap with the exception of projects that fit within the SBA-Approved Waiver Topics list for awards over the statuary budget limitations. NIGMS sets its own budget limits for the specific research topics that are granted a waiver to exceed the U.S. Small Business Administration hard budget caps. The NIGMS budget limit for a Phase I project on an approved topic is \$350,000 in total costs with a project period up to 1 year. The budget limit for a Phase II project on an approved topic is \$2,500,000 in total costs for a project period up to 3 years. If considering a project with a budget exceeding the hard cap, applicants are strongly encouraged to contact NIGMS program officials prior to submission, and preferably in the early stages of application preparation. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIGMS will accept Phase IIB SBIR-only Competing Renewal grant applications to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, or 3) continuing refinements that include but are not limited to cost reduction, testing for performance, safety, reliability and/or durability, and meeting or establishing standards, particularly for basic or clinical research instrumentation or durable medical equipment (DME) designs. This renewal grant should enhance the likelihood that small business will attract interest and investment by third parties. Such products include, but are not limited to research equipment, biological products, devices, drugs, medical implants, etc. within the mission of the NIGMS. Budgets for this Phase IIB Competing Renewal opportunity must follow the guidelines for Phase II applications (described above). For awards that are intended to support completion of research needed to obtain an Investigational New Drug application (IND) or Investigational Device Exemption (IDE), applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements.

Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes. Applicants should describe these consultations and the outcomes in the Progress Report section of the Research Strategy and provide FDA correspondence or meeting minutes as part of Just-in-Time procedures.

Prospective applicants considering a Phase IIB Competing Renewal application are strongly encouraged to contact either the Program person of record for the Phase II award or NIGMS contacts listed at the end of this NIGMS topics announcement.

To assist NIGMS in planning for Phase IIB applications, it is helpful for prospective applicants to submit to the NIGMS Small Business Strategy Coordinator (listed below) a letter of intent that includes the following information:

• Descriptive title of the proposed research

- Phase II grant number
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Notice of Funding Opportunity Number

The letter is non-binding and does not enter the review process. It is anticipated that only a small number of NIGMS SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal award.

Contact Information

For general information on the NIGMS Small Business program, contact:

Eddie Billingslea, Ph.D., NIGMS Small Business Strategy Coordinator

Email: NIGMS SmallBusiness@nigms.nih.gov

For scientific questions about NIGMS-funded SBIR/STTR research, contact:

Division of Pharmacology, Physiology, and Biological Chemistry

Pharmacological and Physiological Sciences

Sailaja Koduri, Ph.D.

Email: Sailaja.Koduri@nih.gov

Biochemistry and Bio-related Chemistry

Kadir Aslan, Ph.D.

Email: kadir.aslan@nih.gov

Division of Biophysics, Biomedical Technology, and Computational Biosciences

Ashley Barnes, Ph.D.

Email: ashley.barnes@nih.gov

Division for Research Capacity Building Krishan Arora, Ph.D. 301-435-0763

Email: arorak@nigms.nih.gov

Research and Development in Science Education

Tony Beck, Ph.D. 301-480-4623

Email: beckL@mail.nih.gov

For administrative and business management questions, contact:

Administrative and Business Management

Mr. Brian Iglesias 301-451-5903

Email: iglesiab@mail.nih.gov

Ms. Ilene Glassman 301-594-4648

Email: ilene.glassman@nih.gov

Ms. Alania Foster 301-451-8255

Email: alania.foster@nih.gov

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

https://www.nhlbi.nih.gov/

For more information on the NHLBI SBIR and STTR programs:

http://www.nhlbi.nih.gov/research/funding/sbir

Budget Guidance

Total funding support (direct costs, indirect costs, and fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. For budgetary, administrative, or programmatic reasons, the NHLBI reserves the right to disapprove funding or decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NHLBI that can be found in the SBA-Approved Waiver Topics. It is strongly recommended for applicants who have a project that falls under one of the SBA-Approved Waiver Topics to reference the corresponding topic in their Budget Justification document. For most projects falling under one of the SBA-approved waiver topics, the NHLBI does not fund Phase I applications greater than the current SBA-mandated budget guidelines (up to \$306,872 total costs for Phase I and up to \$2,045,816 total costs for Phase II applications). However, the NHLBI may occasionally fund projects above these guidelines for proposals falling under one of the approved waiver topics if one or more of the following criteria have been fulfilled:

- 1. The application involves the clinical testing of therapeutics, devices, imaging agents, biologics, diagnostics, clinical and rehabilitation tools, and/or technologies.
- 2. The application involves the use of a large animal model. For the purpose of this guidance, large animal model species include: swine (porcine), sheep (ovine), cattle (bovine), cat (feline), dog (canine), ferret, and nonhuman primates.

Applicants with budget requests exceeding these caps **should be prepared to negotiate their budget down** if their proposal does not fall into one of the above categories.

Furthermore, all applicants with budget questions, or considering requesting a budget greater than the set budget limitation amounts, are **strongly encouraged** to contact the NHLBI SBIR office at http://bit.ly/ContactNHLBIsbir before submitting an application. For more information on the NHLBI Budget Policy for SBIR/STTR grants, please refer to <a href="https://www.nct.number.numbe

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NHLBI only accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities. These opportunities can be found on the NHLBI Funding Opportunities webpage: https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/small-business-program. Applicants are strongly encouraged to contact Dr. Jain Krotz at jain.krotz@nih.gov for additional information on Phase IIB funding opportunities.

The NHLBI welcomes the submission of Commercialization Readiness Pilot (CRP) program applications from current or past Phase II/IIB awardees. The CRP aims to facilitate the transition of previously or currently funded SBIR and STTR Phase II and Phase IIB projects to the commercialization stage by providing additional support for technical assistance and later-stage research and development (R&D) not typically supported through Phase II or Phase IIB grants or contracts. NHLBI will accept budgets up to \$500,000 total costs (direct costs, indirect costs, fee) across up to two years. NHLBI participates in the following CRP NOFOs below:

- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Not Allowed (PAR-23-219)
- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Required (PAR-23-220)

Contact Information

For general questions about the NHLBI SBIR/STTR grant program, please contact:

Stephanie Davis, Ph.D.

Division of Extramural Research Activities

Phone: 1-301-496-8412

Email: nhlbi sbir@mail.nih.gov

For administrative and business management questions, please contact:

Andre Walker

Division of Extramural Research Activities Phone: 1-301-827-8061 Email: walkera@nhlbi.nih.gov

Cardiovascular Sciences

Rahul Thakar, Ph.D.

Division of Cardiovascular Sciences

Advanced Technologies and Surgery Branch

Phone: 301-827-8151 Email: rahul.thakar@nih.gov

Lung Diseases and Sleep and Circadian Biology

Lei Xiao, M.D., Ph.D. Division of Lung Diseases

Restrictive and Vascular Lung Diseases Branch

Phone: 301-827-7852 Email: lei.xiao@nih.gov

Sidd Shenoy, Ph.D. Division of Lung Diseases

Acute and Infectious Lung Diseases Branch

Phone: 301-827-4751 Email: sidd.shenoy@nih.gov

For sleep-related proposals, please contact: Shilpy Dixit, Ph.D. Division of Lung Diseases National Center for Sleep Disorders Research

Phone: 301-402-9064 Email: shilpy.dixit@nih.gov

Blood Diseases and Resources

Ron Warren, Ph.D.

