



# ***HHS SBIR Contract RFP Informational Webinar PHS 2021-1***

**August 11, 2020**

***Robert Vinson***

**HHS Small Business Program Manager, SEED (Small business Education & Entrepreneurial Development)  
Office of the Director | Office of Extramural Research | National Institutes of Health**



## Coronavirus 2019:

[Information for NIH Applicants and Recipients](#)  
[Small Business Relief Options and Resources \(SBA\)](#)



A- | A+ Q



- SBIR/STTR HOME
- ABOUT
- FUNDING
- APPLY
- REVIEW
- POLICY
- TECHNICAL ASSISTANCE
- RESOURCES
- STATISTICS AND SUCCESSES
- ENGAGE AND CONNECT

New to SBIR/STTR

### Clinical Trials & SBIR/STTR Funding

Learn how Clinical trials are changing the NIH SBIR/STTR application requirements, and find out which funding opportunity announcement (FOA) is right for you.

MORE DETAILS



*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 \$1.0 billion  
STTR \$146 million



**Centers for Disease Control and Prevention**  
SBIR \$11 million



**Food and Drug Administration**  
SBIR \$2 million



**Administration for Community Living**  
SBIR \$3 million





*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*



# Congressionally Mandated Programs

**\$1.19 Billion Dedicated Funding via Set-aside from NIH's R&D Budget**



3.20%

\$1.04 billion

## **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

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



0.45%

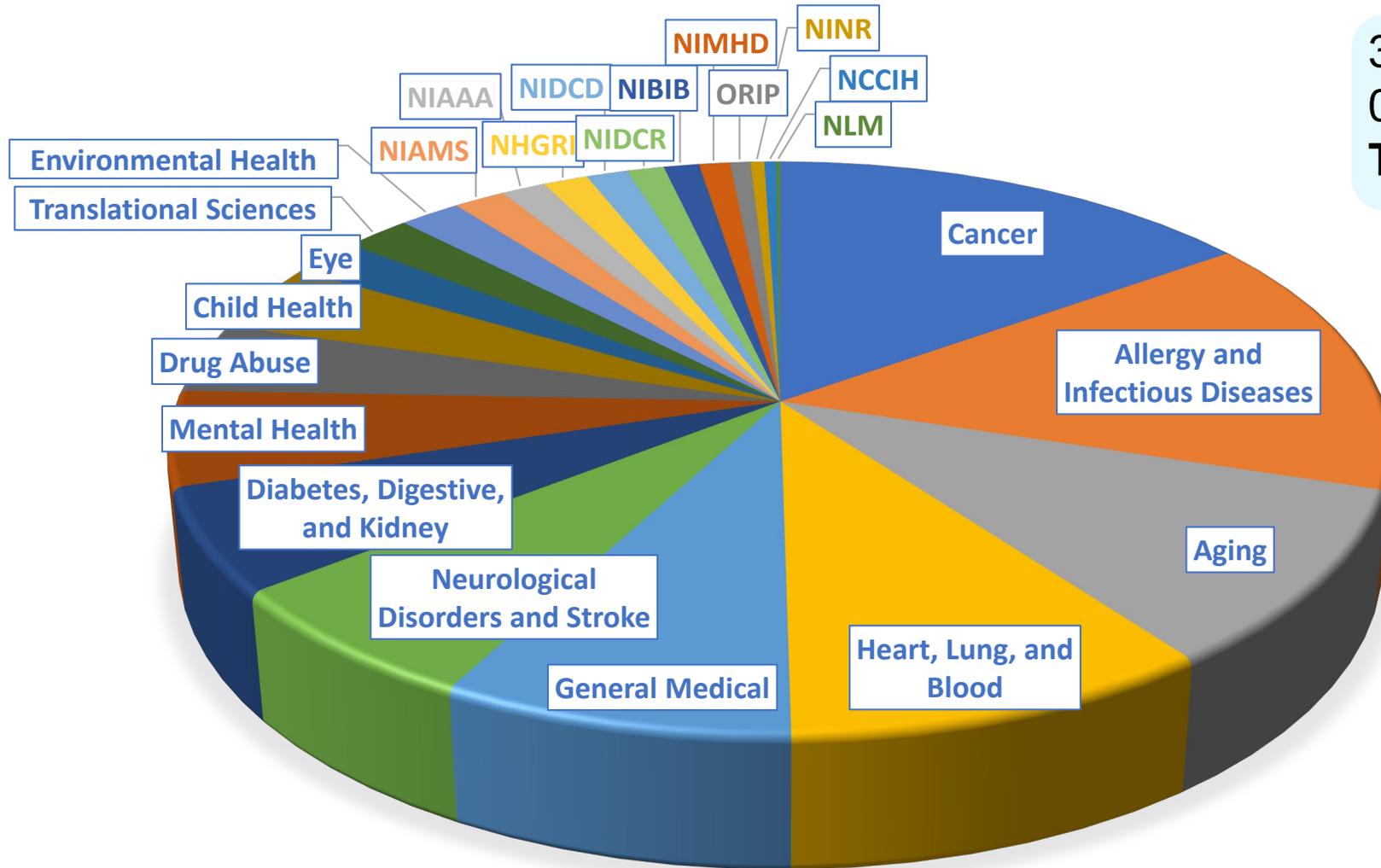
\$146 million

## **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



# NIH SBIR/STTR Budget Allocations FY2020

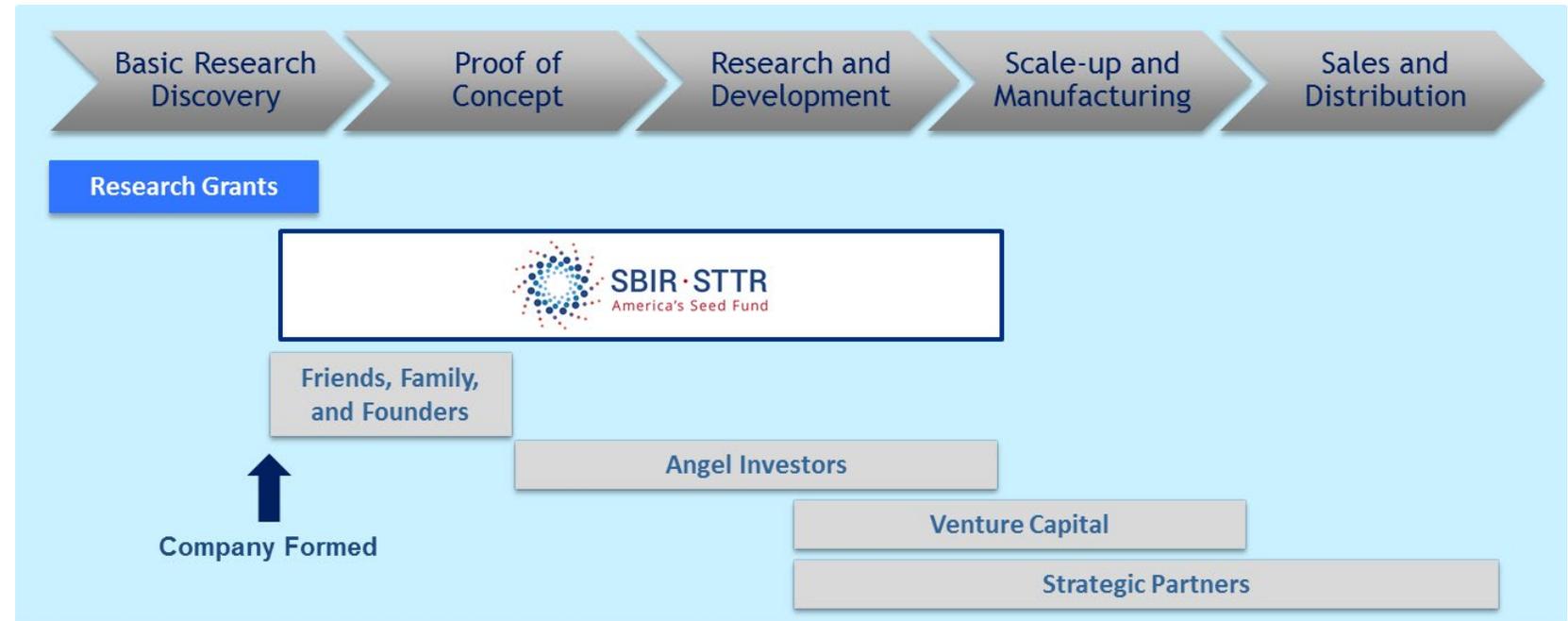


3.20% SBIR \$1.04 billion  
 0.45% STTR \$146 million  
**Total FY20 \$1.19 billion**



## One of the largest sources of early-stage capital for life sciences in the United States

- Not a loan and non-dilutive **capital**
