HHS SBIR Contract RFP Informational Webinar

August 24, 2022 | 1:00pm ET

National Institutes of Health
Office of Extramural Research

NIH SEED

Stephanie Fertig

HHS Small Business Program Lead

SEED (Small business Education & Entrepreneurial Development)

Office Of The Director | Office Of Extramural Research

National Institutes Of Health

National Institutes of Health
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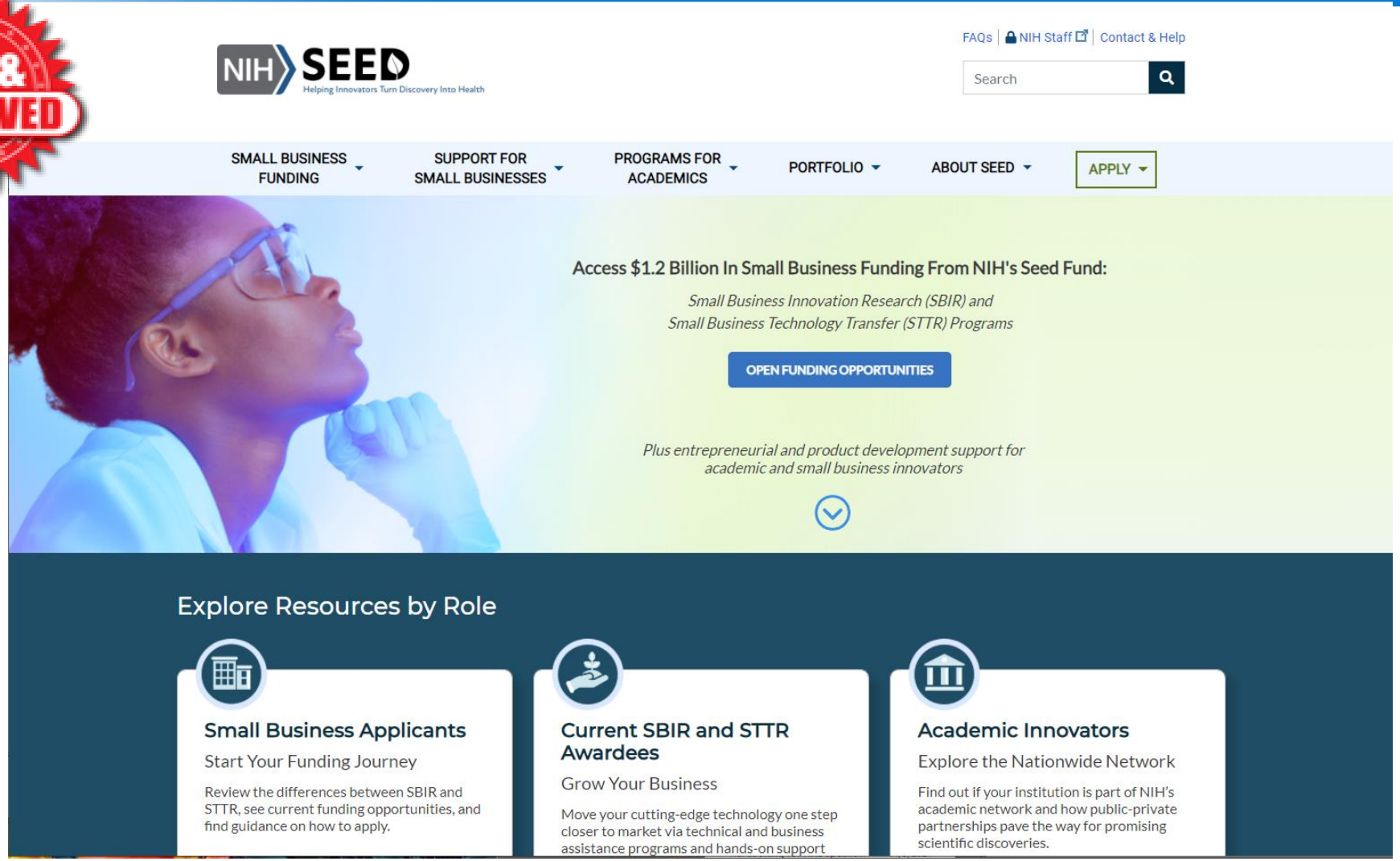
NIH SBIR/STTR Website



Grant Webinar

FAQs | NIH Staff | Contact & Help

NIH SEED
Helping Innovators Turn Discovery Into Health

Search

SMALL BUSINESS FUNDING | SUPPORT FOR SMALL BUSINESSES | PROGRAMS FOR ACADEMICS | PORTFOLIO | ABOUT SEED | APPLY

Home / About SEED / Events

EVENTS

Innovation and entrepreneurship events of interest to the NIH community.

Upcoming Events | Past Events

2022

10 AUG — Invention-Con 2022
12:00 pm - 5:00 pm
Online

05 AUG — Applicant Assistance Program Webinar
3:00 pm - 4:30 pm
Webex

27 JUL — Supporting Biomedical R&D with America's SEED Fund
10:20 am - 12:30 pm
Online

25 JUL — Meet with an HHS Small Business Program expert
9:00 am - 5:00 pm
Online
See Details

21 JUL — America's SEED Fund: Powered by NIH Webinar - Materials Available
1:00 pm - 3:00 pm
Zoom
See Details

Zoom
July 21, 2022

America's SEED Fund: Powered by NIH Webinar - Materials Available

View these materials to learn about the NIH SBIR & STTR program, open funding opportunities, the application and review process, and resources to help your project be successful. You'll also learn how to interpret reviewer comments, how and when to engage with program staff during the post-review process, and where to find resources if you need to resubmit.

Agenda:
Part 1: Dig Into NIH's SEED Fund
Part 2: Secrets of a Successful Submission

Materials

View the recording.

View the slide deck.

View the transcript.

View the useful chat links.