Division of Blood Diseases and Resources

Translational Blood Science and Resources Branch

Phone: 301-827-8288

Email: ronald.warren@nih.gov

Ilana Goldberg, Ph.D. Division of Blood Diseases and Resources Molecular, Cellular & Systems Blood Science

Branch Phone: 301-496-8587 Email: <u>ilana.goldberg@nih.gov</u>

Center for Translation Research and Implementation Science

Karen Plevock Haase, Ph.D. Implementation Science Branch

Phone: 301-435-6820

Email: karen.plevock@nih.gov

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

http://www.genome.gov

For more information on the NHGRI SBIR and STTR programs:

https://www.genome.gov/research-funding/Funding-Opportunities/NHGRI-Small-Business-Program

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website, unless the application fits an SBA-approved NHGRI waiver topic. For topics listed in the SBA-Approved Waiver Topics, the NHGRI generally will not fund Phase I applications to the Omnibus greater than \$400,000 total costs or Phase II applications greater than \$2,150,000 total costs (not including the costs of technical and business assistance). For budgetary, administrative, or programmatic reasons, the NHGRI may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NHGRI does not accept applications for Phase IIB competing renewal awards through this Omnibus solicitation. NHGRI participates in the CRP program

Contact Information

For more information on research topics, contact:

lan Nova, Ph.D. Small Business Program Co-Lead (SBIR)

Phone: 240-987-2885 Email: ian.nova@nih.gov

Renee Rider, M.S., J.D., LCGC Small Business Program Co-Lead (STTR)

Phone: 301-443-4336 Email: renee.rider@nih.gov

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

http://www.nimh.nih.gov

For more information on the NIMH SBIR and STTR programs:

https://www.nimh.nih.gov/funding/sbir

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the <u>NIH SEED website</u>. NIH has received a waiver from the SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NIMH that can be found in the <u>SBA-Approved Waiver Topics</u>. Please note, for budgetary, administrative, or programmatic reasons, the NIMH may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Applicants with budget questions or considering requesting a budget greater than the SBA defined amounts are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

The NIMH will accept Phase IIB SBIR/STTR Competing Renewal grant applications in two categories: 1) to continue research and development of technologies that ultimately require federal regulatory approval, and 2) to continue research and development of complex instrumentation, clinical research tools, or behavioral/digital health interventions and treatments.

Technologies in the former category (those that ultimately require federal regulatory approval) include but are not limited to pharmacologic agents and drugs, biological products, medical devices, vaccines, etc. related to the mission of the NIMH. Phase IIB SBIR/STTR Competing Renewal grants for such technologies should allow small businesses to move research and development to a stage where interest and investment by third parties is more likely.

Companies that are developing technologies that do not focus on drug development, but that require federal regulatory approval prior to commercialization, may be eligible to submit a Phase IIB Competing Renewal application.

For both technology areas, Phase IIB applications may be submitted through the Omnibus SBIR/STTR Notice of Funding Opportunity. Generally, for this opportunity, budget limits of \$3 million total costs and time periods up to 3 years may be requested. These budget allowances have been approved by the SBA through a waiver. For budgets higher than \$3 million, contact NIMH program staff prior to submitting the application.

The following examples would make appropriate topics for proposed NIMH SBIR/STTR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43/R41) and initial Phase II (R44/R42) grants. Some in vivo or in vitro studies would be expected to have been carried out in Phase I or the initial Phase II grant.
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Safety and effectiveness studies of novel medical devices.
- Evaluation of novel imaging approaches for diagnostic purposes.

Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Although technologies in the latter category listed above (complex instrumentation, clinical research tools, or behavioral interventions/treatments) may not require federal regulatory approval, extraordinary time and effort is needed for their research and development. Therefore, NIMH supports Phase IIB Competing Renewal awards of existing Phase II grants for such technologies. The Phase IIB Competing Renewal award for these would provide up to an additional three years of support at total cost funding levels of up to \$3 million (generally) for the project. These budget allowances have been approved by the SBA through a waiver.

Please contact the Program Director in the appropriate Division or Dr. Margaret Grabb (listed below) before beginning the process of putting an application together. In addition, prospective applicants are encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Notice of Funding Opportunity (e.g., <u>PA-19-273</u>).