- **IP/data rights** protection through Bayh-Dole Act and SBIR Policy Directive
- Awardees can **leverage funding** to attract investors and partners



- 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>
  - 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**



# 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 must self-certify by registering your business in the System for Award Management



## SBIR Contract Solicitation

- Only some Institutes/Centers participate
- [FY2021 Contract Solicitation](#) is now available
- Receipt date is **October 26, 2020 5:00PM EDT**

## SBIR/STTR Grant Solicitation Funding Opportunities:

- **General Omnibus Solicitations**
  - Clinical Trial Not Allowed: SBIR ([PA-20-260](#)) and STTR ([PA-20-265](#))
  - Clinical Trials Required: SBIR ([PA-20-262](#)) and STTR ([PA-20-261](#))

*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!



## National Institutes of Health (NIH):

- NCATS
- NCI
- NHLBI
- NIAID

## Centers for Disease Control and Prevention (CDC):

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



**NIH SBIR site:** <https://sbir.nih.gov/funding>

**R&D Contract Solicitation:  
SBIR Phase I, Direct Phase II,  
Fast-Track Contract  
Solicitation, PHS 2021-1**

**Closing Date: October 26, 2020, 5:00PM EDT**

 **PHS 2021-1 (PDF - 1.5 MB)**

 **PHS 2021-1 (MS Word - 303 KB)**

 **Contract Proposal Forms**



# 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 2021-1**

**Closing Date: October 26, 2020, 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 26, 2020, 5:00 PM Eastern Daylight Time.

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

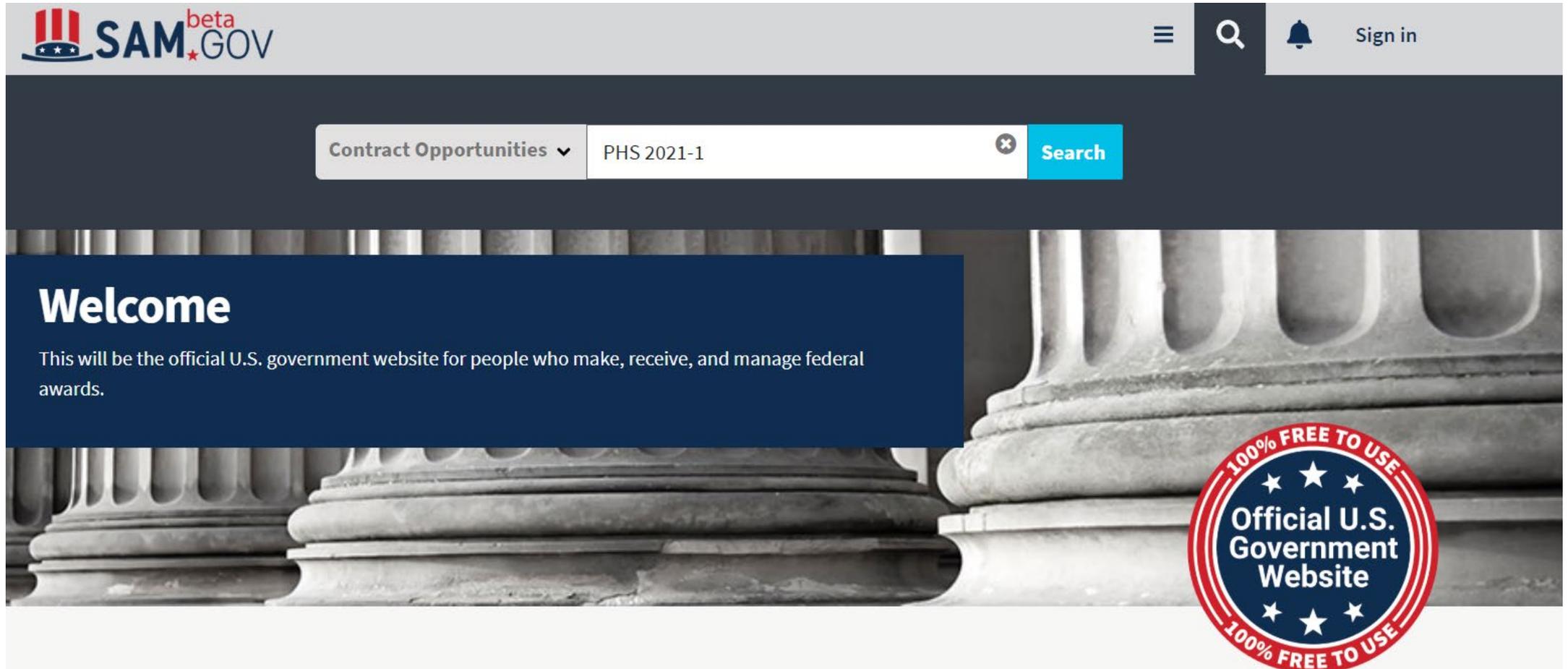
**IMPORTANT:** All proposals must be submitted using the electronic contract proposal submission (eCPS) website.