https://seed.nih.gov/aboutseed/past_events

National Institutes of Health
Turning Discovery Into Health

Department of Health & Human Services Small Business Programs

To enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

National Institutes of Health
SBIR and STTR $1.2B

Centers for Disease Control and Prevention
SBIR $11M

Food and Drug Administration
SBIR $2M

Administration for Community Living
SBIR $3M

THERE ARE NO FDA or ACL SBIR CONTRACTS

National Institutes of Health
Turning Discovery Into Health

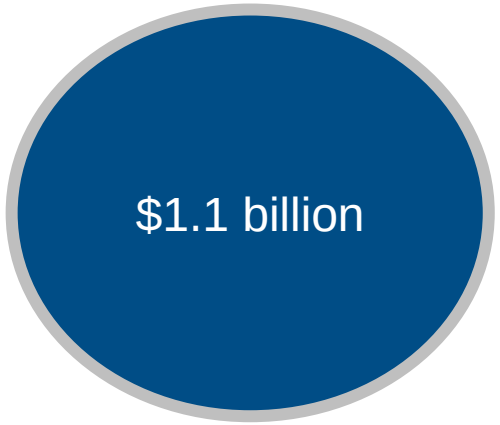
NIH Mission




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

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

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



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

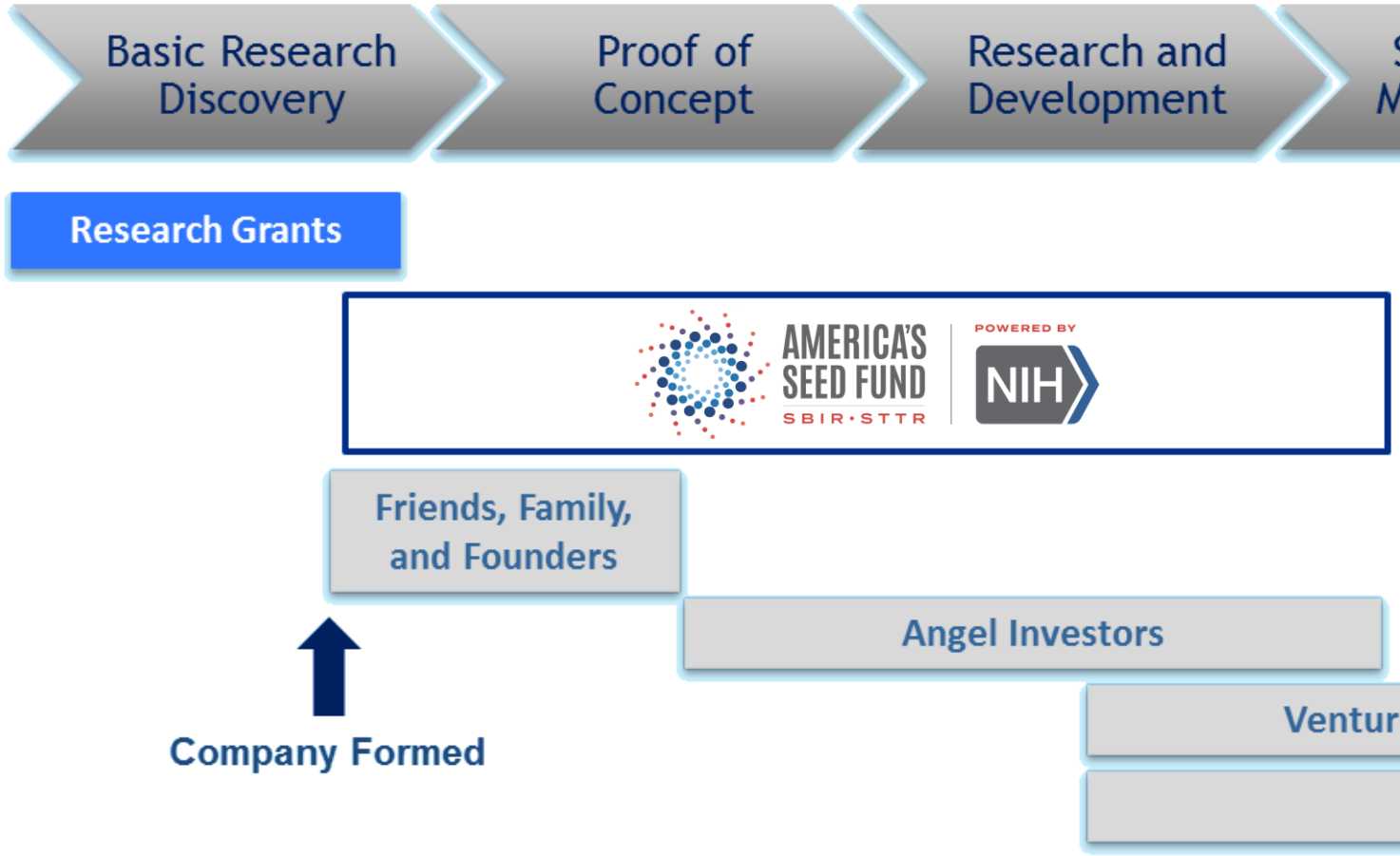
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

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

THERE ARE NO STTR CONTRACTS

The largest sources of early-stage capital for life sciences in the US



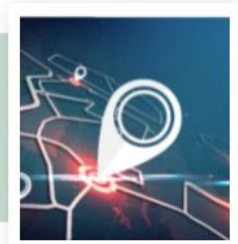
- **"Free Money"-** Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners

Small Business Success Stories

Home / Portfolio / Success Stories

SUCCESS STORIES

Explore companies that received NIH SBIR or STTR funding for early-stage R&D.



NIH is actively turning discovery into health by helping academic innovators and small businesses develop innovative technologies that improve health and save lives.

Technology

- ☐ Diagnostic
- ☐ Digital Health
- ☐ Drug
- ☐ Medical Device
- ☐ Research Tool

Development Stage

- ☐ Approved for Use
- ☐ Early Development
- ☐ Human Testing

Innovator Setting

- ☐ Academic Innovation
- ☐ Small Business
- ☐ Women/Minority

Displaying results 1 to 10 of total 76

Results per page 10

Company / Institution	Story	State - District
Nanovis, LLC	Nanotechnology Promotes Faster Bone Growth Around Spinal Implants	IN - 3
University of Minnesota Research Evaluation and Commercialization Hub	Caring for the Caretakers: Addressing First Responder Burnout with an Online Toolkit	MN - 5

Kansas Biomedical Company Advances Brain Disorder Research

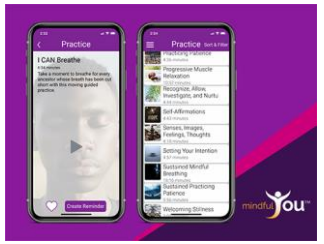
PINNACLE TECHNOLOGY INC

Rural Maine Company Goes Deep in the Brain to Treat Movement Disorders

FHC Neural microTargeting™ Worldwide

Digital Learning Company Supports Parents, Teachers, and Underserved Communities

trifoia®



https://seed.nih.gov/portfolio/stories

National Institutes of Health
Office of Extramural Research

Eligibility Criteria

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

Determined at time of award

WOSB and SDB Definitions

What is a Women-Owned Small Business (WOSB)?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women

What is a Socially and Economically Disadvantaged Business (SDB)?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged

Self-certify by registering your business in the System for Award Management

Phased Programs

Discovery
Phase I

Feasibility

Development
Phase II

Full R&D

Competing Renewal Award
Phase IIB

Commercialization Readiness Pilot (CRP)

Commercial Market
Partner or Investor

Phase I → *Phase II*

Fast-Track

Direct to Phase II
(SBIR only)

Only Some NIH Institutes/Centers Participate

Phase I: $275,766/1-2 years*

Phase II: $1,838,436/1-3 years*

National Institutes of Health
Office of Extramural Research

***NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for selected topics**

SBIR and STTR Critical Differences

Award is always made to the small business

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit res… institution partn… (e.g., univers…
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work … ements: 40% sm… …iness 30% re… …institution …tner
Principal Investigator	Primary employment (>50%) must be with the small business	PI m… …employed by <u>either</u> th… …arch institution partner …or small business

THERE ARE NO STTR CONTRACTS

Open Funding Opportunities

General Grant Omnibus Solicitations

Clinical Trial Not Allowed:
SBIR (PA-22-176) and STTR (PA-22-178)

Clinical Trials Required:
SBIR (PA-22-177) and STTR (PA-22-179)

Read the "Program Descriptions and Research Topics" Section in the Solicitation

Targeted Solicitations

Specific Grant Solicitations: https://seed.nih.gov/small-business-funding/

SBIR Contract Solicitation:
FY2023 Contract Solicitation is available
Receipt date: November 4, 2022 (5:00PM EDT)

READ CAREFULLY!

Not all Institutes/Centers participate

Not all targeted solicitations have specific set-asides or review

SBIR Contract RFP: SEED Site

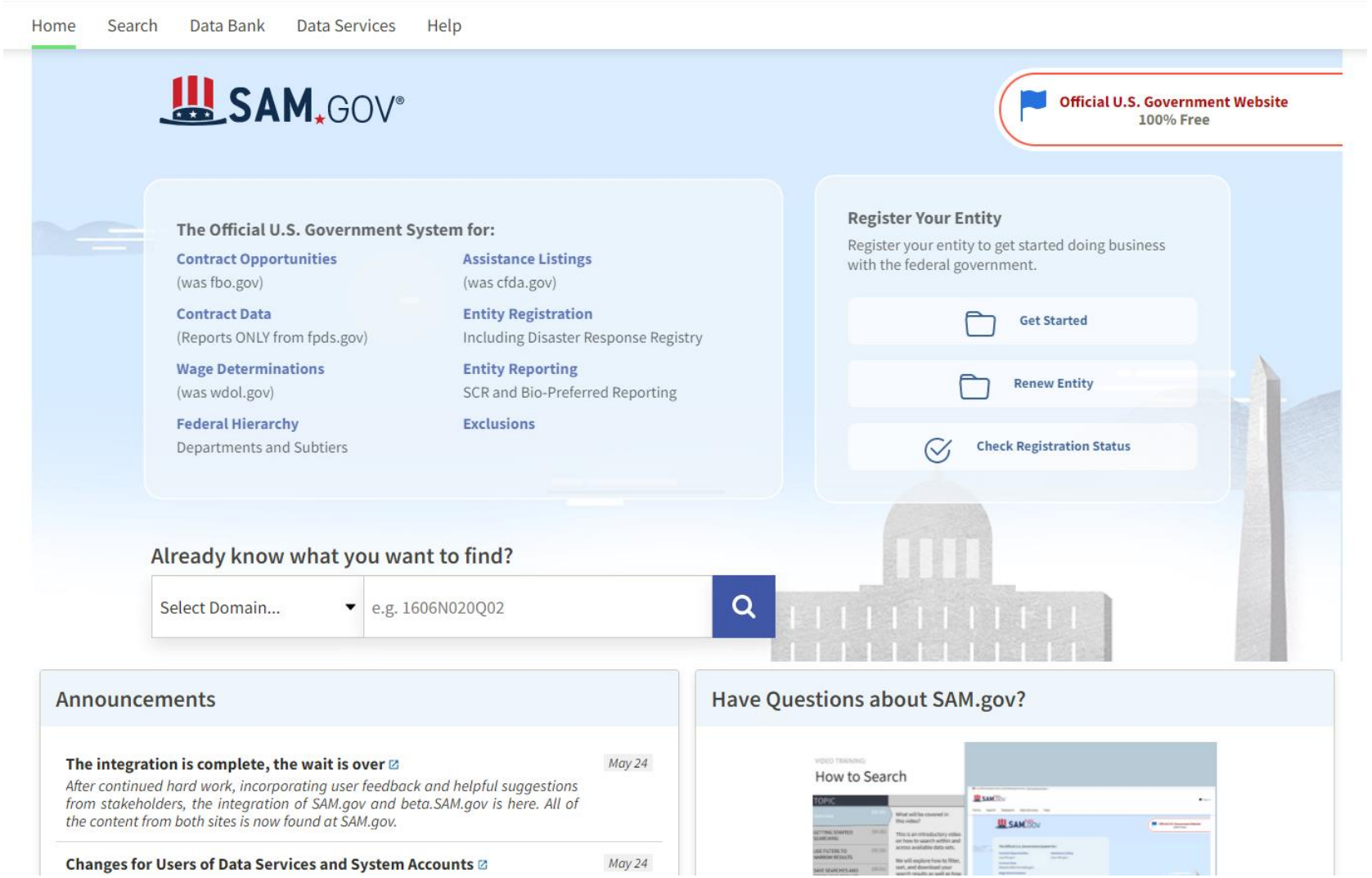
NIH SEED site: https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

