HHS SBIR Contract RFP Informational Webinar

August 12, 2021 | 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)

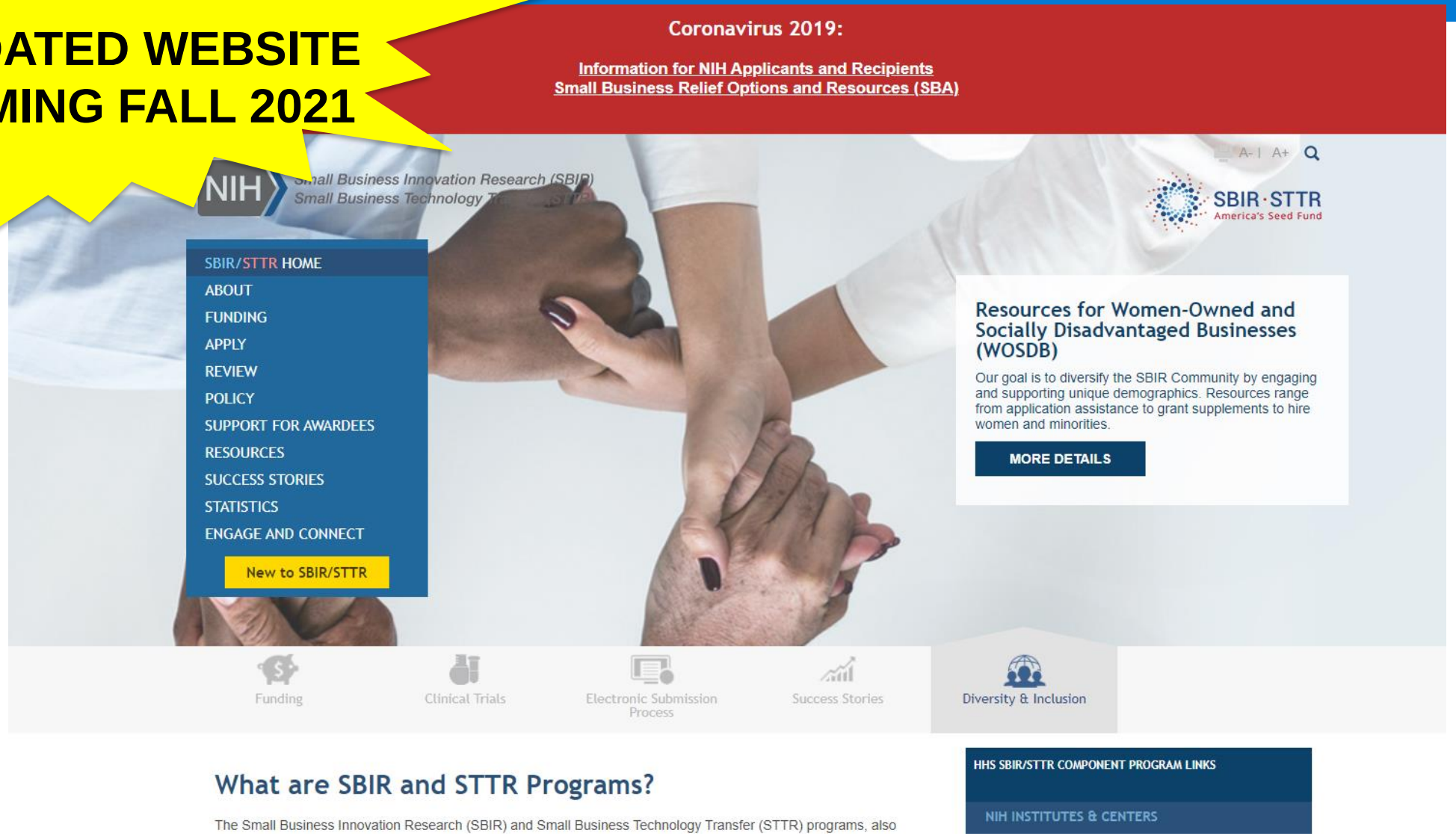
Office Of The Director | Office Of Extramural Research

National Institutes Of Health

National Institutes of Health
Office of Extramural Research

NIH SBIR/STTR Website

UPDATED WEBSITE COMING FALL 2021



National Institutes of Health
Office of Extramural Research

https://sbir.nih.gov

Conference Materials

NIH SEED

2021 HHS Small Business Program Conference

Diverse Perspectives SEEDing Impactful Innovations

VIRTUAL CONFERENCE

APRIL 26 - 30

Conference Sessions

Session Title	Speakers	Video	Slides	Transcript
NIH Welcomes Diverse Perspectives	▪ **Matt McMahon** Director, SEED, Office of Extramural Research, NIH	YouTube (14:00)	N/A	Word (.docx)
Diversity and Bias: Perceptions and Reality	▪ **Ericka Boone**, Director of Division of Loan Repayment and Acting Director of Division of Biomedical Research Workforce, NIH ▪ **Stephanie Fertig**, HHS Small Business Program Lead, NIH ▪ **Charlene E. Le Fauve**, Senior Advisor to the Chief Officer for Scientific Workforce Diversity, NIH ▪ **Eric W. Padmore**, Senior Policy Advisor, NIH (Moderator)	YouTube (50:08)	Slides	Word (.docx)
America's Seed Fund is Open for Business	▪ **Rob Vinson**, Small Business Program Manager, NIH (Moderator) ▪ **Stephanie Fertig**, HHS Small Business Program Lead, NIH	YouTube (42:14)	Slides	Word (.docx)
Secrets to a Successful Submission	▪ **Eva Garland**, CEO, Eva Garland Consulting ▪ **Patti Weber**, Program Director of NCI SBIR Development Center	YouTube	Slides	Word (.docx)