**Paper proposals will not be accepted.**

Please go to [https://www.sbir.gov/sites/default/files/SBIR-STTR\\_Policy\\_Directive\\_2019.pdf](https://www.sbir.gov/sites/default/files/SBIR-STTR_Policy_Directive_2019.pdf) to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.



FedBizOpps is now SAM.GOV <https://fbohome.sam.gov/>



**Read the entire RFP  
several times!!**



## **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)



## 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)

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# Human Subjects or Vertebrate Animal

- 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, and Children in Clinical Research
- 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.

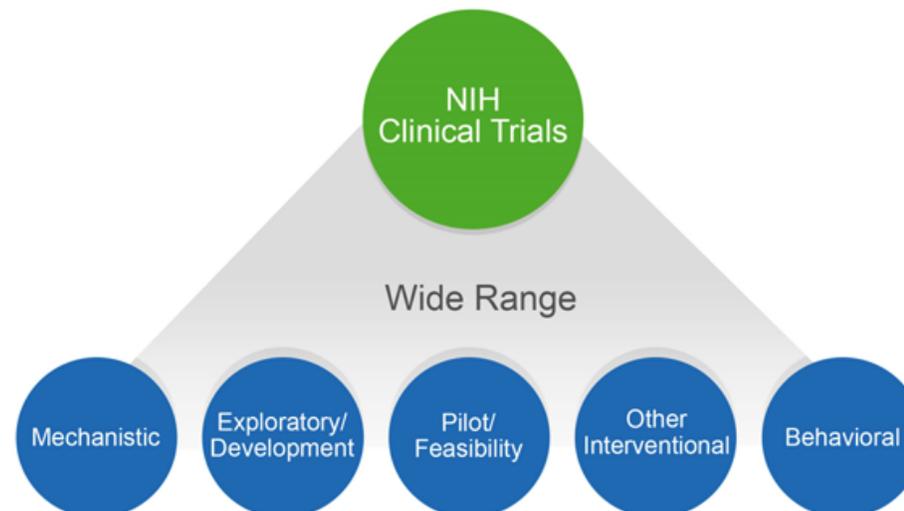
### NIH Definition of a Clinical Trial

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 interventions on health-related biomedical or behavioral outcomes. [Learn more](#)

**DECISION TOOL**

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

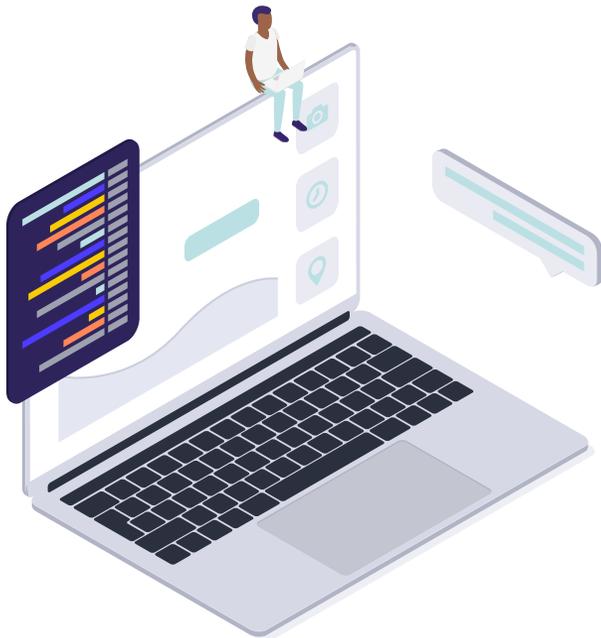
**FIND OUT HERE**



<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)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