View Solicitations

Active Contract Topics	Submission Portal	Amendment
PHS-2023-1 Closing Date: Nov 04, 2022, at 05:00 pm EDT	Electronic Contract Proposal Submission	
NCI SBIR Innovative Concept Award Program Closing Date: August 22, 2022, at 05:00 pm EDT	Electronic Contract Proposal Submission	

National Institutes of Health
Office of Extramural Research

HHS SBIR Contract RFP: sam.gov



https://sam.gov/

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

PROGRAM SOLICITATION PHS 2023-1

Closing Date: November 4, 2022 5:00 PM Eastern Daylight Time

Participating HHS Components:

- The National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)

IMPORTANT

Deadline for Receipt: Proposals must be received by November 4, 2022, 5:00 PM Eastern Daylight

Time. Please read the entire solicitation carefully prior to submitting your proposal.

IMPORTANT: All proposals must be submitted using the electronic contract proposal submission (eCPS) website.
Paper proposals will not be accepted.

Please go to https://www.sbir.gov/sites/default/files/SBA_SBIR_STTR_POLICY_DIRECTIVE_OCT_2020_v2.pdf to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.

Awarding Components

National Institutes of Health (NIH):

- National Center for Advancing Translational Science (NCATS)
- National Cancer Institute (NCI)
- National Institute on Aging (NIA)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Institute on Drug Abuse (NIDA)

Centers for Disease Control and Prevention (CDC):

- National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

TECHNICAL PROPOSAL (1 PDF)

Item 1: Technical Element

- Proposal Cover Sheet (Appendix A)
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element

Item 2: Human Subjects and Clinical Trials Information Form and Attachments (Appendix H.2 and, if applicable, H.3)

BUSINESS PROPOSAL (1 PDF)

Item 3: Pricing Proposal (Appendix C)

Item 4: SBIR Application VCOC Certification, if applicable (Section 4.6)

Item 5: Proof of Registration in the SBA Company Registry (Section 4.12)

Item 6: Summary of Related Activities (Appendix F)

Phase II Submission

TECHNICAL PROPOSAL (2 PDFs)

Item 1: Technical Element

- Technical Proposal Cover Sheet (Appendix D)
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element
- Draft Statement of Work (Appendix E)
- Proposal Summary and Data Record (Appendix G)

Item 2: Human Subjects and Clinical Trials Information Form and Attachments (Appendix H.2 and, if applicable, H.3)

BUSINESS PROPOSAL (1 PDF)

Item 3: Pricing Proposal (Appendix C)

Item 4: SBIR Application VCOC Certification, if applicable (Section 4.6)

Item 5: Proof of Registration in the SBA Company Registry (Section 4.12)

Item 6: Summary of Related Activities (Appendix F)

Electronic Submission - Page Limits

- **SBIR Phase I** Technical Proposals (Item 1) shall not exceed 50 pages
- **SBIR Phase II** Technical Proposals (Item 1) shall not exceed 150 pages
- **Fast Track** = a complete Phase I + a complete Phase II
- The Human Subjects and Clinical Trials Information form and its attachments (Appendix H.2., and, if applicable, Appendix H.3.) are excluded from these page limits.
- Single-sided, single-spaced pages for entire proposal
- All inclusive [including all pages, cover sheet(s), tables, CVs, resumes, references, pictures/graphics, and all enclosures, appendices or attachments, etc.]
- No exclusions to page limits. Pages in excess of the page limitation will be removed from the proposal and will not be considered or evaluated

Human Subjects or Vertebrate Animals

- Section 3 – Definitions
- Section 5.2/5.3 – Care of Vertebrate Animals
- Section 5.4/5.5 – Research Involving Human Subjects
- Section 5.6 – Inclusion of Women, Minorities in Research Involving Human Subjects
- Section 5.7 – Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects
- Section 5.8 – Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials
- Section 5.9 Clinical Trial Registration and Results Information Submission
- Section 5.12 Single Institutional Review Board (sIRB)

NIH Definition of a Clinical Trial

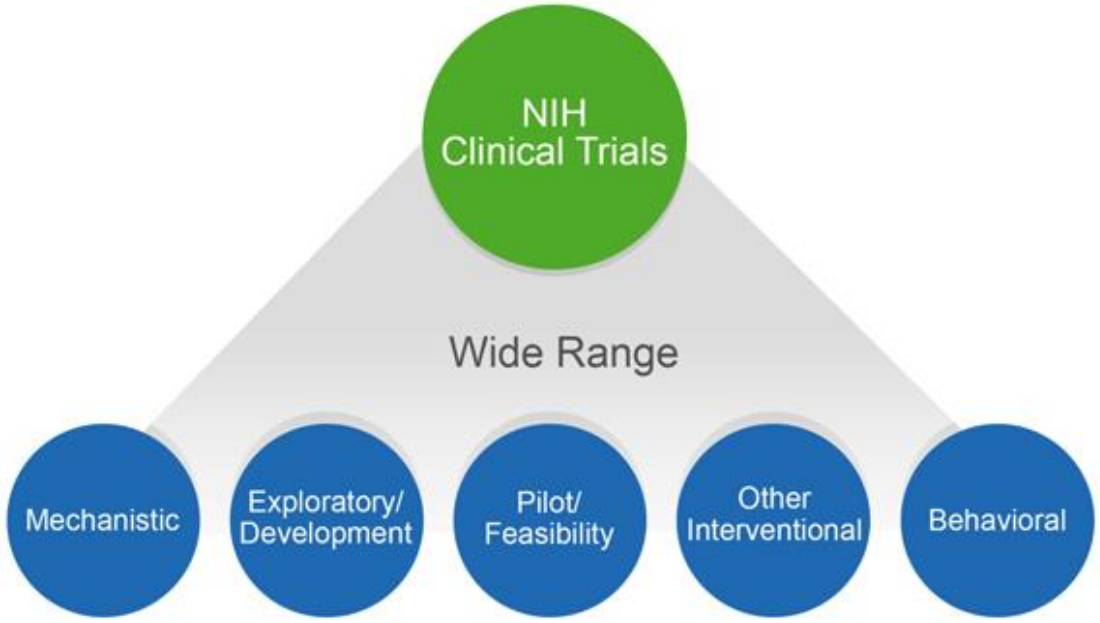
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

DECISION TOOL

Your human subjects study may meet the NIH definition of a clinical trial.

FIND OUT HERE

https://grants.nih.gov/policy/clinical-trials.htm



Read the entire RFP several times!!

Electronic Submission

SBIR Contract proposals must be submitted **electronically**, via electronic Contract Proposal Submission (eCPS) website

REQUIRED REGISTRATIONS

- System for Award Management (SAM) and Unique Entity Identifier (Company)
- SBA Company Registry at SBIR.gov

Two-Factor Authentication is Required

login.gov

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

Submit your proposal a day early!

Questions Deadline

- Reminder, only contact is with Contracting Officer (CO) listed in Section 10
- Questions must be submitted in writing (email) to the CO
- Deadline for Questions is **September 14, 2022** - close of business
- Q&A amendment will be issued in ~ Mid September in SAM.GOV and on NIH SEED websites
  - **Yes, your questions and the answers will be posted to the public**
- Additional questions will be answered at the discretion of the CO

Disbursement of Funds

- **Unlike a grant, funds are not disbursed at the time of award**
- Invoices are submitted after completion of activities or submission of reports
- **Each funding Institute or Center** may set up the payment schedule differently

- **Bottom line:** the company needs to have enough resources to begin work and receive interim payments as work progresses

Technical and Business Assistance (TABA)

Phase I

TABA Needs Assessment*

Provides a third-party, unbiased assessment of areas that are critical to success in the competitive healthcare marketplace

Phase II

TABA Consulting Services*

Available to limited number of awardees in the areas of Intellectual Property, Market Analysis, Regulatory Affairs, or Reimbursement Planning.