https://sbir.nih.gov/resources/events/HHS2021SmallBiz

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 $1.2 billion

Centers for Disease Control and Prevention
SBIR $12 million

Food and Drug Administration
SBIR $2 million

Administration for Community Living
SBIR $3 million

National Institutes of Health
Turning Discovery Into Health

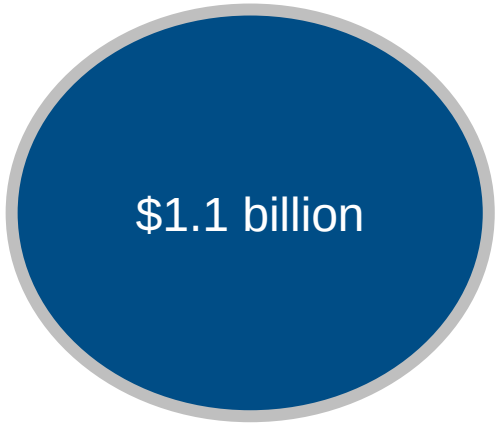
NIH Mission




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

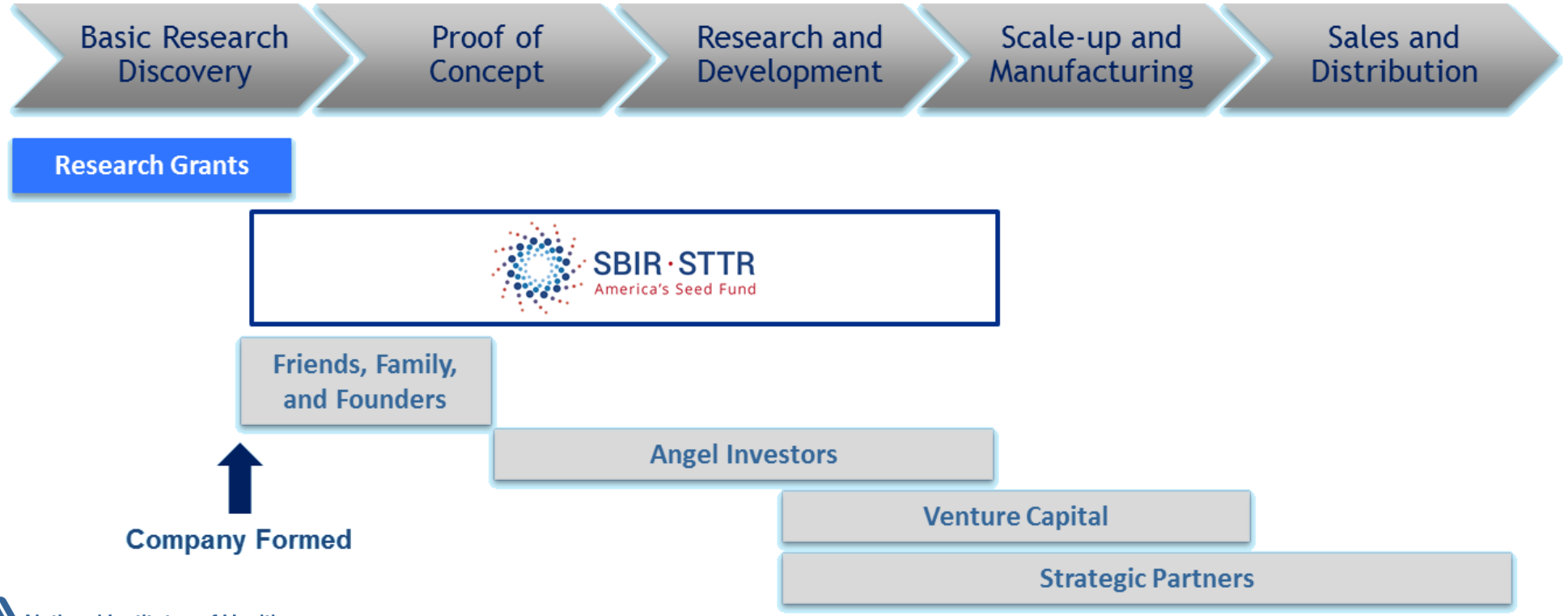
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

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

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

- **“Free Money”-** Non-dilutive capital and not a loan
- **Data and intellectual property rights** are protected
- Awardees can **leverage funding** to attract investors and partners



Small Business Success Stories

Small Business Success Stories

The NIH is actively turning discovery into health by helping 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

Company Ownership

- Woman Owned
- Minority Owned

State

Select State

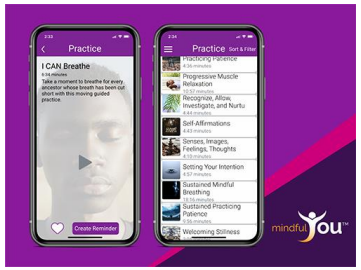
Displaying results 1 to 10 of total 66

Results per page 10

Company	Story	State - District
Cell Podium, LLC	Video Messages Sent Directly to Cell Phones Improve Public Health During Crises	NJ - 6
Advanced Circulatory Systems	A Life-Threatening Experience Inspires Enhanced CPR	MN - 4
Cognition Therapeutics	Alzheimer's Drug Shows Progress in Restoring Cognitive Function	PA - 18

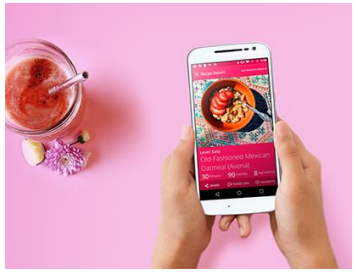
Digital Learning Company Supports Parents, Teachers, and Underserved Communities

trifoia®



Latina-Owned Business Creates Effective Public Health Campaigns

De las mías
Unidas for a healthy life.



sbir.nih.gov/stories

Eligibility Criteria

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

Determined at the Time of Award

Phased Programs - Budget

Discovery
Phase I

Feasibility

Development
Phase II

Full R&D

Phase I → *Phase II*

Fast-Track

Direct to Phase II

Competing Renewal Award Phase IIB

Commercialization Readiness Pilot (CRP)

Commercial Market Partner or Investor

Only Some NIH Institutes/Centers Participate

Phase I: $259,613/1-2 years*

Phase II: $1,730,751/1-3 years*

National Institutes of Health
Office of Extramural Research

***NIH has a waiver from the Small Business Administration to exceed these budgets for many topics**

SBIR and STTR Critical Differences

	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 either th… …arch institution partner …or small business

THERE ARE NO STTR CONTRACTS

Award always made to small business

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
- SBCs self-certify on the SF 424 (R&R) Form

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
- The firm must be small, according to SBA's size standards
- You self-certify by registering your business in the System for Award Management

SBIR Contract Solicitation

- Only some Institutes/Centers participate
- FY2022 Contract Solicitation is now available
- Receipt date is **October 28, 2021 – 5:00PM EDT**

SBIR/STTR Grant Solicitation Funding Opportunities:

- **General Omnibus Solicitations**
  - Clinical Trial Not Allowed: SBIR (PA-21-259) and STTR (PA-21-262)
  - Clinical Trials Required: SBIR (PA-21-260) and STTR (PA-21-261)

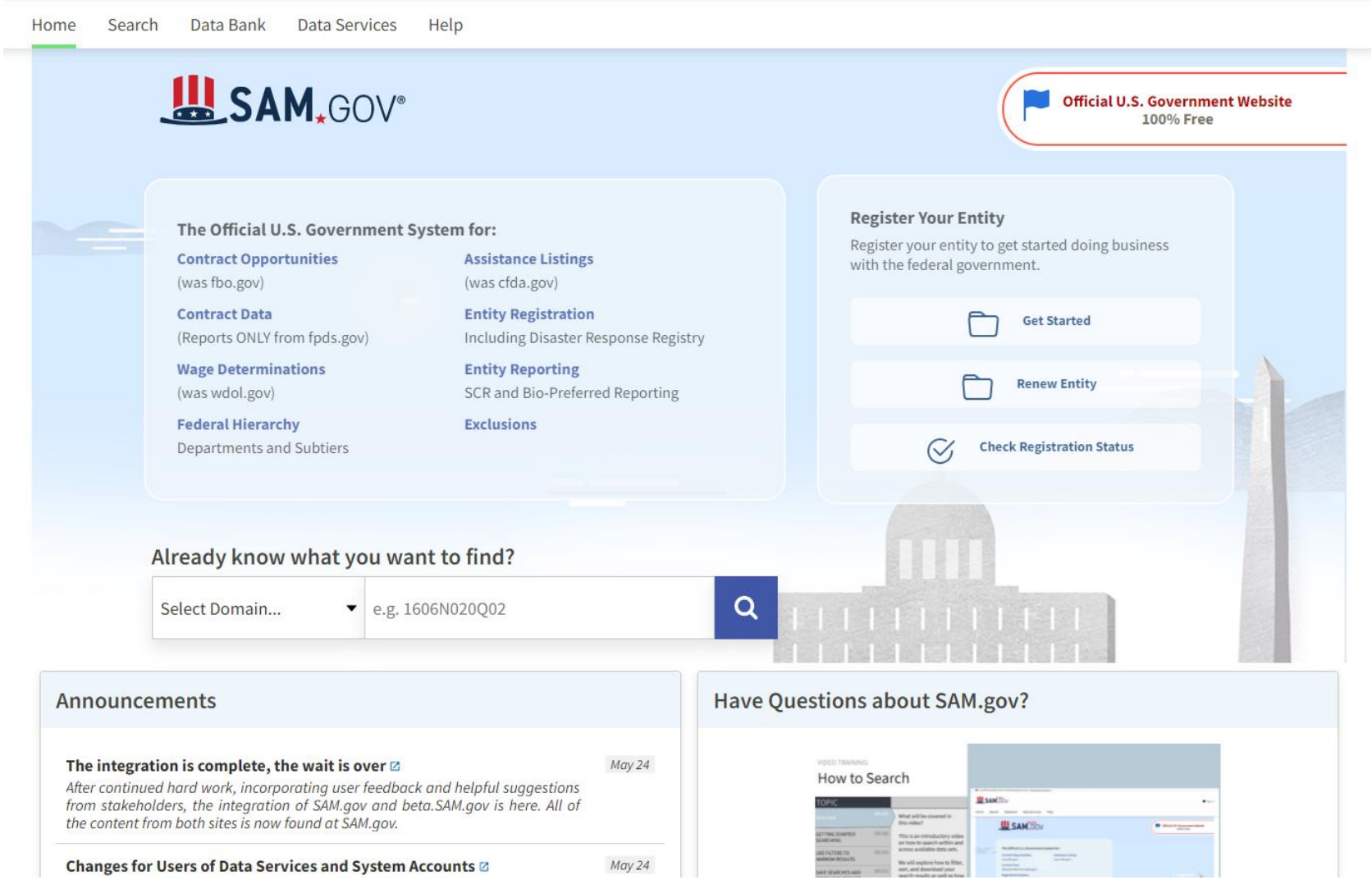
Read the "Program Descriptions and Research Topics" Section in the Solicitation

- **Targeted Solicitations (**https://sbir.nih.gov/funding/individual-announcements**)**
  *Not all of these have a separate set-aside or peer review - Read Carefully!