# 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

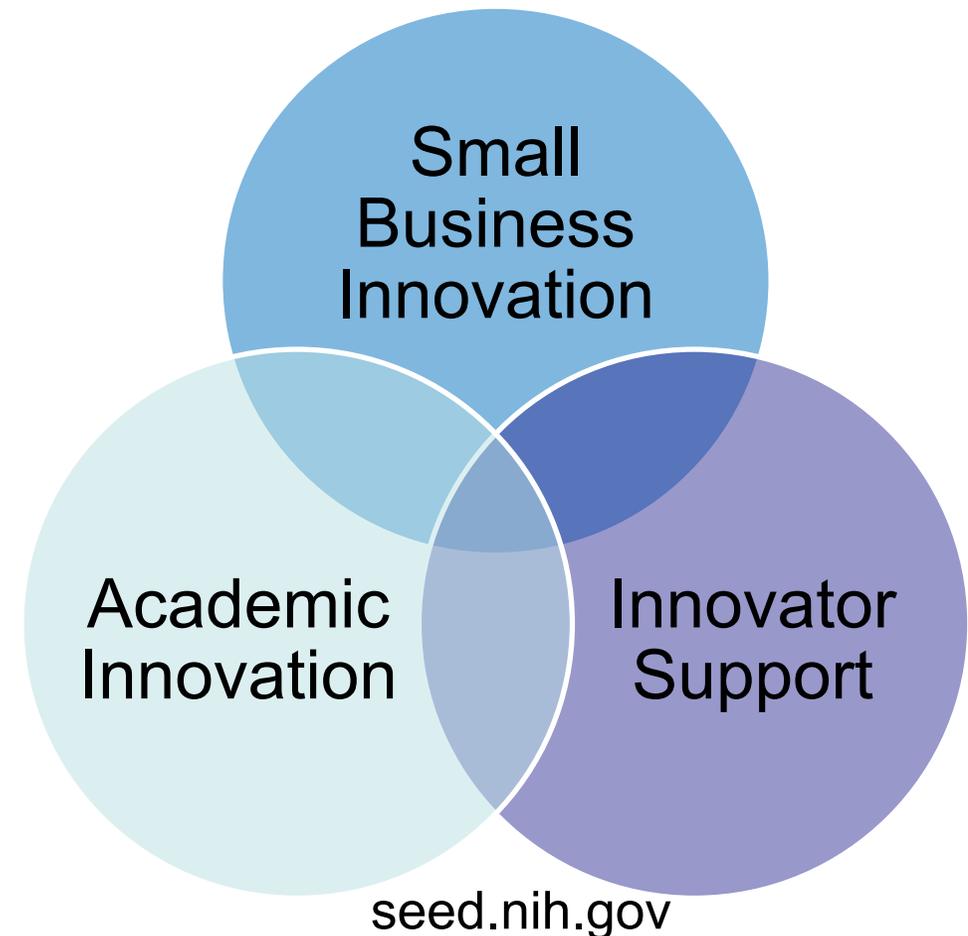


- Reminder, only contact is with Contracting Officer (CO) listed in Section 10
- Questions must be submitted in writing (email) to the CO
- Deadline for Questions is **August 26, 2020** - close of business
- Q&A amendment will be issued in ~ early-mid September in SAM.GOV and on NIH SBIR websites
  - **Yes, your questions and the answers will be posted to the public**
- Additional questions will be answered at the discretion of the CO



## 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.



# Technical Assistance and Training

## *Phase I:*

**Technical and Business Assistance:**  
*Coming Soon:* Needs Assessment Program

**Entrepreneurial Assistance/ Training:**  
NIH I-Corps™

## *Phase II/IIB:*

**Technical Assistance/Training:**  
Commercialization Accelerator Program (CAP)\*

\*Ending in FY2020

## *Phase I and Phase II/IIB: (Grants Only)*

**Entrepreneurial Assistance/ Training:**  
NIH C3i

**Entrepreneurial Training:**  
Diversity Supplement ([PA-18-837](#))

## *Technical Assistance Budget Allowance*

**Phase I- \$6,500/year**

**Phase II- \$50K**

Request in Application

If requested, cannot participate in NIH centralized TABA programs (e.g. Needs Assessment Program)

**Available Technical Assistance/Training:**

<https://sbir.nih.gov/tap>



## Strategy, Finance & Commercialization Experts:

<https://sbir.nih.gov/resources/entrepreneurs-in-residence/index.htm>



Sr. Regulatory Specialist  
Innovator Support Team Lead  
Chris Sasiela, PhD



Ethel Rubin, PhD



John Sullivan, MBA



Steve Wolpe, PhD

Entrepreneurs-in-Residence



## Partnering Opportunities and Pitch Coaching:



ANGEL CAPITAL ASSOCIATION



## 21<sup>st</sup> Annual HHS Small Business Program Conference

April 27-29, 2021 | Las Vegas, Nevada

<https://www.unlv.edu/econdev/hhsconf2021>



# Get Connected

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[sbir@od.nih.gov](mailto:sbir@od.nih.gov)

[NIH Guide for Grants and  
Contracts](#)  
(weekly notification)



[Connect with Us](#)



# National Center for Advancing Translational Sciences



National Center  
for Advancing  
Translational Sciences

- Number of anticipated awards: 1-3
- Budget (total costs per award): Phase I: \$325,000 for 9-12 months; Phase II: \$2,000,000 for 2 years
- Fast Track proposals will not be accepted
- Goal: 020 - Development of Remote Rare Disease Patient Care Environment through Immersive Virtual Reality
- ***Phase I Activities and Expected Deliverables:***
  - An immersive virtual reality environment with a minimum of the following capabilities:
    - An avatar representation for remote patient- healthcare provider interaction.
    - A WebXR instance of the experience through the Unity Game Engine to enable usage on any VR device through the world-wide web.
    - Sensing capabilities to perform runtime health analytics for physician observation.
  - An analytics dashboard for patient- healthcare provider interpretation both in and outside of the virtual environment.
  - A method of personalized gamification for physician prescribed exercises.
  - Assemble appropriate expertise in their teams to meet statement of work goals, which could include clinicians, occupational therapists, physical therapists and other appropriate subject matter experts depending on the deliverables of the contract.
  - Provide NCATS with all data and materials resulting from Phase I Activities and Deliverables.

Please contact NCATS Contracting Officer, Rieka Plugge ([rieika.plugge@nih.gov](mailto:rieika.plugge@nih.gov)), if you have any questions about this topic.