Phase I Phase II

TABA Funding

Provides funding in grant to use your own vendors for Technical and Business Assistance

https://seed.nih.gov/support-for-small-businesses/

*NIH ONLY

Innovator Support

Regulatory & Business Development Consultants

Entrepreneurs-in-Residence

Regulatory/Reimbursement

Intellectual Property

Entrepreneurial Support Programs

I-CORPS at NIH

Concept to Clinic: Commercializing Innovation (C3i)

National Institutes of Health
Office of Extramural Research

Partnering and Investment Opportunities

BIO International Convention

THE MEDTECH CONFERENCE
Powered by AdvaMed

ACA
ANGEL CAPITAL ASSOCIATION

LIFESCIENCES™ SUMMIT

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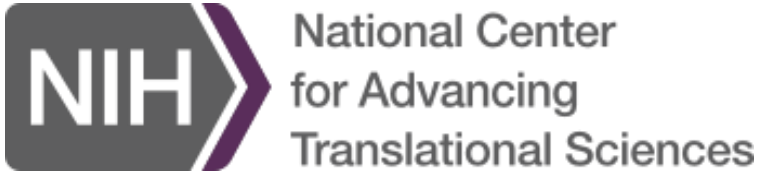
Read our NIH SBIR/STTR Success Stories

NIH Guide for Grants and Contracts

SEEDinfo@nih.gov



Mayra Alvarez Lopez, M.S.

Program Analyst, Office of Strategic Alliances

National Center for Advancing Translational Sciences

Topic 023 - Development of Automated Cell Culture Flask Cleaning Instrument

Budget (total costs, per award): Phase I: $325,000 for 9 months; Phase II: $2,000,000 for 2 years

It is strongly suggested that proposals adhere to the above budget amounts and project periods. Proposals with budgets exceeding the above amounts and project periods may not be funded.

Fast-Track proposals will not be accepted.

Number of anticipated awards: 1 to 2

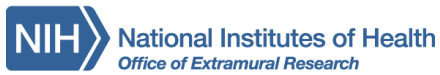
Summary: The purpose of this project is to treat a cell culture flask not as a disposable product meant to act as a vessel for one batch of cells to grow for harvest for use in one experiment, but instead to potentially be a resource that can be used multiple times. The final product will be an instrument or set of instruments that could be integrated as a component of a high throughput cell culture system in an automated fashion, capable of cleaning flasks regardless of the size. The long-term goal of this project is to bring this instrument or process to market to meet the needs of those researchers using high quantities of flasks, for cell-based high throughput screening including complex 3D models and stem cell differentiation.

Phase II information is provided only for informational purposes to assist Phase I offerors with their long-term strategic planning.

Sarra Djemil, PhD
Ming Zhao, PhD

NCI SBIR Development Center

National Cancer Institute



Program Solicitation PHS-2023-1
NCI FY23 Contract Topics

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	Topic Title
NIH/NCI 446	Yes	Yes	Development of Senotherapeutic Agents for Cancer Treatment
NIH/NCI 447	Yes	No	Non-invasive Device Technology Research & Development for Chemotherapy-induced Peripheral Neuropathy Management*
NIH/NCI 448	Yes	Yes	Wearable Devices for Dosimetry of Radiopharmaceutical Therapy
NIH/NCI 449	Yes	Yes	Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment*
NIH/NCI 450	Yes	No	Technology Platforms for Circulating Tumor-Macrophage Hybrid Cells*
NIH/NCI 451	Yes	yes	Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control
NIH/NCI 452	Yes	Yes	Translation of Novel Cancer-Specific Imaging Agents and Techniques to Mediate Successful Image-Guided Cancer Interventions*
NIH/NCI 453	Yes	Yes	Digital Tools to Integrate Cancer Prevention Within Primary Care*
NIH/NCI 454	No	No	Software to Evaluate Artificial Intelligence/Machine Learning Medical Devices in Oncology Settings

NCI [446] Development of Senotherapeutic Agents for Cancer Treatment

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 446	Yes	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The purpose of this contract topic is to support the basic and pre-clinical development of senotherapeutic agents for use in research, neoadjuvant, adjuvant, or combination cancer therapy. Projects supported under this contract topic should extend the pre-clinical development of senotherapeutics as anticancer agent(s). Projects intending to enhance the efficacy of cancer therapies (including radiotherapy) or reduce the toxicities or the severity and duration of adverse effects by the use of senotherapeutics will also be supported.

Phase I Activities and Deliverables Include:

- Demonstrate in vitro efficacy for the agent(s) in human cancer-appropriate models. Appropriate endpoints include demonstration of enhanced anticancer activity in combination with other therapeutic approaches (e.g., chemotherapy or radiotherapy), or the reduction of cancer therapy side effects.
- Conduct structure-activity relationship (SAR) studies, medicinal chemistry, and/or lead biologic optimization (as appropriate).
- Optimize formulation of senotherapeutic agent(s) (as appropriate).
- Perform animal efficacy studies in an appropriate and well-justified animal model of human cancer, for TIS, or aged mouse models that have accumulated senescent cells through aging and increased risk for cancer, and conduct experiments to determine whether senotherapeutic agent(s) confer benefits with respect to reduced side effects and/or cancer therapy efficacy.

NCI [447] Non-invasive Device Technology Research & Development for Chemotherapy-induced Peripheral Neuropathy Management

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 447	Yes	No	1-2	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The purpose of this contract topic is to solicit proposals to advance the development and/or application of new non-invasive device technologies to provide effective mitigation of CIPN and bring them to the marketplace. Such technology would improve the functionality of cancer survivors with CIPN, enhancing their quality of life and reducing the risk of further complications like falls.

Phase I Activities and Deliverables Include:

- Establish a project team, including proven expertise in pain management related to CIPN, device development, user-centered design, software and hardware expertise, and other areas of expertise as appropriate for the proposed project.
- Using user-centric design principles, develop a cost-effective, non-invasive, and accessible device prototype capable of mitigating CIPN symptoms.
- Conduct studies to evaluate and test user acceptability and feasibility in intended use populations.
- Demonstrate accessibility and ease of use of device in an at-home setting with only minimal support from a health care provider.
- Benchmark the device against current practice for reduction in CIPN pain as described in the medical literature using accepted pain measures, and improvements in appropriate quality of life metrics.
- Offerors may need to establish a collaboration or partnership with a research group or medical facility that can provide relevant patient access; offerors must provide a letter of support from the partnering organization(s) in the proposal.

NCI [448] Wearable Devices For Dosimetry of Radiopharmaceutical Therapy

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 448	Yes	Yes	1-3	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this concept is to develop wearable technologies (e.g., dosimetry sensor-incorporated clothing) to allow RPT dose to be measured as patients go about their activities of daily living – providing dynamic, rich, time-based dose data for RPT agents that can be correlated with the patient's anatomy. Products that are compatible for use in the pediatric population are strongly encouraged. It is encouraged that products be able to be used across all ages of patients.

Phase I Activities and Deliverables Include:

- Generate proof-of-concept data that demonstrate feasibility of the proposed solutions to improve quantitative accuracy and precision in RPT dose measurement.
- In the first year of the contract, provide the program and contract officers with a letter(s) of commercial interest from potential end users, which might include those interested in using the solution as a research tool or in collaborating in a business venture.
- Offerors should specify quantitative technical and commercially relevant milestones, that can be used to evaluate the success of the tool or technology being developed.
- Offerors should develop specifications for robustness and durability of the wearable unit overall, and provide appropriate justification relevant to both the development and commercialization of these technologies.
- Quantitative milestones may be relative metrics (e.g., compared to currently used technologies and benchmarks or algorithms and methods) indicating clear advantages of the proposed technologies.
- Build a prototype that demonstrates operability, data transferability, and strong translational potential for use and that demonstrates rigor and reproducibility in benchmark experiments using relevant RPT agents/modalities in appropriate phantoms.
- In the first year of the contract, provide the program and contract officers with a letter(s) of commercial interest.

NCI [449] Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 449	Yes	Yes	2-3	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: Projects may include activities leading to the development of a new device or hardware, or they may leverage existing devices capable of capturing relevant physiological measurements. The primary goal of this topic is the development of a complete remote monitoring capability that includes software and/or analytics capable of supporting clinical decision-making and patient care.

Phase I Activities and Deliverables Include:

- Provide a clear description for the patient treatment monitoring scenario being targeted, including a description of the patient population being targeted, the kinds of treatments, and their known and/or suspected adverse effects that are being tracked in current clinical work practices. Establish a project team including proven expertise in both the technology and methodology to be developed as well as clinical research.
- Select and validate a suitable wearable monitoring device(s) needed to assess required patient measures needed to monitor patient's fitness and detect signs of patient deterioration. Alternatively, describe a plan to build and test a wearable device appropriate for the features/biomarkers to be measured. Design and conduct a needs assessment to ascertain a breadth of relevant use cases and appreciate the potential and challenges for adoption of the proposed technology.
- Develop and validate the analytical methods necessary to assess patients' fitness and detect signs of deterioration while monitoring the selected wearable device(s) in "real world conditions" over extended time periods (at least 72 hours continuous).
- Develop the appropriate data visualization, feedback, and reporting systems for clinical monitoring
- Develop a functional prototype system. Establish user design and user experience wireframes as the basis for the user interface platforms that will ultimately be utilized by the patient being monitored and clinical care team members.