HHS SBIR Contract RFP Sources: sbir.nih.gov

NIH SBIR site: https://sbir.nih.gov/funding

HHS SBIR Contract RFP Sources: sam.gov



FedBizOpps is now SAM.GOV
https://sam.gov/

National Institutes of Health
Office of Extramural Research

HHS SBIR Contract RFP Sources

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 2022-1

Closing Date: October 28, 2021 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 October 28, 2021, 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)

Centers for Disease Control and Prevention (CDC):

- National Center on Birth Defects and Developmental Disabilities (NCBDDD)
- National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
- National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
- National Center for Immunization and Respiratory Disease (NCIRD)

Read the entire RFP several times!!

Submit your proposal a day early!

Phase I Submission

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
- Item 5: Proof of Registration in the SBA Company Registry
- Item 6: Summary of Related Activities (Appendix F)

Phase II Submission

TECHNICAL PROPOSAL (1 PDF)

- 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
- Item 5: Proof of Registration in the SBA Company Registry
- 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 - Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials
- Section 5.8 Clinical Trial Registration and Results Information Submission
- Section 5.9 Single Institutional Review Board (sIRB)

Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

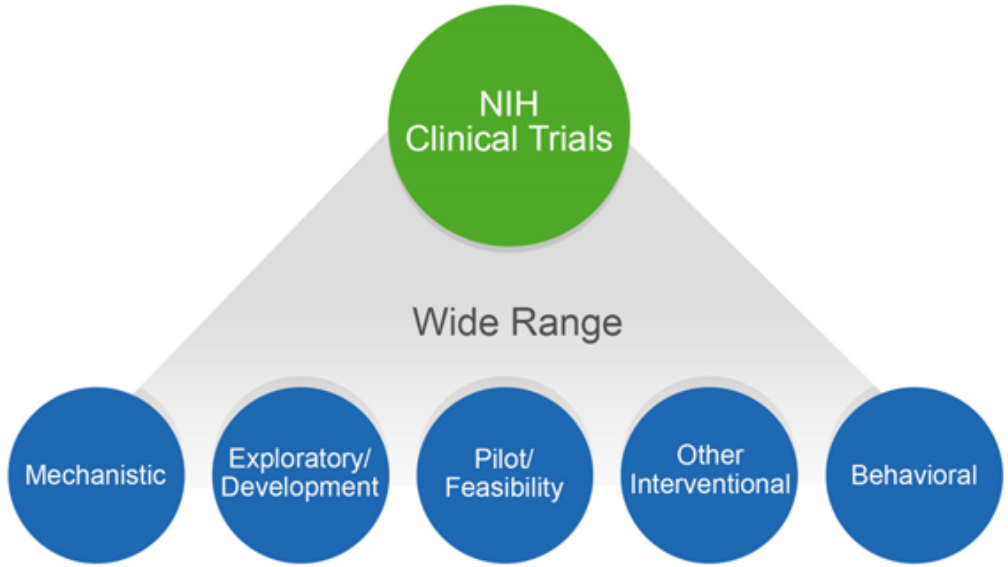
NIH Definition of a Clinical Trial

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 interventior on health-related biomedical or behavioral outcomes. Learn more

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

SBIR Contract proposals must be submitted **electronically**,

with electronic Contract Proposal Submission (eCPS) website

REQUIRED REGISTRATIONS

- DUNS Number (Company)
- System for Award Management (SAM)
- SBA Company Registry at SBIR.gov

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 3, 2021** - close of business
- Q&A amendment will be issued in ~ early-mid September in SAM.GOV and on NIH SBIR 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

Funding and Support for NIH Innovators: Introducing NIH SEED

Small business Education and Entrepreneurial Development (SEED)

- Supports the NIH innovator community (funding and resources) to validate and advance discoveries to products that improve patient care and health.
- Develop relationships with strategic partners and build opportunities for NIH innovators to further their product development efforts.

Matt McMahon
mm@nih.gov

Stephanie Fertig
stephanie.fertig@nih.gov

Ashim Subedee
ashim.subedee@nih.gov

Chris Sasiela
chris.sasiela@nih.gov

SBIR · STTR
America's Seed Fund

SEEDinfo@nih.gov

New Support for Awardees

Technical and Business Assistance (TABA)

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

Education

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

Funding and Support

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

Partnering and Investment Opportunities

- Company Showcase

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

National Institutes of Health
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https://sbir.nih.gov/support-for-awardees

Innovator Support

Regulatory & Business Development Consultants

Investor-in-Residence

Intellectual Property

Entrepreneurs-in-Residence

Regulatory/Reimbursement

Partnering and Investment Opportunities

Company Showcase

BIO International Convention

LIFESCIENCES SUMMIT

THE MEDTECH CONFERENCE Powered by AdvaMed

RESI REDEFINING EARLY STAGE INVESTMENTS

ACA ANGEL CAPITAL ASSOCIATION

NIH National Institutes of Health
Office of Extramural Research

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NIH Guide for Grants and Contracts

Read our NIH SBIR/STTR Success Stories

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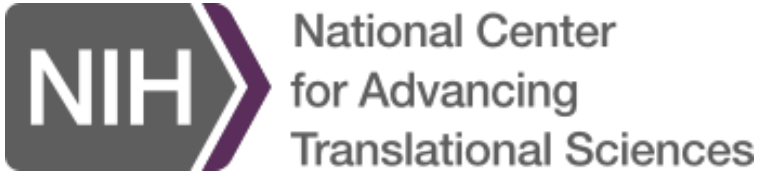


Lili Portilla, MPA

Director, Office of Strategic Allianges

National Center for Advancing Translational Sciences

Topic 22 - Technological Development and Validation of Remote Measures for Use in Clinical Trials in Individuals with Rare Diseases

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 4

Summary: The objective of this contract is to develop and validate digital health technologies for data capture that can be used to assess individuals with rare diseases in remote settings in a manner that is suitably sensitive and specific for use in clinical trials. Technologies should be reliable, secure, and easy to use to monitor study participants remotely.