- Number of anticipated awards: 1-3
- Budget (total costs per award): Phase I: 325,000 for 9 months; Phase II: \$2,000,000 for 2 years
- Fast Track proposals will not be accepted
- Goal: 021 – Platform for Rapidly Deployable Autonomous Laboratory
- ***Phase I Activities and Expected Deliverables:***
- Develop a prototype Platform for Rapidly Deployable Autonomous Laboratory comprised of three components:
  - **Modular instrumentation**
    - Must be used in typical laboratory operations such as HTS, NGS, HCI, PCR, etc.
  - **A cloud based VRO that each distributed automated laboratory is directly connected to with the following core capabilities:**
    - Infrastructure; Data Storage, Access and Catalog; Data Extraction, Aggregation, Integration, and Harmonization; Secure Collaboration; Interoperability and Open Architecture.
  - **Integration of the physical laboratories with the virtual cloud environment to allow for:**
    - Federated AI and Machine Learning (ML) such that AI and ML methods can be utilized to generate hypotheses based on previous experiments that could then be tested in the physical laboratory environment.
    - Accessibility from external collaborator laboratories for use of the VRO and ability to remotely run experiments and process data into the VRO cloud environment
    - Adherence to appropriate safety protocols and procedures for physical control is mandatory of the above requirement within the VRO for anyone to be able to remotely control instrumentation.
- Provide cost estimates to develop a proof of concept platform capable of meeting the specifications listed above.
- Provide NCATS with all data resulting from Phase I Activities and Deliverables

Please contact NCATS Contracting Officer, Rieka Plugge ([rieke.plugge@nih.gov](mailto:rieke.plugge@nih.gov)), if you have any questions about this topic.



# National Cancer Institute (NCI) FY2021 Contracts

Questions about NCISBIR Contracts?

Ms. Rosemary Hamill

E-mail: [ncioasbir@mail.nih.gov](mailto:ncioasbir@mail.nih.gov)

*(Please reference solicitation PHS 2021-1 and the Topic number with any questions.)*

Check Individual Contract Topics:

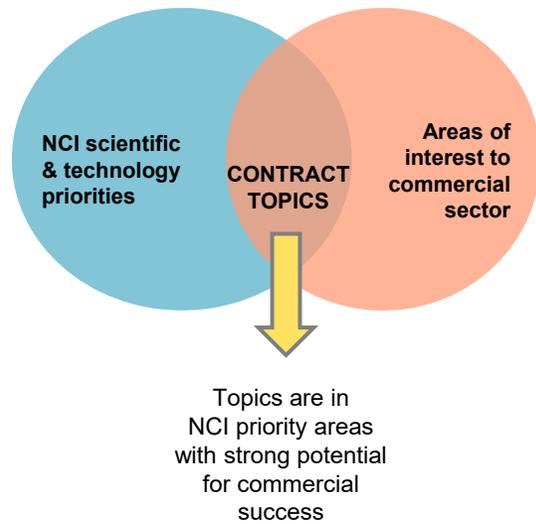
<https://sbir.cancer.gov/funding/contracts/currentcontracts>

**SBIR**

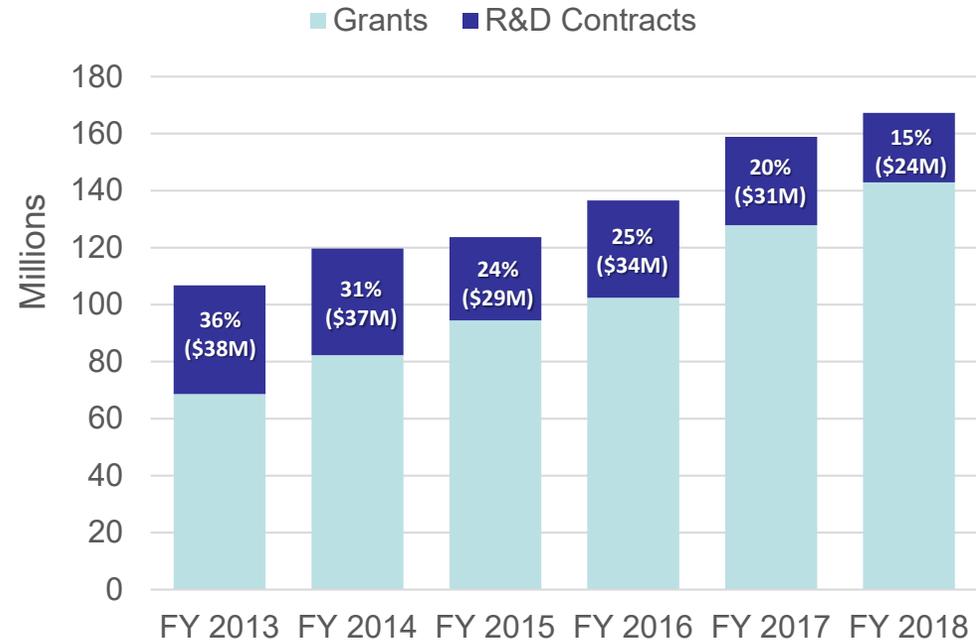
DEVELOPMENT CENTER



# NCI SBIR Contracts



Contracts in NCI SBIR Portfolio



# CONTRACTS FY2021 – NIH/NCI TOPICS

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	Topic Title
NIH/NCI 413	Yes		Next Generation 3D Tissue Culture Systems with Tertiary Lymphoid Organs
NIH/NCI 414	No	Yes	Synthetic Biology Gene Circuits for Cancer Therapy
NIH/NCI 415	Yes		Applicator-Compatible Electronic Brachytherapy Sources for Cancer Radiotherapy
NIH/NCI 416	Yes	Yes	Self-Sampling Devices for HPV-Testing-Based Cervical Cancer Screening
NIH/NCI 417	Yes		Quantitative Imaging Software Tools for Cancer Diagnosis and Treatment Planning
NIH/NCI 418	Yes		3D Spatial Omics for Molecular and Cellular Tumor Atlas Construction
NIH/NCI 419	Yes		Understanding Cancer Tumor Genomic Results: Technology Applications for Providers
NIH/NCI 420	No		Single-Cell “Unbiased Discovery” Proteomic Technologies
NIH/NCI 421	Yes		Quantitative Biomimetic Phantoms for Cancer Imaging and Radiation Dosimetry
NIH/NCI 422	Yes		Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research and Precision Medicine
NIH/NCI 423	Yes		Software to Address Social Determinants of Health in Oncology Practices
NIH/NCI 424	Yes		Digital Tools to Improve Health Outcomes in Pediatric Cancer Survivors
NIH/NCI 425	Yes		Information Technology Tools for Automated Analysis of Physical Activity, Performance, and Behavior from Images for Improved Cancer Health
NIH/NCI 426	Yes		Tools and Technologies for Visualizing Multi-Scale Data
NIH/NCI 427	No		De-Identification Software Tools and Pipelines for Cancer Imaging Research
NIH/NCI 428	Yes		Cloud-Based Multi-Omic and Imaging Software for the Cancer Research Data Commons
NIH/NCI 429	Yes		Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-Based Therapies