NCI [450] Technology Platforms for Circulating Tumor-macrophage Hybrid Cells

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 450	Yes	No	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The immediate goals of this contract topic are to support development of platforms to isolate, enrich, enumerate, and identify the cTMHCs in blood from cancer patients or animal models of cancer. Individual project goals should align with the clear unmet need and the deliverables. Offerors are expected to utilize technologies that are common to research and clinical diagnostic labs, and not the highly specialized technologies only available in major research core facilities to establish the platform to facilitate easy adoption of the platforms for clinical applications.

Phase I Activities and Deliverables Include:

- Develop technologies to isolate and enrich cTMHCs from blood
- Integrate the technologies with the approaches to enumerate and confirm identity of the TMHCs
- Show reproducibility and repeatability of the isolation and enrichment
- Develop and establish a QA/QC plan
- Demonstrate that the enriched preparation has >80% purity
- Demonstrate performance of the platform using at least 50 blood samples (1-10 ml) from patients of one cancer type
- Demonstrate that the platform can provide sufficient quantity of cells for downstream cellular phenotyping or molecular analysis
- Establish sample handling and storage conditions prior- to and post- cTMHC enrichment to ensure the enriched cTMHC preparation is useful for downstream analysis
- Develop training modules for lab personnel to perform the isolation, enrichment, enumeration, and identification using the platform
- Develop a design prototype of the integrated platform
- Show access to patient cohorts or clinical trials needed for the robust validation of the technology platforms in Phase II
- Submit protocols, SOPs, designs, performance characteristics, training modules, cost parameters, and time factors to NCI SBIR

NCI [451] Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 451	Yes	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: Projects in response to this FOA should first develop a functioning prototype for a portable HPV diagnostic designed for near-patient use. The device should enable rapid detection and genotyping for HPV. Projects should establish initial clinical performance for the device using clinician-collected samples before moving to a larger prospective validation of the device using self-collected specimens, reducing training needs for its use.

Phase I Activities and Deliverables Include:

- Using end-user design principles, develop the prototype diagnostic device with the following characteristics:
  - Ease of use: the device must be suitable for use by local caregivers with minimal training in its operation and maintenance.
  - Operable in locations with limited clinical infrastructure (i.e., design for use outside of laboratory settings).
  - Designed for use at the community level and in non-traditional healthcare settings.
  - Intended for use with either provider or self-collected cervicovaginal specimens obtained with one of the current commercially available kits. Note: Showing that the test works only with provider collected specimen is not sufficient for this deliverable.
- Demonstrate a working relationship with the site(s) where the clinical validation study will take place.
- Conduct studies to establish analytical performance (analytical sensitivity, specificity) and other performance characteristics (e.g., limit of detection, consistency, reproducibility) with self-collected samples.
- Conduct studies to evaluate and test user acceptability and feasibility in both average-risk and high-risk (e.g., women living with HIV) populations.
- Conduct initial cross-validation with at least one of the current FDA-approved HPV testing assays to determine the clinical performance measures.

NCI [452] Translation of Novel Cancer-Specific Imaging Agents and Techniques to Mediate Successful Image-Guided Cancer Interventions

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 452	Yes	Yes	2-3	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: Projects in response to this solicitation will bring a new enabling imaging technique capable of sensitive tumor detection to clinical utility. Identify the targeted cancer patient population and explicitly define how the identified cancer patient population would benefit clinically from the proposed imaging probe or technique. The goal is to build upon existing development successes with activatable diagnostic probes to translate these methods into clinical utility and to demonstrate that exceedingly small tumor cell clusters (1mm3 in volume) can be detected in human subjects by imaging methods. Studies will focus on first in human protocols which demonstrate small tumor volume imaging feasibility.

Phase I Activities and Deliverables Include:

- Identify the targeted cancer patient population and explicitly define how the identified cancer patient population would benefit clinically from the proposed imaging probe or technique.
- Develop and/or refine a GMP grade selected probe to yield maximal biological safety and validate very small volume tumor detection of primary and metastatic cancers in selected animal models, with keen interest in eliminating potential false positives and false negatives.
- Acquire institutional IRB approval to perform selected optimized molecular probe dose-escalation safety studies on small number (5 – 10) of healthy human subjects.
- Convene the project team with expertise in imaging science, cancer surgery, and pathology.
- Submit and acquire single IRB approval for recruitment of patients undergoing cancer surgery with the selected molecular probe labeling for the selected cancer to validate the molecular probe's capabilities to identify additional cancers that were not detected by normal white light or palpation.
- Develop plans for a pre-regulatory submission dialogue with the FDA, to be completed before submission of an SBIR Phase II proposal, so that FDA requirements can be included in the SBIR Phase II research plan.

NCI [453] Digital Tools to Integrate Cancer Prevention Within Primary Care

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 453	Yes	Yes	2-4	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The overall goal of this solicitation is to develop a digital platform that provides PCPs with validated cancer risk assessment tools, cancer prevention guidelines, and clinical recommendations based on a patient's risk factors to discuss with their patients. This technology will compile evidence-based tools/guidelines/recommendations related to cancer prevention for multiple cancer types, beyond routine screening and behavioral interventions, into a centralized platform that can be readily integrated within routine primary care workflows so that they do not provide an additional burden on PCPs given the time constraints of clinical management.

Phase I Activities and Deliverables Include:

- Establish a project team with expertise in digital healthcare platforms/EHR, cancer prevention and primary care, software development, user-centric design, patient navigation/engagement as appropriate for this proposed project.
- Complete a systematic review to compile and assess current cancer prevention guidelines and recommendations for multiple cancer types beyond routine screening, vaccines, and behavioral interventions.
- Engage stakeholders and determine clinical consensus in cases of differing recommendations or insufficient data. Develop a pilot digital platform that incorporates the compiled research into a tool that PCPs can efficiently use to assess their patients' cancer risks, and effectively communicate these risks and evidence-supported preventive recommendations to their patients. Include a patient-facing interface for data collection within the digital platform. Include the ability to continuously incorporate new information on cancer risk assessment and recommendations as it is released by the appropriate organizations.
- Ensure privacy protection as required by law. Identify at least two clinical settings, including a community-based clinic, where the digital platform may be used and integrated within a primary care practice for pilot user testing. Test the feasibility/usability of the digital platform in a sample population of at least 25 PCPs and patients. Test the feasibility of the digital platform within an EHR testing environment.

NCI [454] Software to Evaluate Artificial Intelligence/Machine Learning Medical Devices in Oncology Settings

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 454	No	No	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this contract topic is to stimulate the participation of small businesses in the FDA's MDDT Program to develop and qualify software tools for evaluating and monitoring AI/ML devices in oncology settings. A MDDT can be a method, material, or measurement used to assess the safety, effectiveness, or performance of a medical device.

Phase I Activities and Deliverables Include:

- Develop a working prototype of the software tool that meets the criteria defined by the FDA MDDT program.
- Prepare a MDDT Qualification Plan using the MDDT Qualification Plan Submission Template which outlines specific information necessary to submit a MDDT Qualification Plan. For additional details review Qualification of Medical Device Development Tools - Guidance for Industry, Tool Developers, and Food and Drug Administration Staff.
- Demonstrate the suitability of the software tool for use in regulatory decision-making (e.g., demonstrate how the tool supports the safety, effectiveness, or performance of the medical device).
- Submit a complete Qualification Plan to the FDA's MDDT Program. It should include description of the MDDT, context of use, and a detailed plan to collect evidence based on the context of use for qualification of the tool. Use the MDDT Qualification Plan Template for this submission.
- Specify the quantitative technical and commercially relevant milestones that will be used to evaluate the success of the software tool.
- Conduct a pilot usability study of the prototype software tool.
- Develop a strategy/plan which includes a timeline for when you expect to submit a Full Qualification Package for a MDDT.