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIMH SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Contact Information

Margaret Grabb, Ph.D. (general questions about the NIMH SBIR program, Phase IIB program, DNBBS, DTR divisional interests)
National Institute of Mental Health
6001 Executive Boulevard, Room 7133
Rockville, MD 20852 Telephone: 301-443-3563

Email: mgrabb@mail.nih.gov

Adam Haim, Ph.D. (DSIR divisional interests)
Division of Services and Intervention Research
6001 Executive Boulevard
Room 7273

Rockville, MD 20852 Telephone: 301-445-3593

Email: haima@mail.nih.gov

Maggie Sweeney, Ph.D. (DSIR divisional interests; send initial inquiries to Dr. Adam Haim above)

Division of Services and Intervention Research

6001 Executive Boulevard Telephone: 301-480-1582

Email: maggie.sweeney@nih.gov

Dr. Vasudev R Rao M.B.B.S, M.S. (DAR divisional interests) Division of AIDS Research 5601 Fishers Ln Rockville MD 20852 Telephone: 240-669-5609

Email: vasudev.rao@nih.gov

Paige Anderson, M.S. (preclinical assay development) 6001 Executive Boulevard, Room 7120.3 Bethesda, MD 20892-9645 Rockville, MD 20852 (for express/courier service) Telephone: 301-827-6550

Email: paige.anderson@nih.gov

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

http://www.nimhd.nih.gov

For more information on the NIMHD SBIR and STTR programs:

https://www.nimhd.nih.gov/programs/extramural/sbir-sttr.html

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. For budgetary, administrative, or programmatic reasons, the NIMHD may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NIMHD that can be found in the SBA-Approved Waiver Topics. Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIMHD welcomes Phase IIB Competing Renewal Applications for Phase II grants and contracts via the Omnibus Solicitation for SBIR or STTR Grant Applications, and as indicated by other NIMHD Notices of Funding Opportunities (NOFOs). Standard NIMHD Phase II funding policy applies unless otherwise stated in the NOFO. Non-NIMHD Phase II awardees must contact NIMHD prior to submission to confirm programmatic interest.

Contact Information

For additional information on research topics, contact:

LCDR Michael Banyas, USPHS, M.P.A, M.A, Program Manager Division of Community Health and Population Science National Institute on Minority Health and Health Disparities,

NIH Email: michael.banyas@nih.gov

Phone: 301-827-7478

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

http://www.ninds.nih.gov

For more information on the NINDS SBIR and STTR programs:

https://www.ninds.nih.gov/funding/ninds-small-business-program

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website, unless the application fits an SBA-approved waiver topic. For topics listed in the SBA-Approved Waiver Topics, NINDS generally will not fund Phase I applications to the Omnibus greater than \$700,000 total costs, with no more than \$500,000 total cost in an year or project periods greater than 2 years; or Phase II applications greater than \$3,000,000 total costs, with no more than \$1,500,000 or project periods greater than 3 years. For budgetary, administrative, or programmatic reasons, NINDS may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Information about the NINDS budget guidelines can be found on the NINDS SBIR webpage https://www.ninds.nih.gov/funding/ninds-small-business-application.

For all other funding opportunities, applications should follow the guidelines in the Award Budget section of those announcements carefully.

All applicants are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NINDS only accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NINDS Funding Opportunities webpage: https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities. Contact ninds_sbir@ninds.nih.gov for additional information.

Contact Information

Scientific/Research Contact

Emily Caporello, Ph.D.

Director, NINDS Small Business Program

Phone: 301-496-1779

Email: emily.caporello@nih.gov

Program-wide Email: ninds sbir@ninds.nih.gov

Financial/Grants Management Contact:

Chief Grants Management Officer

National Institute of Neurological Disorders and Stroke (NINDS)

Email: ChiefGrantsManagementOfficer@ninds.nih.gov

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

http://www.ninr.nih.gov

For more information on the NINR SBIR and STTR programs:

https://www.ninr.nih.gov/funding/small-business-funding

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SBIR website. For budgetary, administrative, or programmatic reasons, NINR may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from the SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to NINR that can be found in the SBA-Approved Waiver Topics. NINR will generally not fund:

- Phase I applications to the Omnibus greater than \$385,000 total costs or project periods greater than 2 years, or
- Phase II applications greater than \$2,500,000 total costs or project periods greater than 3 years.