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

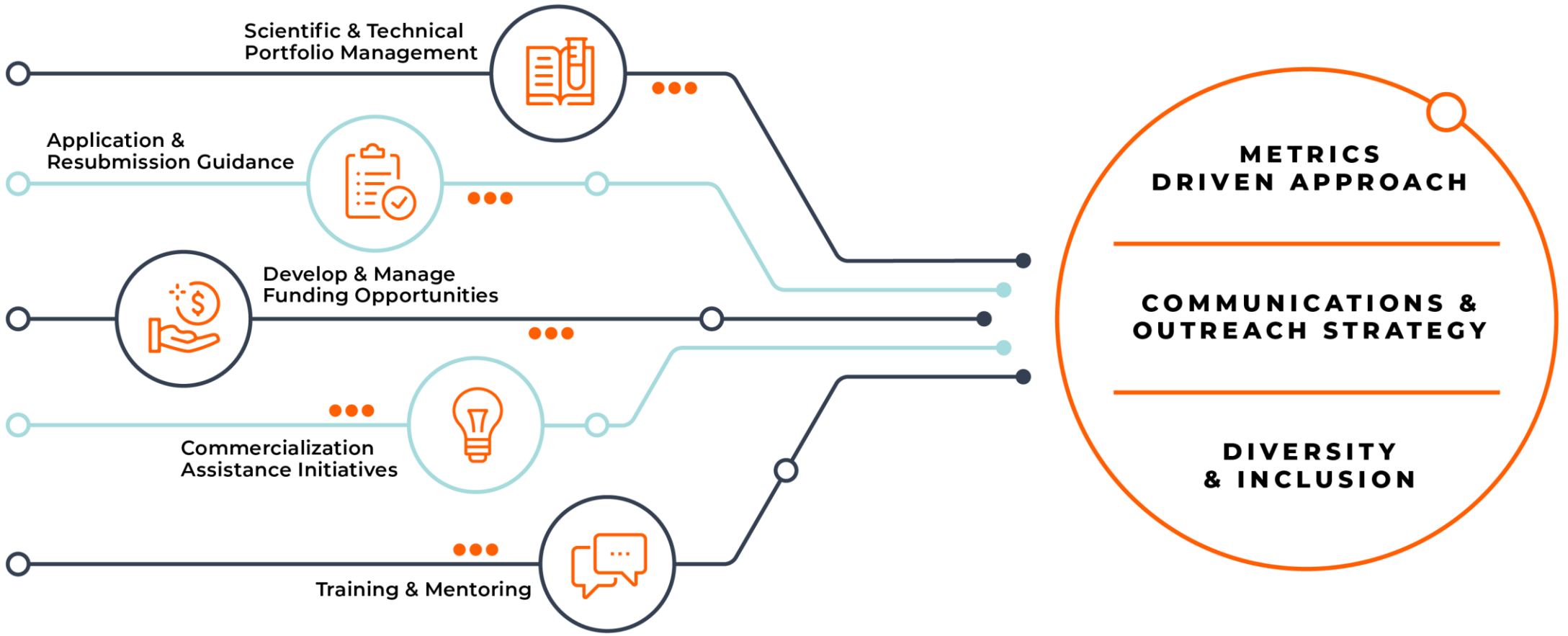
NIH NATIONAL CANCER INSTITUTE

Reema Railkar

Program manager, NCI SBIR Development Center

National Cancer Institute

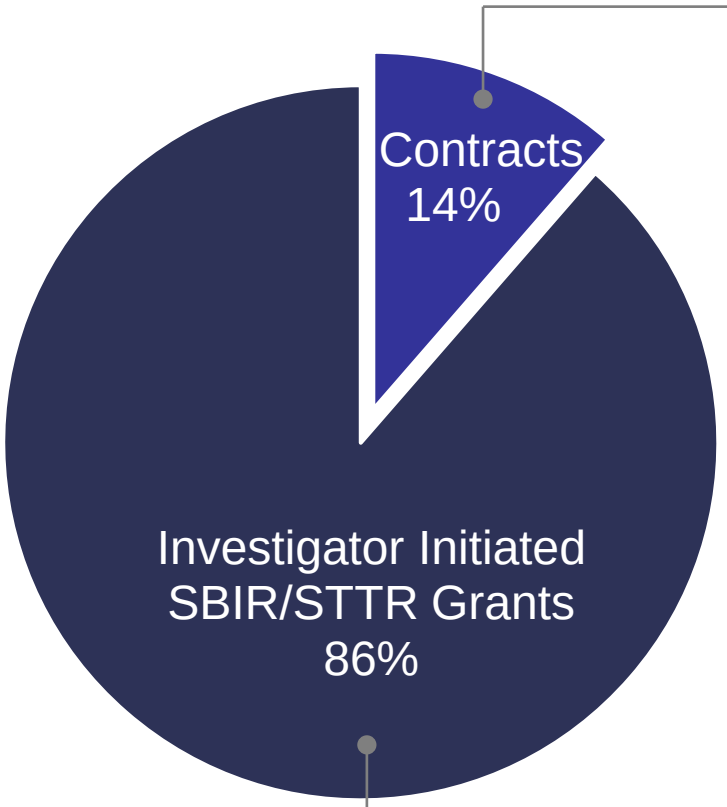
NCI SBIR CORE ACTIVITIES



NCI SBIR SUPPORTS GRANTS & CONTRACTS

SBIR
Small Business Innovation Research (**3.2%**)

STTR
Small Business Technology Transfer (**0.45%**)

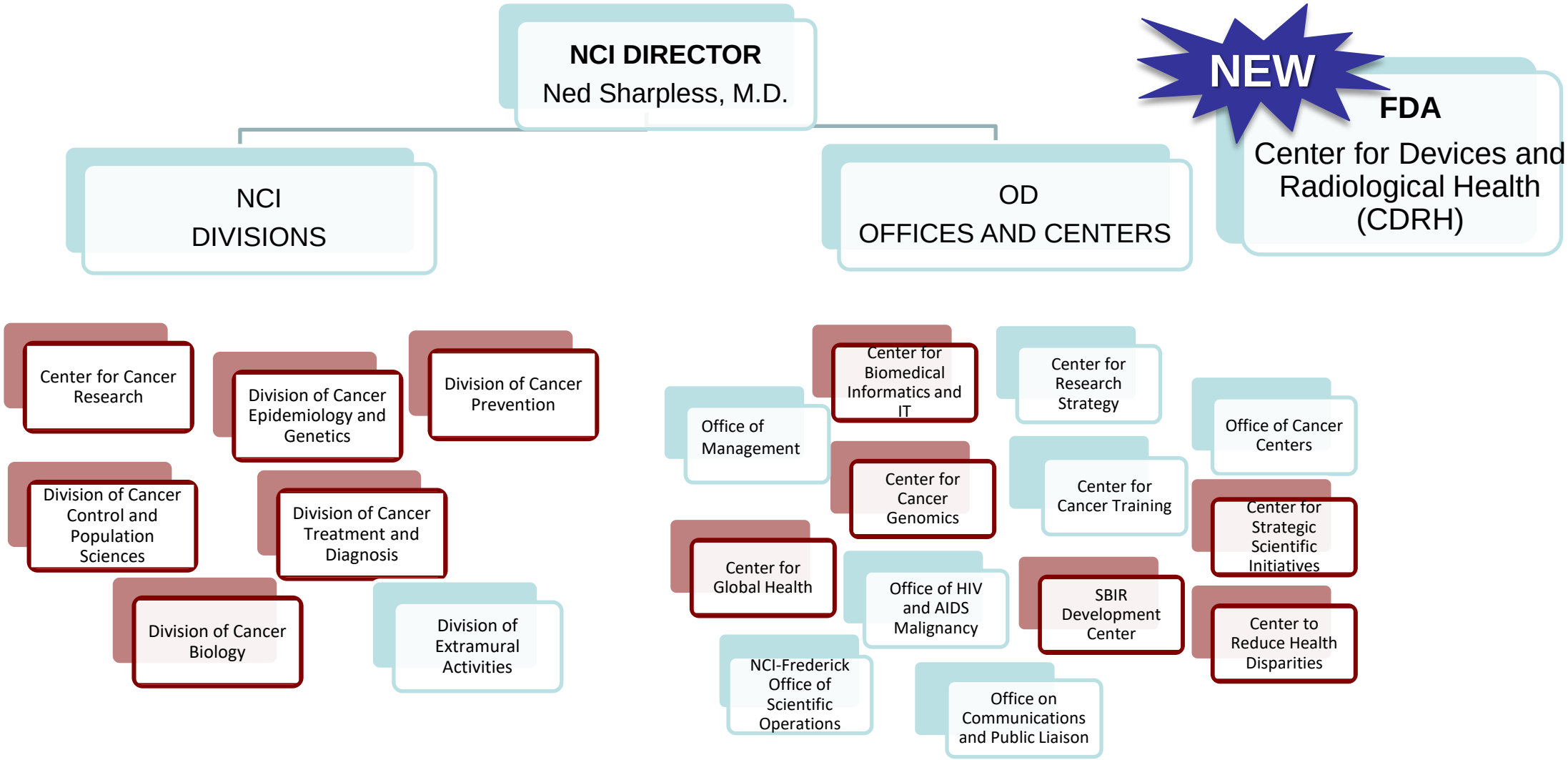


SBIR Contracts
$25M (FY2020)