Armineh Ghazarian, MSF

Portfolio Manager, Office of Small Business Research

National Institute on Aging

Program Solicitation PHS-2023-1
NIA FY23 Contract Topics

	FOAs	Due Date	Phase Eligibility	
SBIR	PHS-2023-1 (FY2023 Contracts Solicitation)	Application: November 4, 2022, 05:00 pm EDT	Fast Track	Direct to Phase II
Topic 007	**High Throughput CHIP (clonal hematopoiesis of indeterminate potential) Assay as a Powerful Tool to Study CHIP Related Age Associated Diseases** *Budget (total costs, per award):* *Phase I: $300,000 for 12 months; Phase II: $2.0 million for 2 years*		✓	✓
Topic 008	**Improving Microphysiological Systems for AD/ADRD Therapy Development** *Budget (total costs, per award):* *Phase I: $500,000 for 12 months; Phase II: $2.5 million for 2 years*		✓	✓
Topic 009	**AI/ML Tool for Visualizing Behavioral and Social Science Research** *Budget (total costs, per award):* *Phase I: $500,000 for 12 months; Phase II: $2.5 million for 2 years*		✓	✓

DGCG - High Throughput CHIP (Clonal Hematopoiesis of Indeterminate Potential) Assay as a Powerful Tool to Study CHIP Related Age Associated Diseases

Scope of Work

- Develop an inexpensive, high throughput assay to detect CHIP mutations for research purposes, which could eventually be translated into a diagnostic/prognostic assay for use in healthcare settings for patient management.

Background

- CHIP has emerged as a potent biological mechanism for multiple aging diseases.
- Interest in examining the role of clonal hematopoiesis in the context of age-related diseases, but no low cost, scalable assay for analyses available.
- Further work is required to develop and validate the CHIP assay for use in human cohort studies and relevant animal models and CLIA standardization for application in clinical screening.

Phase I

- Optimization and expansion of the current research focused CHIP assay by inclusion of additional CHIP related genes that may be associated with age-related diseases.
- Development of a bioinformatics workflow to analyze and report the data.
- Plans to meet with the FDA to understand the requirements for approval for clinical implementation.

Phase II

- Conversion of the research CHIP assay into a CLIA certified CHIP assay to meet FDA regulations.
- Conducting clinical studies to demonstrate validity of the CHIP assay to meet the requirement for a prognostic claim.
- Establishment of studies to claim the CHIP assay as a companion diagnostic tool through clinical studies.

DN - Microphysiological Systems for AD/ADRD Therapy Development

Scope of Work

- The development of 3D human MPS that accurately mimic the AD/ADRD microenvironments, including factors that recapitulate both vast complexity of the human brain while emulating the heterogeneity of the disease for use in AD/ADRD drug development.

Background

- MPS hold the promise to improve and expedite the entire drug development process including both drug discovery and pre-clinical testing.
- Critical need for the development of more predictive and high-throughput *in vitro* MPS as simple, reproducible, and scalable platforms that recapitulate organ-level functions to be used in different stages of AD/ADRD drug development.

Phase I

- Develop 3D culture system prototype that recapitulates human AD/ADRD.
- Submit a statement to NIA that specifies metrics used and criteria for prediction of clinical efficacy prior to demonstration of accurate prediction of clinical efficacy.
- Demonstrate accurate prediction of clinical efficacy in the developed prototype.

Phase II

- Benchmark performance in developed system against applicable in vivo animal models.
- Assess genomic, proteomic, metabolomic, and epigenomic profile of the AD/ADRD system.
- Compare dose-response relationship of known AD/ADRD therapeutic agents.

BSR – AI/ML Tool for Visualizing Behavioral and Social Science Research

Scope of Work

- To develop an AI-based tool for BSR-specific literature visualization and hypothesis discovery, that can be marketed to behavioral science investigators and research institutions that consume scientific research with a particular emphasis on AD/ADRD.

Background

- Behavioral and social science research represents an important segment of the research funded by the NIH and is key to developing effective new approaches for supporting individuals with cognitive impairment.
- A major barrier lies in the challenge of compiling, collating and comprehending the literature.
- No tool exists that allows users of BSR research to quickly derive a causal overview of the relevant literature, so that they can uncover promising new associations between variables.

Phase I

- Establish feasibility of an AI/ML based tool for BSR specific literature visualization and hypotheses discovery.
- Conduct user testing to prove efficiency over “standard” search.
- Conduct user feedback survey to gauge interest.

Phase II

- Develop user management system for enhanced literature navigability and result accuracy.
- Verify of the tool’s efficiency, output comprehensibility, and efficacy for hypothesis discovery.
- Broaden the type of science indexed – with an emphasis on AD – in conjunction with ontology development for more comprehensive literature exploration.

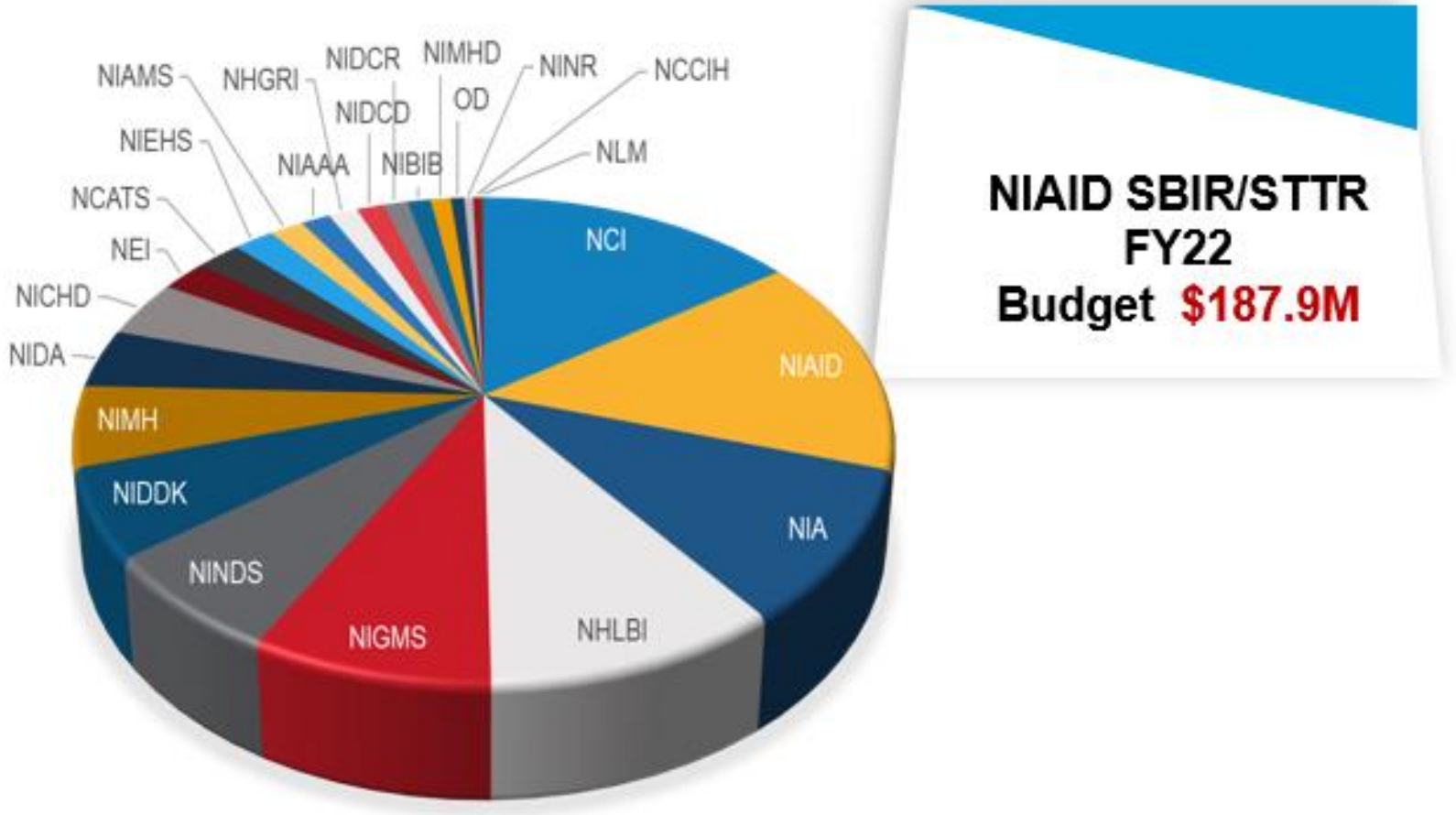
National Institute of Allergy and Infectious Diseases

Natalia Kruchinin Ph.D.

SBIR/STTR Program Coordinator, Team Lead, ORTSP, DEA

National Institute of Allergy and Infectious Diseases

NIAID SBIR/STTR Budget Allocation FY22



NIAID Organization

Office of the Director (OD)

1. Division of AIDS (DAIDS)
2. Division of Allergy, Immunology, and Transplantation (DAIT)
3. Division of Microbiology and Infectious Diseases (DMID)
4. Division of Extramural Activities (DEA)

5 Division of Clinical Research (DCR)

6.Division of Intramural Research (DIR)

7. Vaccine Research Center (VRC)

These program Divisions direct and managed the extramural research portfolio. Most of the NIAID budget supports research at academic and research institutions through grants, contracts and cooperative agreements

DEA oversees policy and management activities related to funding grants and contracts and conducts initial peer review for grants and contracts that address NIAID specific needs or focus.