Applicants that are considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NINR does not accept Phase IIB applications.

NINR does not participate in the Commercialization Readiness Pilot (CRP) Program.

Contact Information

For additional information please contact:

Dr. Karen Kehl

Director, Small Business Innovation Research Program National Institute of Nursing Research (NINR) Division of Extramural Science Program (DESP) 6701 Democracy Blvd, Room 727

Bethesda, MD 20892-4870 Office: (301) 594-8010 Email: karen.kehl@nih.gov

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

https://ncats.nih.gov

For additional information on the NCATS SBIR and STTR programs:

http://ncats.nih.gov/smallbusiness

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the <u>NIH SEED website</u>. For budgetary, administrative, or programmatic reasons, NCATS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

For certain topical areas, there is an <u>SBA-Approved Waiver Topics</u> list for which the NCATS generally will not fund:

- Phase I applications greater than \$350,000 total costs or project periods greater than 2 years
- Phase II applications greater than \$2,150,000 total costs or project periods greater than 3 years

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

Occasionally, NCATS may accept Phase IIB SBIR Competing Renewal grant applications of NCATS supported Phase II awards to continue research and development of products that have a potential to address bottlenecks in the translational process, and where additional time and effort is needed to reach a stage where interest and investment by third parties would be likely. Such products are expected to have broad applicability and be consistent with the mission of NCATS. Applicants are strongly encouraged to speak to NCATS Program staff prior to submitting their Phase IIB application. Budgets for Phase IIB grant applications must be approved by NCATS Program staff prior to submission.

Contact Information

For additional information on research topics, please contact:

Krishna 'Balki' Balakrishnan, PhD, MBA NCATS SBIR/STTR Acting Program Director

National Center for Advancing Translational Sciences, NIH

Phone: 301-827-7149

Email: NCATS-SBIRSTTR@mail.nih.gov

Meena U. Rajagopal, PhD

NCATS SBIR/STTR Program Officer

National Center for Advancing Translational Sciences, NIH

Phone: 301-827-1921

Email: NCATS-SBIRSTTR@mail.nih.gov

Mayra A. Alvarez Lopez, MS NCATS SBIR/STTR Program Analyst National Center for Advancing Translational Sciences, NIH Phone: 301-827-7146

Email: NCATS-SBIRSTTR@mail.nih.gov

For Administrative, business management and grants policy questions, please contact:

Ms. Imoni Williams

Grants Management Specialist, SBIR/STTR Project Liaison

Phone: 301-435-2939

E-mail: imoni.williams@nih.gov

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

http://nccih.nih.gov

For additional information on the NCCIH SBIR and STTR programs:

https://www.nccih.nih.gov/grants/sbir-sttr

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the Small Business Association (SBA), which can be found on the NIH SEED website. NCCIH policy on grant duration is described in NOT-AT-20-017.

There is an SBA-Approved Waiver Topics list, for which NCCIH generally will not fund:

- Phase I applications greater than \$325,000 total costs per year or project periods greater than 2 years.
- Phase II applications greater than \$2,000,000 total costs for the duration of the project or project periods greater than 3 years.

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NCCIH does not accept applications for Phase IIB.

Contact Information

For additional information on research topics, please contact:

Emrin Horgusluoglu, PhD

Program Director, Division of Extramural Research National Center for Complementary and Integrative Health (NCCIH) 6707 Democracy Boulevard, Suite 401

Telephone: 240-383-5302

Email: emrin.horgusluoglu-moloch@nih.gov

NATIONAL LIBRARY OF MEDICINE (NLM)

http://www.nlm.nih.gov

For more information on the NLM SBIR and STTR programs:

https://www.nlm.nih.gov/ep/grantsbir.html

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the NIH SEED website. For budgetary, administrative, or programmatic reasons, the NLM may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NLM that can be found in the SBA-Approved Waiver Topics. Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NLM does not accept Phase IIB applications and does not participate in the CRP program.