- New topics once a year
- NIH-wide RFP
- R&D scope for topics defined by NCI

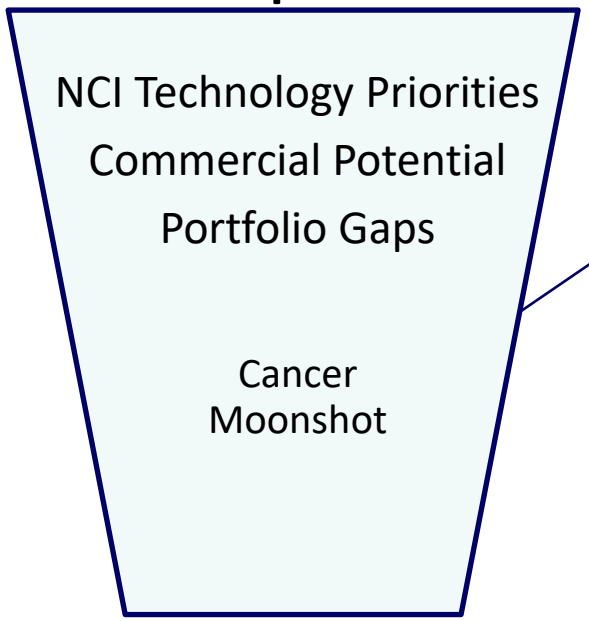
SBIR/STTR Grants
$150M (FY2020)

Trans-NCI Process



Contract Topic Selection Process: FY2022

Concept Ideas



Technology Advisory Groups

1. Therapeutics, Clinical Diagnostics, and Molecular Analysis Techniques
2. Radiation Therapy, Medical Devices, and Information Technology

Topics → SPL → BSA → Publish RFP

NCI Contracts Solicitation

Check PHS 2022-1 Contracts Solicitation Document:
https://sam.gov/opp/dec33d2b73f245f18e8d8d9f559b3698/view
Check Individual Contract Topics:
https://sbir.cancer.gov/funding/contracts/currentcontracts

Questions about NCISBIR Contracts?

Ms. Cherie Wells
E-mail: ncioasbir@mail.nih.gov
(Please reference solicitation PHS 2022-1 and the Topic number with any questions.)

Note: Please Read the Document Carefully!

CONTRACTS FY2022 – NIH/NCI TOPICS

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	Topic Title
NIH/NCI 430	Yes	Yes	Development of Senotherapeutic Agents for Cancer Treatment
NIH/NCI 431	Yes	Yes	Cancer Treatment Technologies for Low-resource Settings
NIH/NCI 432	No	Yes	Synthetic Biology Gene Circuits for Cancer Therapy
NIH/NCI 433	Yes	Yes	Developing Unbiased Medical Technologies to Reduce Disparities in Cancer Outcomes
NIH/NCI 434	Yes	Yes	Ultra-fast Dose Rate (FLASH) Radiation Detectors and Safety Systems
NIH/NCI 435	Yes	No	Devices to Treat Secondary Lymphedema Following Cancer Treatment
NIH/NCI 436	Yes	No	New Technologies to Analyze Extra-chromosomal DNA in Cancer
NIH/NCI 437	No	Yes	3D Spatial Omics for Molecular and Cellular Tumor Atlas Construction
NIH/NCI 438	No	No	Understanding Cancer Tumor Genomic Results: Technology Applications for Community Providers
NIH/NCI 439	No	Yes	Advanced Sample Processing Platforms for Downstream Single-cell Multi-omic Analysis
NIH/NCI 440	Yes	Yes	Cancer Prevention and Diagnosis Technologies for Low-resource Settings
NIH/NCI 441	Yes	Yes	At-home Screening for Hepatitis C Virus
NIH/NCI 442	No	No	Quantitative Biomarkers as Medical Device Development Tools for Cancer
NIH/NCI 443	Yes	Yes	Development of Computer-aided Diagnosis Tools for Upper and Lower Gastrointestinal Tract Cancer Prevention
NIH/NCI 444	No	No	Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies
NIH/NCI 445	Yes	Yes	Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-based Therapies

NIH/NCI 430: Development of Senotherapeutic Agents for Cancer Treatment

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 430	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.
- Conduct structure-activity relationship (SAR) studies, medicinal chemistry, and/or lead biologic optimization
- Optimize formulation of senotherapeutic agent(s)
- 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.

NIH/NCI 431:
Cancer Treatment Technologies for Low-resource Settings

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 431	Yes	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this solicitation is to encourages applications from SBCs to develop or adapt, apply, and validate existing or emerging technologies into low-resource setting-appropriate technologies for cancer treatment. Projects proposed for this contract topic will require multidisciplinary efforts to succeed, and, therefore, all applicant teams must include expertise in oncology, engineering, global health, and healthcare delivery in low-resource settings. Products addressing cancers of the cervix, colon/rectum, esophagus, and oral cavity are particularly encouraged for this solicitation.

Phase I Activities and Deliverables Include:

- Develop a working prototype based on adaptation of existing technology, or development of new technology.
- Demonstrate the feasibility of the technological innovation for use in a low-resource setting (real or modeled), using a small number of biological samples or animals, where appropriate.
- Deliver to NCI the SOPs of the system for cancer treatment
- Develop a regulatory strategy/plan and timeline for seeking approval from the appropriate regulatory agency to market the product
- Provide a brief business plan, which is likely to require partnering with healthcare staff local to the low-resource setting of interest

NIH/NCI 432:
Synthetic Biology Gene Circuits for Cancer Therapy

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 432	No	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of the topic is to stimulate the development of gene circuit therapies for cancer. Engineering of immune cells and/or cancer cells is encouraged, while other cell types are not excluded. The activities that fall within the scope of this solicitation include the development of the gene circuits designed and created using synthetic biology approaches into cancer therapies through engineering immune cells ex vivo, or by delivering directly into cancer cells in patients using viral or non-viral gene transfer approaches/vectors, including engineering of bacteria to specifically target cancer. The approach should also allow precise control over timing, dose, and location of the therapies.

Phase I Activities and Deliverables Include:

Establishing proof-of-concept efficacy and/or toxicity:

- Demonstrate *in vitro* sustained and controllable transgene expression with efficacy in appropriate cell lines and/or 3D models
- Demonstrate *in vivo* sustained and controllable transgene expression with efficacy in appropriate small animal models
- Conduct gene circuit optimization (as appropriate).
- Perform (optional) animal toxicology and pharmacology studies as appropriate.
- Demonstrate (optional) increased efficacy and/or decreased toxicity as compared with standard-of-care for the cancer indication in appropriate animal model(s).

NIH/NCI 433: Developing Unbiased Medical Technologies to Reduce Disparities in Cancer Outcomes

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 433	Yes	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal is to create scalable health IT-based informatics tools that measure care coordination in order to assess and improve quality of care and patient outcomes, assist the ongoing healthcare delivery system transformation and improve research efficiency. Activities that fall within the scope of this solicitation include development of unbiased medical technologies to replace existing bias in technologies that contribute to disparities in cancer control outcomes.

Phase I Activities and Deliverables Include:

- Establish a project team including personnel with training and research experience in the specific type of medical technology targeted, knowledge of the relevant area of cancer prevention and control, and expertise in structural inequalities/health disparities;
- Provide a report including a detailed description and/ or documentation of –
  - Existing racial/ethnic bias in the targeted medical technology;
  - The role of such biased technology in perpetuating or exacerbating disparities in cancer prevention and control;
  - Potential mechanisms underlying biases in the target medical technology; etc.
- Develop a functional prototype of the newly developed technology;
- Provide preliminary evidence for potential efficacy for newly developed technology in reducing or eliminating bias.

NIH/NCI 434: Ultra-fast Dose Rate (FLASH) Radiation Detectors and Safety Systems

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 434	Yes	Yes	2-3	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this concept is to solicit proposals to advance the development and/or application of devices, to allow FLASH radiation therapy to be properly evaluated and ultimately translated into the clinic. In particular, ultra-fast radiation dose rate detectors, and related components are the focus of this topic solicitation. By prompting the development of new, commercialized, ultra-fast detectors and safety systems, this solicitation has the potential to facilitate validated translation of laboratory findings to patients in this new and exciting domain – that of FLASH radiation therapy.