High-Priority Areas of Interest

Summary of FY23 SBIR Contract Topics NIAID – Page 95-109

Topic 113 – Development of a Simian Immunodeficiency Virus (SIV) and Simian Human Immunodeficiency Virus (GHIV) Database

Topic 114 – Point-of-Care HIV Viral Load, Drug Resistance, and Adherence Assays

Topic 115 – Development of Diagnostics to Differentiate HIV Infection from Vaccine Induced Seropositivity

Topic 116 – Adjuvant Discovery for Vaccines and for Infectious and Immune-Mediated Diseases

Topic 117 – Adjuvant Development for Vaccines and for Infectious and Immune-Mediated Diseases

Topic 118 – Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models

Topic 119 – Adaptation of CRISPR-based *in vitro* Diagnostics for Rapid Detection of Select Eukaryotic Pathogens

Topic 120 – Modular Sample Preparation for In-Field Viral Discovery

Topic 121 – Artificial Intelligence to Improve Clinical Microscopy for Diagnosis of Infectious Diseases

Topic 122 – Advanced and Immersive Visualization Tools for Infectious and Immune-mediated Disease Research

Topic 123 – Data Science Tools for Infectious and Immune-mediated Disease Research

- **Check Summary of HHS Components Anticipated # of Awards, NIAID page 63 and time of the award**

ANTICIPATED NO. OF AWARDS	ANTICIPATED TIME OF AWARD
19-38	Scientific and Technical Merit Review: March 2023 Anticipated Award Date: August 2023

- **Check page 2 – summary table regarding Fast-Track or Direct to Phase II is allowed or not**

- **Check budget limits: NIAID page 95-109**

Example:

Fast Track Proposals will be accepted
Direct to Phase II will not be accepted
Number of anticipated awards: 1-3 Budget (total costs)
Phase I: $300,000 for up to 1 year; Phase II: $2,000,000 for up to 3 years

DIVISION OF AIDS (DAIDS)

Topic # and Title (page 95-99)

- **Topic 113 -** *Development of a Simian Immunodeficiency Virus (SIV) and Simian Human Immunodeficiency Virus (SHIV) Database*
- **Topic 114 -** *Point-of-Care HIV Viral Load, Drug Resistance, and Adherence Assays*
- **Topic 115 -** *Development of Diagnostics to Differentiate HIV Infection from Vaccine Induced Seropositivity*

DIVISION OF Allergy, Immunology, and Transplantation (DAIT)

Topic # and Title (page 99-103)

- **Topic 116 -** *Adjuvant Discovery for Vaccines for Infectious and Immune-Mediated Diseases*
- **Topic 117 -** *Adjuvant Development for Vaccines for Infectious and Immune-Mediated Diseases*
- **Topic 118 -** *Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models*

DIVISION OF Microbiology and Infectious Diseases (DMID)

Topic # and Title (page 104-106)

- **Topic 119 -** *Adaptation of CRISPR-based in vitro Diagnostics for Rapid Detection of Select Eukaryotic Pathogens*
- **Topic 120 -** *Modular Sample Preparation for In-Field Viral Discovery*
- **Topic 121 -** *Artificial Intelligence to Improve Clinical Microscopy for Diagnosis of Infectious Diseases*

Office of Data Science and Emerging Technologies

Topic # and Title (page 107-109)

- **Topic 122 -** *Advanced and Immersive Visualization Tools for Infectious and Immune-mediated Disease Research*
- **Topic 123 -** *Data Science Tools for Infectious and Immune-mediated Disease Research*

NIAID Contracting Officer Contact

For all technical questions regarding NIAID topics included in this solicitation

Please contact: Charles H. Jackson, Contracting Officer,
Office of Acquisitions, DEA, NIAID
Phone: (240) 669-5175

Email: Charles.Jackson@nih.gov

NIAID SBIR Program Contact Information

To learn more about the SBIR program at NIAID

- **Contact:** Dr. Natalia Kruchinin, SBIR/STTR Program Coordinator, Team Lead, NIAID, NIH
  - **Email:** kruchininn@niaid.nih.gov
- **Visit our website:** SBIR/STTR NIAID
- **NIAID Small Business Program Team**

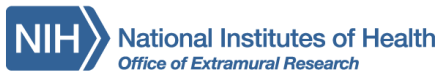
Julia Berzhanskaya, PhD

Health Scientist Administrator, Office of Translational Alliances and Coordination

Allison Cristman

Contracting Officer, Office of Acquisitions

National Heart, Lung, and Blood Institute



Program Solicitation PHS-2023-1
NHLBI FY23 Contract Topics

Topic #	Topic Title	# of Phase I Awards	Phase I Budget	# of Phase II Awards	Phase II Budget	Fast-Track option?	Direct-to-Phase II?
NHLBI 113	Clinical Instrument for Para-hydrogen (p-H_2)-based Signal Amplification by Reversible Exchange (SABRE) for hyperpolarizing ^{13}C-pyruvate and other probes for MRI	1	$350,000	1	$3,000,000	Yes	Yes
NHLBI 114	Device to Permit Continuous Self-Monitoring of Blood Oxygen Saturation During Activities of Daily Living for Individuals at Risk for Desaturation During Physical Exertion	2	$300,000	1	$3,000,000	Yes	Yes

Topic 113: Clinical Instrument for Para-hydrogen (p-H_2)-based Signal Amplification by Reversible Exchange (SABRE) for hyperpolarizing ^{13}C-pyruvate and other MRI probes

Unmet Medical Need

- 13C MRI allows for imaging of metabolic activity in vivo, but current methods of hyperpolarizing carbon are slow, expensive and use toxic heavy metals (iridium) as catalyst
- Signal amplification by reversible exchange (SABRE) using novel fluorinated catalyst facilitates removal of toxic iridium and provides a safer method of generating hyperpolarized probes

Project Goals

- Develop a Class II medical device to deliver hyperpolarized MRI probes for medical imaging

Anticipated Number of Awards

- One Phase I ($350K)
- One Phase II ($3M)

  Fast-Track and Direct-to-Phase II proposals accepted

Phase I Expected Deliverables

- An instrument to provide hyperpolarized probes for MRI **animal imaging** based on SABRE using parahydrogen and fluorous catalyst removed by filtration through a column.

Phase II Expected Deliverables

- A Class II medical device **for clinical delivery** of hyperpolarized probes via parahydrogen-based SABRE with documentation for 510(k) submission.

Topic 114: Device to permit continuous self-monitoring of blood oxygen saturation during ADLs for individual at risk for desaturation

Unmet Medical Need

- An FDA-approved wearable device that will continuously monitor blood oxygen levels (SpO_2) during sleep and activities of daily living (ADLs) that cause physical exertion

Anticipated Number of Awards

- Two Phase I ($300K x 2)
- One Phase II ($3M)

  Fast-Track and Direct-to-Phase II proposals accepted

Phase I Expected Deliverables

- Develop an initial prototype of the device and test it in a small set of patients (~20 patients) while they are performing common physical ADLs and during exercise of varying type and difficulty

Phase II Expected Deliverables

- Focus group studies for usability and durability to optimize user interface and data output of prototype and the corresponding clinical trials in collaboration with the NHLBI Division of Intramural Research
- FDA approval or clearance of the device

NHLBI Contacts

All NHLBI Contract SBIR Omnibus proposal related questions should be directed to:

Allison Cristman, Contracting Officer
Office of Acquisitions, Office of Management
National Heart, Lung, and Blood Institute (NHLBI)
Email: allison.cristman@nih.gov

General SBIR related questions may be directed to:

Julia Berzhanskaya, PhD, Health Scientist Administrator
Office of Translational Activities and Coordination (OTAC)
National Heart, Lung, and Blood Institute (NHLBI)
Email: nhlbi_sbir@mail.nih.gov

Tam Nguyen, PhD

Program Officer, Office of Translational Initiatives and Program Innovations (OTIPI);
Email: tam.Nguyen@nih.gov

Tracy L. Cain

Contracting Officer, Contracts Management Branch Red;
Email: tracy.cain@nih.gov

National Institute on Drug Abuse

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NIDA 167	Yes	Yes	3-4	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Background

- 20% of drug overdose death records did not specify the drug involved
- This severely hinders accurate monitoring and ability to effectively respond

Scope of Work

- Research and development of new portable and affordable postmortem toxicology screening devices for rapid, accurate and accessible testing
- Goal is to improve overall identification of drugs involved in overdose cases

Phase I

- Develop product platform methods and software
- Develop a proof-of-concept prototype

Phase II

- Determine performance characteristics, validation testing, design for scale-up manufacturing
- Finalize prototype

SBIR 2023-1 Contract Informational Webinar

Sean David Griffiths, MPH
Small Business Innovation Research (SBIR) Program Manager
Office of Science, Office of Technology and Innovation