# NIH/NCI 413: Next Generation 3D Tissue Culture Systems with Tertiary Lymphoid Organs

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 413	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal is to advance the development of next generation 3D tissue/tumor cell culture systems that develop and maintain self-assembled Tertiary Lymphoid Organs (TLOs) for months. The solicitation will focus on the development of 3D tissue cultures that contain self-assembling TLOs with key morphological and functional characteristics, such as B cell and T cell zones. Offerors will be required to interrogate the functional aspects of the TLOs including tumor antigen presentation by DCs within the TLO, and activation and expansion of T cells and B cells. It includes establishing a 3D culture system representing at least one tumor type and develop 3D cultures from multiple donors.

## Phase I Activities and Deliverables Include:

- Identify appropriate cell types needed to create the 3D systems
- Create the 3D systems with TLOs representing at least one cancer type (such as pancreas, breast, prostate, lung, colon or liver)
- Show that the 3D systems can be developed reproducibly, by showing that the developed systems maintain genotypic and phenotypic characteristics for given time period.
- Characterize different types of immune and accessory cells in the 3D system

# NIH/NCI 414: Synthetic Biology Gene Circuits for Cancer Therapy

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 414	No	Yes	3-5	Phase I – 400K up to 9 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. It includes 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 415:Applicator-Compatible Electronic Brachytherapy Sources for Cancer Radiotherapy

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 415	Yes	No	1-3	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

This contract solicitation seeks to stimulate research, development, and commercialization of innovative devices to replace and enhance the radiation space currently occupied by radioactive sources in brachytherapy. The offerors should develop an appropriate electronic device and control system to allow integration into the clinic. Measure and define the radiation characteristics of this device. And finally validate that the planned (final) device will be deployed in a clinical setting using existing brachytherapy devices (applicator sets). Devices must be able to move around curves and cannot depend on waveguides.

## Phase I Activities and Deliverables Include:

- Develop a fully functional prototype that can be used with existing HDR medical devices (tandems, rings, sarcoma catheters, partial breast devices).
- Confirm that the device delivers dose at an energy and dose rate required of this announcement
- Demonstrate device stability in a model (phantom) of clinical use
- Develop SOPs to confirm dose delivery/validation of device function and stability.
- Perform *in vitro* efficacy studies in relevant cancer cell line(s) with normal tissue and standard brachytherapy source device controls.

# NIH/NCI 416: Self-Sampling Devices for HPV-Testing-Based Cervical Cancer Screening

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 416	Yes	Yes	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The overall goal of the contract solicitation is to facilitate the commercial development and regulatory approval pathway for novel self-sampling devices for HPV-testing-based cervical cancer screening. In particular, companies are expected to propose designing and manufacturing of devices for self-collection and transport/storage of cervicovaginal specimens and to demonstrate their clinical accuracy with a goal to seek FDA clearance via the 510(K) pathway.

## Phase I Activities and Deliverables Include:

- Using user-centric design principles, develop the prototype self-sampling device, transport media and shipment kits for evaluation.
- Conduct studies to establish analytical performance
- Conduct studies to evaluate and test user acceptability and feasibility in both intended use populations
- Conduct initial clinical testing with at least one of the current FDA-approved HPV testing assays to determine the clinical performance measures

# NIH/NCI 417: Quantitative Imaging Software Tools for Cancer Diagnosis and Treatment Planning

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 417	Yes	No	2-3	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

Quantitative imaging software tools developed in academic settings are typically developed for specific research purposes and are often validated only within the home institution. However, for such software tools to become widely useful in the clinical oncology community, the tools require rigorous validation at multiple sites, and with dynamic interplay between the tool developer and the clinician end users. The goal of this solicitation is to support commercial development by small businesses of new, or existing quantitative imaging (QI) software tools with utility to radiologists who rely on patient medical images for accurate cancer diagnosis and radiation treatment planning.

## Phase I Activities and Deliverables Include:

- Build Alpha software prototype
- Evaluate Alpha software performance via retrospective analysis of deidentified medical image data sets
- Refine software as needed, and repeat software evaluation via retrospective analysis of deidentified medical image data sets
- Perform small-scale Usability testing, requiring a minimum of 10 end users at 5 different sites

# NIH/NCI 418: 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)	
NIH/NCI 418	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal is to advance the development and dissemination of imaging workflows capable of omics-level measurements in thick tissue resections or whole biopsy cores that can scale for use in atlas building initiatives. Proposals should enable interrogation in a manner that combines high resolution (preferably single-cell) -omics level data (i.e. genomics, 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:

- Define relevant use cases for the technology including, but not limited to, what tissues can be analyzed, what imaging resolution can be expected, what -omic measurement(s) will be completed, desired throughput of the system, and identification of benchmark technologies.
- Prepare a report that specifies quantitative technical and commercially relevant milestones that can be used to evaluate the success of the technology versus current state-of-the-art 3D high resolution imaging platforms.
- Generate proof-of-concept dataset that addresses the use case above 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.
- Develop and provide preliminary Standard Operating Procedures for system use, including a validated list of reagents addressing the use case identified above.

# NIH/NCI 419: Understanding Cancer Tumor Genomic Results: Technology Applications for Providers

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 419	Yes	No	2-3	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal is to design and develop tools, technologies, or products to: (i) inform oncologists and other health care providers treating cancer patients in settings with low access to genetic counselors about NGS testing and current NCCN guidelines, (ii) help such providers evaluate the need for NGS somatic testing for their cancer patients, (iii) assist providers with interpretation of NGS results (including distinguishing between somatic and incidental germline findings), and (iv) help providers communicate NGS results to their patients.