Phase I Activities and Deliverables Include:

- Establish a project team
- Design and build proof-of-principle prototype system to measure the time structure of FLASH beam delivery than can both sum dose and collect time structure data and allow the analysis of such data to confirm if it is with 5% of planned beam delivery immediately after treatment
- Demonstrate that the prototype has a high probability of development into a clinically-relevant radiation measurement tool and/or safety device component that has is able to work in the FLASH regime (40-120 Gy/s).
- Provide a report on the results of the first round of usability testing and any resultant modifications of the platform based on this user feedback.

NIH/NCI 435: Devices to Treat Secondary Lymphedema Following Cancer Treatment

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 435	Yes	No	2-4	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this contract topic is to support the development of technologies that prevent, reduce, or eliminate lymphedema following removal or radiation of lymph nodes due to cancer in the upper body, i.e. neck, chest, arm(s), or thoracic cavity. These technologies will provide healthcare providers with solutions for preventing and treating lymphedema, which can cause a serious reduction in function and quality-of-life for patients following treatment for cancer.

Phase I Activities and Deliverables Include:

- Develop a prototype of a device with appropriate specifications.
- Demonstrate preliminary proof-of-concept of the device in a suitable animal model or phantom model.
- Specify the quantitative technical and commercially relevant milestones that will be used to evaluate the success of the technology.
- Identify required specifications necessary to make the device clinic ready.
- Develop a regulatory strategy/plan and timeline that is necessary to file a regulatory application for the device.
- Implantable device specifications and regulatory plans must include a description of infection risk and plans to test and mitigate the risk of infection or spreading infection.

NIH/NCI 436:
New Technologies to Analyze Extra-chromosomal DNA in Cancer

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 436	Yes	No	2-3	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this contract topic is to spur the development of new and/or advanced analytical approaches that can support research into the mechanisms giving rise to ecDNA formation and organization, and its role in cancer. his solicitation seeks both completely new approaches, as well as “better, faster, cheaper” versions of existing technologies, to advance this field. Responsive proposals may include novel methods and/or reagents to selectively enrich, isolate, detect, and/or visualize ecDNA targets.

Phase I Activities and Deliverables Include:

- Demonstrate the ability to selectively analyze (e.g., enrich, purify, isolate, detect, image) ecDNAs found in cancer-relevant biological systems
- Provide a clear justification for the biological systems (e.g., cell lines) used for analytical validation; include a summary of what is currently known about the role of ecDNA in these systems and how this may impact the interpretation of the proposed validation experiments
- Demonstrate the specificity of the assay/technique to distinguish ecDNA from all other forms of cellular DNA in the chosen cancer cells
- Fully characterize the relevant analytical parameters of the assay/technique including sensitivity, specificity, limit of detection, dynamic range, etc. (as appropriate)
- Describe target performance measures (i.e., quantitative milestones) for key analytical parameters, including the methods by which they will be assessed

NIH/NCI 437:
3D Spatial Omics for Molecular and Cellular Tumor Atlas Construction

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 437	No	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this concept is to solicit proposals to advance the development and dissemination of imaging workflows capable of omics-level measurements in thick tissue resections or whole biopsy cores. Proposals should enable interrogation in a manner that combines high resolution (preferably single-cell) omics level data (i.e. genomic, transcriptomic, proteomic, metabolomic, etc) with information about 3D native tumor architecture (i.e. extracellular matrix, vasculature, higher order structure, etc).

Phase I Activities and Deliverables Include:

Phase I activities should generate data to confirm feasibility and potential of the technology(ies) to provide 3D images of high-resolution omics-level data in thick resections or whole biopsy cores by completing the following deliverables:

- Define the relevant use cases for the technology (i.e. what tissues can be used, what imaging resolution can be expected, what -omic measurement(s) will be completed).
- Generate proof-of-concept dataset using resection tissue or biopsy cores from solid human cancers or from a generally accepted mammalian cancer model (i.e. PDX, xenograft, GEMM) that demonstrates the ability to capture and visualize molecular omics measurements in 3D.
- Development of preliminary Standard Operating Procedures for system use, including a validated list of reagents for a specific tumor type.

NIH/NCI 438: Understanding Cancer Tumor Genomic Results: Technology Applications for Community Providers

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 438	No	No	2-3	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal is to design and develop products such as tools, technologies, and/or services to: (i) inform oncology providers about tumor/somatic testing and current NCCN guidelines, (ii) help oncology providers evaluate the need for tumor/somatic testing for specific cancer patients, (iii) assist oncology providers with interpretation of tumor/somatic test results, including the impact of incidental germline findings, and (iv) help oncology providers communicate NGS results to their patients. Interpretation of NGS results must be personalized for individual patients.

Phase I Activities and Deliverables Include:

The goal of Phase I is to design and develop tools, technologies, or products to 1) inform the user about the role of tumor (somatic) genetic testing and counseling in cancer research and treatment 2) aid understanding and interpretation of somatic genetic findings; 3) aid in effective communication of tumor (somatic) genetic test results.

- Establish a project team with expertise in the area of genetic counselling, software development, user-centric design, oncology, patient navigation as appropriate for this proposed project.
- Develop a prototype tool or technology based on formative research, to explain genetic tests and test result to physicians for them to provide to their patients.
- Identify at least one clinical setting where the tool may be used and integrated within a research or practice setting and develop process maps and algorithms to set up appropriate data flows and ensure privacy protections.
- Test the feasibility /usability of tool in a sample population of physicians and patients and providing written report and recommendations on the best practices for use of the tool in research and practice settings.

NIH/NCI 439: Advanced Sample Processing Platforms for Downstream Single-cell Multi-omic Analysis

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 439	No	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The activities that fall within the scope of this solicitation include development of technologies to improve single-cell multi-omic preanalytical microfluidic platforms that integrate steps of the preanalytical workflow such as sample processing, single-cell separation or isolation and enrichment, technologies for solid tumor dissociation/isolation, enrichment and tracking of cancer cells and/or biomolecules for scMulti-omics.

Phase I Activities and Deliverables Include:

Phase I activities should demonstrate the feasibility of a technology to improve single-cell multi-omic preanalytical platforms.

- Develop an early/proof-of-principle prototype, single-cell multi-omic preanalytical device/platform or technology for at least one improved step of the scMulti-omic preanalytical workflow
- If the technology developed is a novel technology for at least one step of the scMulti-omic preanalytical workflow, describe its capability for integration with other steps in the scMulti-omic workflow into a device/platform
- Establish assays and/or metrics, especially functional comparability and quality attributes, and benchmark the approach against current methods used in single-cell analysis preanalytical workflows using at least two tumor types.
- Define the target for analysis and demonstrate compatibility with the downstream analytical step (at least two downstream readouts for example DNA and RNA sequencing technologies)

NIH/NCI 440: Cancer Prevention and Diagnosis Technologies for Low-resource Settings

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 440	Yes	Yes	4-6	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this solicitation is to encourages applications from SBCs to develop or adapt, apply, and validate existing or emerging technologies into low-resource setting-appropriate technologies for cancer prevention early detection and/or diagnosis. For cervical cancer, this solicitation is particularly focused on the development of rapid HPV diagnostics at the point-of-need suitable for taking to scale (e.g., a portable loop-mediated isothermal amplification (LAMP) based assays).

Phase I Activities and Deliverables Include:

- Develop a working prototype based on adaptation of existing technology, or development of new technology
- Demonstrate the feasibility of the technological innovation for use in a low-resource setting (real or modeled), using a small number of biological samples or animals, where appropriate
- For software/IT tool development, applicants are required to conduct a pilot usability study with at least 25 users
- Deliver to NCI the SOPs of the system for cancer prevention, and/or diagnosis.
- Develop a regulatory strategy/plan and timeline for seeking approval from the appropriate regulatory agency to market the product
- Provide a brief business plan, which is likely to require partnering with healthcare staff local to the low-resource setting of interest

Specific activities and deliverables for applications focused on HPV diagnostics are mentioned.