Contact Information

For additional information on research topics, contact:

Dr. Rebecca Moen Program Officer Division of Extramural Programs National Library of Medicine 301-594-7593

Email: rebecca.moen@nih.gov

For administrative and business management questions, contact:

Ms. Samantha Tempchin
Grants Management Officer
Extramural Programs Division National
Library of Medicine

301-496-4222, Fax: 301-402-0421 Email: <u>samantha.tempchin@nih.gov</u>

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

https://orip.nih.gov

For more information on the ORIP SBIR and STTR programs:

https://orip.nih.gov/funding/small-business

Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the <u>NIH SEED website</u>. For budgetary, administrative, or programmatic reasons, ORIP may not fund an application, may decrease the length of an award, and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to ORIP that can be found in the <u>SBA-Approved Waiver Topics</u>. Applicants who have budget questions or are considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

ORIP will only accept Phase IIB SBIR Competing Renewal grant applications of ORIP-supported Phase II awards to continue research and development of methods, technologies, tools, and devices for basic or translational research where extraordinary time and effort are needed for completion of these projects. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to reach a stage where interest and investment by third parties would be more likely. Such products are expected to have broad applicability, consistent with the mission of ORIP. Budgets that do not exceed \$1M per year in total costs (for up to 2 years), may be requested for this Phase IIB Competing Renewal opportunity; however, it is expected that, in most cases, the requested budget would not exceed the final year budget of the applicant's previous Phase II award. This opportunity is available for the SBIR program only.

Please contact your Program Officer before beginning the process of preparing a Phase IIB Competing Renewal application. In addition, prospective applicants are strongly encouraged to submit to the Program Contact (listed after each section) a letter of intent by email that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other Key Personnel
- Participating organizations
- Notice of Funding Opportunity Number (e.g., PA-22-XXX)

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. It is expected that only a few of ORIP SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

ORIP does not participate in the Commercialization Readiness Pilot (CRP) program at this time.

Contact Information

For additional information on DCM research topics, contact:

Miguel Contreras, Ph.D.

Division of Comparative Medicine, Office of Research Infrastructure Programs,

Division of Program Coordination, Planning, and Strategic Initiatives,

Office of the Director Phone: 301-451-7845

Email: miguel.contreras@nih.gov

For additional information on DCI research topics, contact:

Xiang-Ning Li, Ph.D.

Director

Division of Construction and Instruments, Office of Research Infrastructure Programs,

Division of Program Coordination, Planning, and Strategic Initiatives

Office of the Director Phone: 301-435-0766 Email: xiang-ning.li@nih.gov

For administrative and business management questions, contact:

Ms. Donna James

Grants Management Specialist,

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

Office of Research Infrastructure Programs (ORIP),

6705 Rockledge Drive, 202-G

Bethesda, MD 20817 Phone: 301-827-8063

Email: donna.james@nih.gov

OFFICE OF RESEARCH ON WOMEN'S HEALTH (ORWH)

https://orwh.od.nih.gov/

Budget Guidance

ORWH does not award grants but co-funds women's health-related applications that have received an award from one of the participating NIH Institutes and Centers (ICs) listed in the announcement. Budgets should be discussed with Institute or Center program staff, not ORWH.

Contact Information

For additional information on ORWH priorities, please contact:

Elizabeth Barr, Ph.D.
ORWH Associate Director for Interdisciplinary Research
Office of Research on Women's Health, NIH

Phone: 301-402-7895

Email: Elizabeth.Barr@nih.gov

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. For more than 70 years, we've put science into action to help children stay healthy so they can grow and learn; to help families, businesses, and communities fight disease and stay strong; and to protect the public's health.