## Phase I Activities and Deliverables Include:

- Conduct or utilize formative/exploratory research during the trial period to identify barriers and facilitators faced by oncology providers in staying up to date regarding genetic testing best practices and regulations, understanding test results, and accessing counseling resources based on currently available platforms for genetic counseling.
- Develop a prototype tool or technology based on formative research, to explain to oncology providers the basis for somatic testing and the meaning of test results.
- 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 oncology care providers and patients and providing written report and recommendations on the best practices for use of the tool in research and practice settings.

# NIH/NCI 420: Single-Cell “Unbiased Discovery” Proteomic Technologies

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Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 420	No	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The short-term goal of this concept is to stimulate the development of unbiased (i.e. untargeted) discovery proteomic technologies with the capacity to identify proteins in a single cell with a typical size (~10 µm in diameter). The mid-term goal is to provide efficient research tools with the ability to generate more complete and accurate human cancer proteome information without relying on antibodies or inferring proteomes from mRNA sequencing. The long-term goals also include providing efficient clinical tools for precision medicine by matching patients to therapies based on their proteomic results from clinically relevant samples.

## Phase I Activities and Deliverables Include:

- Benchmark the new technology against existing approaches.
- Provide an analytical validation report that describes the studies performed for analytical validation of your technology and its performance characteristics
- Address signal-to-noise issues by evaluating and interpreting “noise” of the measurements.
- Deliver detailed SOPs related to the sample preparation and sequencing protocols used for your single-cell proteomic technology to NCI for evaluation.
- Describe the potential pitfalls of the experimental measurements.
- Develop a proof-of-principle prototype.

# NIH/NCI 421: Quantitative Biomimetic Phantoms for Cancer Imaging and Radiation Dosimetry

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 421	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal of this concept is to stimulate growth in development of scalable quantitative tissue-equivalent technologies that would benefit patients who rely on cancer imaging modalities for diagnosis, dosimetry, and treatment. By prompting availability of new commercialized “smart-phantoms,” the solicitation has potential to catalyze scientific discovery in the broader cancer community wherein these commercialized devices could be used by researchers traditionally without access to tissue engineering biomimetic technologies. Small business development of Quantitative Biomimetic Phantoms (QBP) as organ-specific surrogates have potential to accelerate computational testing of sequences and algorithms to derive new quantitative radiomic and dosimetric data from cancer patients.

## Phase I Activities and Deliverables Include:

- Define the cancer imaging modality or application(s) the QBP device(s) or combined device-computational approaches addresses (such as MRI, SPECT, CT, PET).
- Define the tissue type(s) or organ site(s) the QBP device is intended to simulate.
- Define the key tissue type or organ specific physical characteristics the QBP device is intended to simulate.
- Generate proof-of-concept data that demonstrate the means to objectively detect, measure, and spatially resolve imaging probe(s) in the context of the QBP device’s tissue-equivalent environment(s) using the respective cancer imaging scanner(s).

# NIH/NCI 422: Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research and Precision Medicine

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 422	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The short-term goal of this concept is to stimulate the development of technologies that generate sequence information from slides without losing the histological context of the targets. The long-term goal is to provide research and/or clinical tools to improve cancer early detection, diagnosis, prognosis for precision medicine. Such tools can be used to identify location of aggressive/mutated clones within the tumor; differentiate between the center and infiltrating edges of the tumor; find correlation between molecular changes and cytology or atypia; evaluate molecular changes in the stroma infiltrated by the tumor verse stroma outside the tumor; and discover epithelial mesenchymal transition.

## Phase I Activities and Deliverables Include:

- Demonstrate sensitivity, resolution, reliability, robustness and usability in basic and/or clinical cancer research.
- If it is for RNA sequencing, it should be able to reveal RNA splicing and post-transcriptional modifications (e.g. methylation) while preserving their spatial context.
- For DNA sequencing it should indicate how the sequence information is being used to determine Single Nucleotide Variation (SNV), Copy Number Variation (CNV), Methylation patterns, Gene rearrangements/translocations, Microsatellite Instability etc. while preserving the spatial context
- Develop a computational platform to visualize spatial sequencing information.
- Provide the technology workflow and a working protocol, including the instrumentation, reagents and time needed for running samples, as well as estimations on speed of data generation and analysis.

# NIH/NCI 423: Software to Address Social Determinants of Health in Oncology Practices

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 423	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal of this concept is to solicit proposals that develop and evaluate software to address Social Determinants of Health (SDH) in oncology practices. The software will be cancer-specific and developed in close collaboration with oncology practices. The software should be designed to support and enhance existing clinical workflows and reduce the burden of SDH data collection and synthesis in care settings. It will support appropriate evidence-based clinical actions, including referral, to address identified patient needs. The software will meet current IT interoperability standards, using FHIR (Fast Healthcare Interoperability Resources) when feasible, and privacy standards.

## Phase I Activities and Deliverables Include:

- Conduct a focused environmental scan of existing software to screen and address SDH, as well as a targeted literature review on the accuracy of screening instruments and effectiveness of interventions for identified patients.
- Conduct key informant interviews with members of at least two oncology practices to understand what is currently being done to address SDH, how IT systems are currently configured, how SDH data are collected and analyzed, and how new software would help.
- Develop a prototype of the software.
- Conduct pilot usability testing of the prototype

# NIH/NCI 424: Digital Tools to Improve Health Outcomes in Pediatric Cancer Survivors

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 424	Yes	No	2-4	Phase I – 251,131 up to 9 months	Phase II – 1,680,879 up to 2 years

## Goal:

The goal of this solicitation is to stimulate the development and evaluation of innovative digital tools (software, database systems, digital platforms and/or mobile applications) that are integrated with existing EHRs or other clinical IT systems and that support delivery of patient-centered, coordinated, high-quality care to pediatric cancer survivors. To accomplish these goals, the offerors should build a system/tool/app with one of the following two capabilities: 1. Creation and implementation of survivorship care plans or, 2. Integration of accountability tools, checklists, and reminders that improve follow-up care adherence and clinical workflow.