NIH/NCI 441:
At-home Screening for Hepatitis C Virus

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 441	Yes	Yes	3-5	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The purpose of this solicitation is to develop and validate a rapid, sample-to-answer, point-of-care test for HCV exposure or active infection that has the following required specifications: 1) can be used as a self-test in non-clinical settings including at home; 2) testing requires only the use of non-invasive specimens that can be safely collected at home such as (but not limited to) blood via finger prick, oral samples (e.g., saliva or buccal cells collections), or urine; and 3) achieves the same analytic performance as predicate tests that use blood for the detection of anti-HCV antibodies as a measure of exposure or HCV RNA or proteins as a measure of active infection.

Phase I Activities and Deliverables Include:

Offers must propose to conduct activities that lead to development of a working prototype device ready for clinical evaluation, including but not limited to:

- Develop a working diagnostic assay and/or prototype point-of-care diagnostic device that can identify people exposed to or have an infection by HCV using oral salivary specimens, urine, or sample of blood that can be collected using a lancet.
- Demonstrate that the prototype diagnostic assay can be operated as a self-test by the target population.
- Determine the sensitivity, specificity, and other performance characteristics
- Conduct initial testing using samples from animal models and/or preferably on patient isolates to demonstrate feasibility.
- Offerors may need to establish a collaboration or partnership with a medical facility or research group in the US that can provide relevant positive control and patient samples.

NIH/NCI 442: Quantitative Biomarkers as Medical Device Development Tools for Cancer

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 442	No	No	2-3	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 quantitative biomarker tests. Activities that fall within the scope of this solicitation include development and optimization of a biomarker-based assay that meets the criteria defined by the FDA MDDT Program.

Phase I Activities and Deliverables Include:

- Develop a working biomarker-based assay that meets the criteria defined by the FDA MDDT program.
- Prepare an MDDT proposal using the MDDT Qualification Plan Submission Template which includes specific requirements and activities with respect to the proposed MDDT. 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 assay for use in a regulatory setting.
- 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 Submission Template for this submission.
- Specify the quantitative technical and commercially relevant milestones that will be used to evaluate the success of the biomarker-based assay.
- Develop a regulatory strategy/plan and timeline to file a regulatory application for an MDDT.

NIH/NCI 443: Development of Computer-aided Diagnosis Tools for Upper and Lower Gastrointestinal Tract Cancer Prevention

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 443	Yes	Yes	2-4	Phase I – 400K up to 12 months	Phase II – 2M up to 2 years

Goal: The goal of this topic is to solicit proposals to advance the development and application of artificial intelligence-based algorithms to improve the visual human-based determination of precancerous lesions examined through visual inspection of upper and lower endoscopies. The activities that fall within the scope of this solicitation include the development and application of algorithms for computer-aided diagnosis of Barrett's esophagus and dysplasia and colorectal polyps and adenomas.

Phase I Activities and Deliverables Include:

- Establish a multidisciplinary project team with expertise in computer-aided diagnosis, medical imaging software design, informatics, and gastroenterology or medical oncology to oversee the development of software.
- Develop tools for an artificial intelligence-based system that can analyze cell nuclei, crypt structure, and micro-vessels in endoscopic images, for the identification of esophageal or colon neoplasms (including polyps, precancers, dysplasia, and metaplasia).
- Develop an algorithm for evaluating endoscopic images for prediction of progression to more advanced disease and / or response to cancer interception intervention.
- Develop a system where the primary outcome is accurate differentiation between normal tissue, precancers, and cancers.
- Design and build a computer-aided diagnosis (CAD) tool as a prototype.
- Evaluate CAD performance via available (retrospective) image data sets.
- Refine CAD tool as needed to improve performance and sensitivity and specificity.
- Perform small scale usability testing (5-10 end users) at multiple sites.
- Finalize discussion with FDA for regulatory requirements to be completed in the SBIR Phase II.

NIH/NCI 444: Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 444	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 demonstrate the utility of qualified datasets as MDDTs to assess medical devices subject to regulation by CDRH. An MDDT can be a method, material, or measurement used to assess the effectiveness, safety, or performance of a medical device. The functionalities of such medical devices run the gamut in the cancer care continuum including prevention, detection, diagnosis, treatment planning etc. Datatypes of interest cover a broad range of data produced by those devices, and include, but are not limited to, imaging (radiology and pathology), cancer genomics, proteomics, structured data extracted from unstructured EHR, and treatment outcome data.

Phase I Activities and Deliverables Include:

- Develop a pilot dataset that demonstrates how the data will be collected and what it will look like.
- Develop an algorithm-assessment plan and corresponding software.
- If truth data is from a clinician or alternate modality, characterize the related uncertainty and account for it in all analyses.
- Identify precision and performance-level parameters necessary for the dataset to become a clinically relevant tool that can be used for testing and evaluation of novel medical devices.
- Prepare an MDDT Qualification Plan Submission Template using the MDDT Qualification Plan Submission Template.
- Demonstrate suitability of the dataset for the targeted test population and planned reference standard(s).
- Submit a complete Qualification Plan to the FDA’s MDDT Program.

NIH/NCI 445: Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-based Therapies

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	Budget (Max)
NIH/NCI 445	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 stimulate the development of advanced manufacturing technologies that substantially improve the speed and cost of producing autologous cell-based therapies. Technical solutions are expected to address a key bottleneck in the current manufacturing process for individual cell-based therapies. Ideal solutions will involve parallel processing, rapid release testing, or point of care technology development, although other approaches may also be considered responsive.

Phase I Activities and Deliverables Include:

- Provide proof of collaboration with an immunologist(s), clinician(s), and an engineer(s) if device development activities are proposed.
- Establish defined specifications to enable integrated high throughput parallel manufacturing at faster speed and lower cost than current manufacturing methods;
- Develop an early prototype device or technology for integrated high throughput autologous-cell manufacturing that include specifications designed to substantially reducing the speed, as well as any cost savings based on the new manufacturing approach;
- Demonstrate the suitability of the approach within the cell manufacturing process;
- Demonstrate pilot-scale beta-testing of the approach comparing it against appropriate benchmarking technology;
- Demonstrate the immunological functionality of the cells based on the previously identified functional comparability assays and/or metrics, and compare cell function to appropriate benchmarking technology;
- Establish cell culturing technology compatible with high throughput production and technology to monitor the cells.

- **Upcoming Events**
  - NCI SBIR x FDA Contract Solicitation Webinar(August 24th, 2021) https://sbir.cancer.gov/newsevents/events/NCIxFDAcontracts21
  - NCI SBIR Contracts Solicitation Webinar (Sept. 21, 2021). See the upcoming link on NCI SBIR Events Page: https://sbir.cancer.gov/newsevents/events
  - Sign up for e-newsletter for the latest update: https://sbir.cancer.gov/emailsignup

Todd Haim

Chief, Office of Small Business Research

National Institute on Aging

NIA Research Topics: FY2022 SBIR Contract Solicitation

Topic	Fast-Track	Direct-to-Phase II
Topic 004 - Improving Central Nervous System (CNS) Gene Delivery Systems for Alzheimer's Disease and Related Dementias (AD/ADRD) Therapy Development	✓	✓
Topic 005 - Geroscience-Based Chronic Wound Treatment Product Development	✗	✗
Topic 006 - The Development of Mechanism-Based Adult Stem Cell Treatments to Combat Aging Pathologies	✓	✗

- **Budget (total costs, per award):** Phase I: $500,000 for 12 months; Phase II: $2.5 million for 2 years
- **Budget (total costs, per award):** Phase I: $350,000 for 12 months; **Phase II: $2.5 million for 2 years
- **Budget (total costs, per award):** Phase I: $350,000 for 12 months; Phase II: $2 million for 2 years

***Phase II information provided for informational purposes only to assist Phase I offerors in long-term strategic planning*

Improving CNS Gene Delivery Systems for AD/ADRD Therapy Development

Background

- AMP-AD identified 542 unique targets; only half are druggable by small molecules
- Expanding Therapeutic Modalities for AD/ADRD Workshop to discuss various biologic modalities, such as gene therapy

Scope of Work

- Improve gene delivery systems to overcome current challenges

Phase I

- Gene delivery system development and point-of-care *in vivo* testing
- Primary requirements:
  - Immunogenicity
  - Biodistribution
  - Brain permeability
  - Cell-targeting