Budget Guidance

Total funding support (direct costs, indirect costs, fees) <u>normally</u> may not exceed \$306,872 for Phase I awards and \$2,045,816 for Phase II awards. These are the amounts currently defined by the U.S. Small Business Administration (SBA), which can also be found on the <u>CDC SBIR</u> <u>website</u>. Applicants considering a requested budget greater than these limits are <u>strongly encouraged</u> to contact CDC program staff before applying. For budgetary, administrative, or programmatic reasons, the CDC may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. CDC has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by SBA for specific topics relevant to CDC that can be found in the <u>SBA-Approved Waiver Topics Over Statutory</u> Budget Limitations document.

Before considering and/or preparing an application to the CDC SBIR program, applicants are encouraged to review the websites of CDC's participating components and to contact the SBIR program staff listed below.

Specific SBIR and STTR Program Information

CDC does not accept STTR applications.

CDC does not accept Direct to Phase IIs, Fast-Track, or Phase IIB.

For additional information about CDC, please visit: http://www.cdc.gov.

Research Topics/Specific Areas of Interest

Additional information on the awarding components (CIOs) and their research interests is available electronically on the home pages shown throughout the "Research Topics/Specific Areas of Interest" sections below.

CDC encourages investigator-initiated applications that focus on support for the prevention, detection, and response to emerging public health threats. CDC also encourages investigator-initiated applications that align with the agency's overall mission and the research areas of interest of the participating CDC components below.

Contact Information

General questions about the CDC SBIR program should be directed to: Small Business Innovation Research Program (SBIR) Office of Science (OS)

Centers for Disease Control and Prevention (CDC)

Email: SBIR@cdc.gov

GLOBAL HEALTH CENTER (GHC)

Please visit the GHC website at: https://www.cdc.gov/GlobalHealth/. For GHC programmatic information, contact:

Lata Kumar, MS, MPH, MBA
Office of the Director
Center for Global Health Center
Centers for Disease Control and Pre

Centers for Disease Control and Prevention (CDC) Mail Stop H21-9

1600 Clifton Road NE Atlanta, GA 30329

Phone: (404) 639-7618 Email: <u>LKumar@cdc.gov</u>

Email: AEN4@cdc.gov

For grants specific, administrative information, contact:

Angie Willard, Team Lead
Office of Grant Services
Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop TV-2
2939 Flowers Road NE
Atlanta, GA 30341
Phone: 770-498-2596

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES (NCBDDD)

Please visit the NCBDDD website at: http://www.cdc.gov/ncbddd/index.html. For NCBDDD programmatic information, contact:

Natalie Brown, MPH
Office of the Director
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention (CDC)
Mail Stop S107-8
4770 Buford Highway
Atlanta, GA 30341
Phone: 404-639-4601

Phone: 404-639-4601 Email: NBrown3@cdc.gov

For grants specific, administrative information, contact:

Brownie Anderson-Rana
Office of Grant Services
Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop K-75
2920 Brandywine Rd.
Atlanta, GA 30341
Phone: 770-488-2771

Email: BAndersonRana@cdc.gov

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)

Please visit the NCCDPHP web site at: http://www.cdc.gov/chronicdisease/index.htm. For NCCDPHP programmatic information, contact:

Natalie Brown, MPH
Office of the Director
National Center for Chronic Disease Prevention and Health
Promotion
Centers for Disease Control and Prevention
(CDC)
Mail Stop S107-8
4770 Buford Highway
Atlanta, GA 30341

Phone: 404-639-4601 Email: NBrown3@cdc.gov

For grants specific, administrative information, contact:

Angie Willard, Team Lead
Office of Grant Services Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop, T2939 Flowers Road NE Atlanta, GA 30341
Phone: 770,409, 2506

Phone: 770-498-2596 Email: <u>AEN4@cdc.gov</u>

NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES (NCEZID)

Please visit the NCEZID website at: http://www.cdc.gov/ncezid. For NCEZID programmatic information, contact:

Amy Yang, PhD National Center for HIV, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention (CDC) Phone: 404-718-8836

Email: VDZ9@cdc.gov

For grants specific, administrative information, contact:

Angie Willard, Team Lead
Office of Grant Services Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop TV-2
2939 Flowers Road NE Atlanta, GA 30341

Phone: 770-498-2596 Email: <u>AEN4@cdc.gov</u>

NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)

Please visit the NCEH web site at: https://www.cdc.gov/nceh/. For NCEH programmatic information, contact:

Tonia Linley
Program Specialist
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention CDC
Phone: 770-488-3593

Email: lMX9@cdc.gov or NCIPC_ERPO@cdc.gov

For grants specific, administrative information, contact:

Brownie Anderson-Rana
Office of Grant Services Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop K-75
2920 Brandywine Rd.
Atlanta, GA 30341
Phone: 770-488-2771

Email: BAndersonRana@cdc.gov

NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD, AND TB PREVENTION (NCHHSTP)

Please visit the NCHHSTP website at: http://www.cdc.gov/nchhstp/. For NCHHSTP programmatic information, contact:

Amy Yang, PhD
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention (CDC)
Phone: 404-718-8836

Phone: 404-718-8836 Email: VDZ9@cdc.gov

For grants specific, administrative information, contact:

Angie Willard, Team Lead
Office of Grant Services Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop TV-2
2939 Flowers Road NE Atlanta, GA 30341

Phone: 770-498-2596 Email: AEN4@cdc.gov

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)

Please visit the NCIRD website at: http://www.cdc.gov/ncird/. For NCIRD programmatic information, contact:

Amy Yang, PhD
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention (CDC)
Phone: 404-718-8836

Email: VDZ9@cdc.gov

For grants specific, administrative information, contact:

Angie Willard, Team Lead
Office of Grant Services Office of Financial
Resources Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop TV-2
2939 Flowers
Road NE Atlanta,
GA 30341

Phone: 770-498-2596 Email: <u>AEN4@cdc.gov</u>

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC)

To learn more about NCIPC, please visit the NCIPC website at: http://www.cdc.gov/injury/index.html. For NCIPC programmatic information, contact:

Tonia Linley

Program Specialist

National Center for Injury Prevention and Control Centers for Disease Control and Prevention CDC

Phone: 770-488-3593

Email: IMX9@cdc.gov or NCIPC ERPO@cdc.gov

For grants specific, administrative information contact:

Angie Willard, Team Lead
Office of Grant Services
Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC)
Mail Stop TV-2
2939 Flowers Road NE Atlanta, GA 30341

Phone: 770-498-2596 Email: AEN4@cdc.gov

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

For additional information about NIOSH, please visit their web site at: http://www.cdc.gov/niosh/programs.

NIOSH typically supports Phase I awards at the maximum allowable total cost as stated in the funding announcement. However, in most cases Phase II applications are limited to a maximum total cost of \$1M for the two-year period of performance.

Visit the NIOSH homepage for more information on NIOSH's research program areas http://www.cdc.gov/niosh/homepage.html.

For NIOSH programmatic information, contact:

Steve Dearwent, PhD
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention
Mail Stop V24-4

Phone: 404-498-6382 Email: sdearwent@cdc.gov

For grants specific, administrative information, contact:

Brownie Anderson-Rana
Office of Grant Services Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention (CDC) Mail Stop K-75
2920 Brandywine Rd.
Atlanta, GA 30341
Phone: 770-488-2771

Email: BAndersonRana@cdc.gov

FOOD AND DRUG ADMINISTRATION (FDA)

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information they need to use medicines and foods to improve their health.

For additional information about areas of interest to the FDA, please visit our home page at http://www.fda.gov.

Budget Guidance

FDA will not fund:

- Phase I applications greater than \$200,000
- Phase II applications greater than \$1,500,000

Contact Information

For additional information on research topics and administrative and business information, contact

Kimberly Pendleton

Director, Division of Grants, Agreements, and Acquisition Support

Email: Kimberly.Pendleton@fda.hhs.gov

Food and Drug Administration

Division of Acquisition Support and Grants