SBIR Contract Request For Proposal PHS 2023-1

August 24, 2022

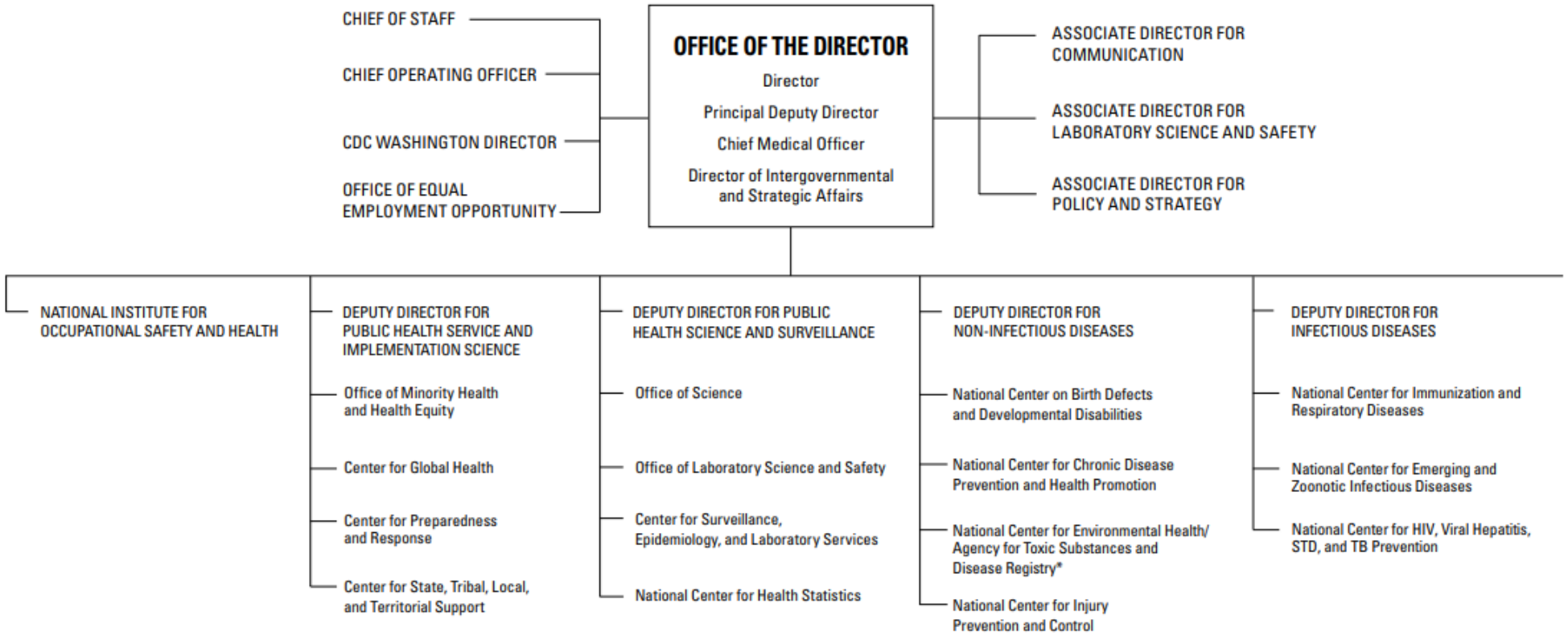
CDC's Mission

CDC works 24/7 to protect America from health, safety, and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats and responds when these arise.

Mission, Role, and Pledge | About | CDC

CDC's Centers Institute and Offices (CIO)



* ATSDR is an OPDIV within DHHS but is managed by a common director's office.

Updated March 19, 2021

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

[CDC Organizational Chart]

CDC's Strategic Framework

CDC's 2022-2027 CDC Strategic Plan consists of five core capabilities:

- Diverse public health workforce
- World-class data and analytics
- State-of-the-art laboratories
- Rapid response to outbreaks at their source
- Strong global capacity and domestic preparedness

CDC photo, Alex D. Rogers/ Studio.

FY22 CDC SBIR Program Overview

Website: www.cdc.gov/sbir
Questions? Email: SBIR@CDC.GOV

10 Different CDC Centers and NIOSH

SBIR Funding Opportunities

- Grant Omnibus Funding Opportunity Announcements (FOAs) — Parent
- Contract Solicitation

CDC FY 2022 SBIR Budget $13 Million

CDC SBIR FAST FACTS

Topics
20-40 SBIR topics published per year in both the grant omnibus and contract solicitations

Emerging Public Health Issues
CDC will accept investigator-initiated proposals for emerging issues (e.g., monkeypox virus, COVID-19, opioid overdose, etc.)

SBIR America's Seed Fund™ POWERED BY HHS

CDC 24/7

CDC SBIR Technical Assistance

CDC SBIR Subject Matter Experts, Technical and Business Assistance (TABA), I-Corps™ @ NIH, etc.

Tips for SBC Applying

- Talk to CDC
- Apply Early!!!
- Continue to Apply!

How Can I Engage?

- Email: SBIR@cdc.gov
- Annual HHS SBIR/STTR Conference
- Apply for Technical Assistance

CDC SBIR Program Overview

- Budget - CDC SBIR set-aside approximately $13 million (FY22)
  - Phase I contract awards up to $243,500 — typically, up to 6 months
  - Phase I grant awards up to $275,800 — typically, up to 6 months
  - Phase II contract and grant awards up to $1.8M — for a 2-year project period

- CDC participates in both the SBIR HHS Omnibus Grant Solicitations (PA-22-176 & PA-22-177) and the HHS SBIR Contract Solicitation (PHS 2023-1)

- CDC does participate in the I-Corps™ at NIH program (NCEZID and NIOSH)

- CDC does not participate in the Small Business Technology Transfer (STTR) Program, Fast Track, Direct to Phase II, Phase II B, or Commercialization Readiness Pilot (CRP)

CDC SBIR PHS 2023-1 Contract Topics – CDC Topics 030 & 054

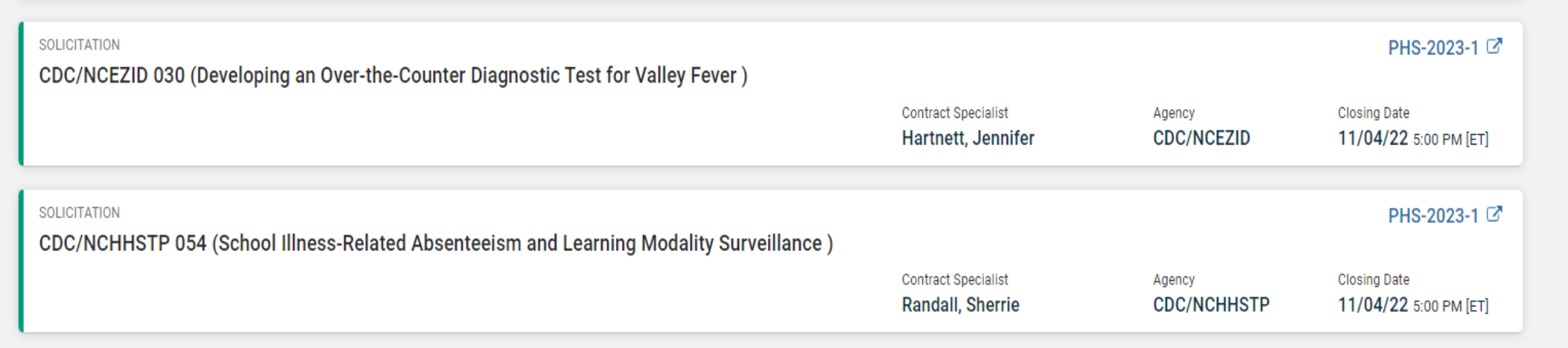
- **National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)**
  - (**030**) — Developing an Over-the-Counter Diagnostic Test for Valley Fever

- **National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)**
  - (**054**) — School Illness-Related Absenteeism and Learning Modality Surveillance

Getty Images photo.

NIH's electronic Contract Proposal Submission (eCPS) for 2023-1 SBIR Contract Solicitation – CDC Topics 030 & 054

- CDC only accepts applications via NIH's eCPS (electronic Contract Proposal Submission) secured system



CDC SBIR Contract Informational Webinar (PHS 2023-1)

- Please **read** the contract solicitation and any future amendments to the solicitation carefully. We encourage you to apply early!
- If you have questions after today's webinar, during the open question/answer period, please contact the CDC Office of Financial Resources, Office of Acquisition Services (OFR/OAS) associates listed in the solicitation.
- Reference the responsible contracting officer/specialist, the solicitation (SBIR PHS 2023-1) and the CDC topic number along with your specific question(s).

Thank You

For more information, contact us at:
SBIR: 404-718-1386 or SBIR@cdc.gov
OTI: 404-639-1330 or OTI@cdc.gov
www.cdc.gov; www.cdc.gov/sbir

Friday, November 4, 2022

5:00 PM Eastern Daylight Time

Electronic submission must be complete

No paper submissions

Submit proposals a day early if possible

Any Questions?