Phase II

- Late-stage development to FDA approval
- Requires close monitoring of quantitative milestones for developing gene delivery systems with improved properties

Geroscience-Based Chronic Wound Treatment Product Development

Background

- Chronic wounds include pressure ulcers, venous ulcers, and diabetic foot ulcers
- Common in complex geriatric patients with multiple chronic conditions
- Usual care comprises several marginally effective products, wound management, and surgery

Scope of Work

- Development of wound treatment that incorporates geroscience-based therapeutic modalities, such as stem cell therapies, senolytics, and inflammation modulators

Phase I

- Development and testing of a prototype for one potential product
- Prepare for human studies
- Regulatory strategy/approach

Phase II* (solicitation limited to Phase I only)

- Perform *in vitro* studies of product release over time
- Perform *in vivo* pharmacokinetic and biodistribution studies
- Develop a commercialization plan that includes a go-to-market strategy

*Phase II information provided for informational purposes only to assist Phase I offerors in long-term strategic planning

The Development of Mechanism-Based Adult Stem Cell Treatments to Combat Aging Pathologies

Background

- Stem cell rejuvenation via heterochronic parabiosis in mice demonstrated blood stem cells and their factors from young mice contribute to improved wound repair and motor function in old mice
- Most study-based efficacy and mode of action on young animal models despite need and market pressure to treat older people
- Need a better understanding of how aging stem cells or tissue environments respond to potential treatments

Scope of Work

- Develop a stem cell-based therapeutic with a defined mechanistic understanding of how it promotes regeneration and/or rejuvenation of aging tissues

Phase I

- Physiological, molecular, and cell characterization of the mechanism of action for adult stem cell-based treatment for repair or regeneration of aging tissues
- Preclinical studies that contribute to conducting clinical trials that address specific clinical indications.
- Development of methods, standards, and cGMP for adult stem cell-based regenerative medicine products for use in aging

Phase II

- Perform large-scale usability study with at least 100 *in vivo* animal studies or 500 *ex vivo* human cells or tissue assays
- Perform large-scale validation study in *in vivo* animal studies or *ex vivo* human cells or tissue assays
- Demonstrate commercial partnering/investment interest and submission of a regulatory application to FDA

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

Program Solicitation PHS 2022-1
Summary of FY22 SBIR Contract Topics NIAID topics page 103 - 118

Topic 101 - Novel Platforms for Delivery and/or Expression of HIV Env Immunogens for HIV Vaccines

Topic 102 - Genetically Engineered Mice for Pre-clinical Evaluation of HIV Vaccine Candidates

Topic 103 - Development of Diagnostics to Differentiate HIV Infection from Vaccine Induced Seropositivity

Topic 104 - Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases

Topic 105 - Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases

Topic 106 - Production of Adjuvants Mimics

Topic 107 - Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models

Topic 108 - Development of Rapid POC Diagnostics for Treponema pallidum

Topic 109 - Development of Monoclonal Antibody-mediated Interventions to Combat Malaria

Topic 110 - Point of Care (POC) Diagnostics for Antimicrobial Resistant (AMR) Enteric Bacterial and Parasitic Pathogens

Topic 111 - Data Science Tools for Infectious and Immune-mediated Disease Research

Topic 112 - Digital Tools Against Misinformation about Infectious Disease Treatments and Vaccines

- **Review the "Summary of HHS Components Anticipated # of Awards", NIAID is page 59**

ANTICIPATED NO. OF AWARDS	ANTICIPATED TIME OF AWARD
19-41	Scientific and Technical Merit Review: March 2022 Anticipated Award Date: August 2022

- **Review the summary table (pages 2, 3) to confirm whether Fast-Track or Direct-to-Phase II proposals will be accepted for each topic**

- **Review the NIAID topics pages 103 – 118 for Budget information:**

***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 101 - Novel Platforms for Delivery and/or Expression of HIV Env Immunogens for HIV Vaccines**
- **Topic 102 - Genetically Engineered Mice for Pre-clinical Evaluation of HIV Vaccine Candidates**
- **Topic 103 - Development of Diagnostics to Differentiate HIV Infection from Vaccine Induced Seropositivity**

❖ DIVISION Of ALLERGY, IMMUNOLOGY AND TRANSPLANTATION (DAIT)

- Topic 104 - Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases
- Topic 105 - Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases
- Topic 106 - Production of Adjuvants Mimics
- Topic 107 - Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models

❖ DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES (DMID)

- Topic 108 - Development of Rapid POC Diagnostics for Treponema pallidum
- Topic 109 - Development of Monoclonal Antibody-mediated Interventions to Combat Malaria
- Topic 110 - Point of Care (POC) Diagnostics for Antimicrobial Resistant (AMR) Enteric Bacterial and Parasitic Pathogens

❖ OFFICE OF DATA SCIENCE AND EMERGING TECHNOLOGIES

- **Topic 111 - Data Science Tools for Infectious and Immune-mediated Disease Research**

- **Topic 112 - Digital Tools Against Misinformation about Infectious Disease Treatments and Vaccines**

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

SBIR Contract RFP Informational Webinar

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

SBIR Contract RFP PHS 2022-1

August 12, 2021

CDC - SBIR Contract RFP Informational Webinar (PHS 2022-1)

- Please read the contract solicitation and any future amendments to the solicitation and apply early!

- If you have questions after today's webinar, during the open question/answer period or prior to the receipt date, please contact CDC's Office of Financial Resources, Office of Acquisition Services (OFR/OAS).

- Reference the responsible contracting officer/specialist, the solicitation (SBIR PHS 2022-1), the CDC topic number, and your specific question(s).

CDC's Mission

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 dangerous health threats and responds when these arise.

CDC's Strategic Framework

CDC's Strategic Framework consists of five core capabilities that enable the agency's three strategic priorities as follows:

- 5 Core Capabilities:
  - World-class data and analytics
  - State-of-the-art laboratory capacity
  - Elite public health expertise
  - Responding to outbreaks at their source
  - Global capacity and domestic preparedness

- 3 Strategic Priorities:
  - Securing Global Health and America's Preparedness
  - Eliminating Disease
  - Ending Epidemics

CDC's SBIR Program Overview

- Budget - CDC SBIR set-aside approximately $11 million (FY21)
  - Awards: ≈ 15-20 Phase I's up to $243,500 each and ≈ 2-6 Phase II's per year up to $1.0 M each

- CDC participates in both the SBIR HHS Omnibus Grant Solicitations (PA-21-259 & 260) and the HHS SBIR Contract Solicitation (PHS 2022-1)

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

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

CDC's SBIR Contract Topics (PHS 2022-1)

- **National Center on Birth Defects and Developmental Disabilities (NCBDDD) –**
  - (020) Open-Source and User-Friendly Record Linkage/De-duplication Tool

- **National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) –**
  - (044) Algorithmic Database Food Product Tool to Align Food Service with Guidelines

- **National Center for Emerging Zoonotic and Infectious Diseases (NCEZID) –**
  - (028) - Develop Rapid, Portable, Point-of-Care C. auris Diagnostic
  - (029) - Product to Inactivate and Stabilize Wastewater Samples for Shipping and Transport

CDC's SBIR Contract Topics (PHS 2022-1)- continued

- **National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)-**
  - (052) - Electronic Health Record Algorithm to Identify Persons with HIV Not in Care
  - (053) - Simultaneous Detection of Molecular and Serological Markers via Next-Generation Sequencing

- **National Center for Immunization and Respiratory Disease (NCIRD) –**
  - (035) - Nanoparticle-based Multi-Antigen Influenza Vaccine that Induces both Antibody and Cell-Mediated Immune Responses

Contact Information

For more information, contact CDC's Office of Science (OS),
Office of Technology and Innovation (OTI) at:
SBIR: 404-718—1386 or SBIR@cdc.gov
OTI: 404-639-1330 or OTI@ CDC.gov
www.cdc.gov; www.cdc.gov/sbir

Wednesday, October 28, 2021

5:00 PM Eastern Daylight Time

Electronic submission must be complete

No paper submissions

Submit proposals a day early if possible

Any Questions?