## Phase I Activities and Deliverables Include:

- Perform an environmental scan of relevant, existing software systems and apps designed to support the delivery of pediatric survivorship care, especially during the transitions of care, and identify major gaps that need to be addressed.
- Conduct a small number of key informant interviews with childhood and adolescent cancer survivors, adult caregivers, pediatric oncology providers, and primary care providers to further refine and prioritize areas of unmet needs.
- Develop a functional prototype of the tool
- The information management tool (dashboard or other innovative tool) needs to have a either patient/caregiver-facing and/or clinician-facing interface and the ability to download and upload relevant information as it becomes available.

# NIH/NCI 425: Information Technology Tools for Automated Analysis of Physical Activity, Performance, and Behavior from Images for Improved Cancer Health

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 425	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

This SBIR contract topic is designed to attract proposals for new and innovative image analysis tools to extract information concerning physical activity, performance and behavior. Each of these interrelated elements of human action have distinct associations with health and health monitoring needs. The long-term goal of the project is to develop software that can automatically extract data from images concerning people and their activities. Data from already available algorithms could help multiple aspects of cancer prevention and control from primary prevention such as improved evaluation of interventions to encourage physical activity, to enhanced epidemiological studies, to automation in monitoring of symptoms and response to treatment for disease affecting physical performance, to improved compliance with cancer treatments or physical rehabilitation regimens. This interplay could advance health research and lead to improved commercial products for diverse applications.

## Phase I Activities and Deliverables Include:

- Develop a precis of the proposed tool and carry out structured interviews or one or more focus groups aimed at defining specific subject matter needs.
- Create or identify an open access image data source
- Develop a functional prototype system
- Conduct a usability study with at least 15 users not affiliated with the study team and in several distinct user groups

# NIH/NCI 426: Tools and Technologies for Visualizing Multi-Scale Data

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Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 426	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal of this project is to promote development of technologies that allow integrative multi-scale data visualization to facilitate building and sharing of atlases. Potential tools or technologies include:

- Establish Web-based or containerized visualization tools that allow seamless traversal across scales of heterogenous or integrated datasets from genetic to molecular to cellular to tissue scales.
- Virtual Reality/Augmented Reality systems that let users manipulate multi-scale data in novel ways.
- Visualization tools/methods for intuitive display of high-dimensional multi-scale data and metadata.
- Tools that combine existing visualization sources to facilitate and construct multi-scale visualizations.

## Phase I Activities and Deliverables Include:

- Identify and define at least three scales of data (Genomic; Molecular/subcellular; Cellular; Tissue; Individual patient; Population) that will be part of the visualization tool.
- Identify relevant use cases for the proposed tool and user communities the tool will support.
- Develop a viable product for visualizing multi-scale data capable of ingesting and visualizing the relevant data types, and carry out initial alpha-testing by the appropriate user communities.

# NIH/NCI 427: De-Identification Software Tools and Pipelines for Cancer Imaging Research

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 427	No	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The goal of this contract topic is to support development and sustainment of software tools and pipelines for image de-identification, specifically for images produced by radiologic and pathology imaging modalities. Within that goal, the following objectives should be met: 1) Removal of PHI from expected fields in multiple imaging formats, 2) Scanning for PHI in fields not designed for their insertion, identification and subsequent removal, 3) Scanning of imaging data for PHI and PII, identification, labeling and subsequent resolution, and 4) Produce processed images that meet a threshold level of de-identification.

## Phase I Activities and Deliverables Include:

- Identify different clinical imaging or WSI file types and the fields that contain PHI (i.e. conduct landscape analysis)
- Ability to recognize and open multiple clinical imaging or WSI file formats
- Display PHI field variable values
- Remove or alter PHI field values
- Produce a log of removed and altered PHI and PII parameters

# NIH/NCI 428: Cloud-Based Multi-Omic and Imaging Software for the Cancer Research Data Commons

Topic No.	Fast Track Allowed?	Direct to Phase II Allowed?	No. of Anticipated Awards	Budget (Max)	
NIH/NCI 428	Yes	No	3-5	Phase I – 400K up to 9 months	Phase II – 2M up to 2 years

## Goal:

The primary goal of this contract topic is to solicit commercial sector participation in the CRDC to develop strong commercial cloud-based analytic tools, specifically on multi-omics and/or imaging analysis, that can be disseminated and sustained within the cancer research community. To that end, leveraging of open standards to the extent that is possible is highly encouraged. The SBIR contract funding mechanism will offer the opportunity for small business participants to contribute solutions to address unmet challenges of big data analysis that are not currently provided by existing tools in the CRDC by developing and extending tools and resources to integrate into the rapidly evolving CRDC.

## Phase I Activities and Deliverables Include:

- Design specification for the development/extension of cloud-based informatics tools to operate in the Cancer Research Data Commons.
- Develop an early phase prototype.
- Demonstrate the feasibility of CRDC integration through DCF.
- Conduct a pilot usability testing by at least 25 users
- Provide a report on the results of the first round of usability testing and the approach to modify the prototype based on this user feedback.

# NIH/NCI 429: 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)	
NIH/NCI 429	Yes	No	2-4	Phase I – 400K up to 9 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 involve parallel processing (i.e., multiplexing) of individual cell-based therapies, although other approaches are encouraged. New technologies must produce cell-based products of equal or superior quality as compared to current manufacturing methods. In addition, the NCI encourages system design features that enable rapid and iterative customization to support bench-to-bedside-to-bench research.

## Phase I Activities and Deliverables Include:

- Establish assays and/or metrics, especially functional comparability and quality attributes, for benchmarking the approach against current manufacturing methods;
- 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 to manufacture a minimum of two cell products in parallel
- Demonstrate pilot-scale beta-testing of the approach comparing it against appropriate benchmarking technology

# NHLBI FY2021 SBIR Contract topics

To learn more about the SBIR program at NHLBI  
Contact: Dr. Mike Pieck [NHLBI\\_SBIR@mail.nih.gov](mailto:NHLBI_SBIR@mail.nih.gov)  
Or visit our website: [sbir.nih.gov/NHLBI](http://sbir.nih.gov/NHLBI)

For technical questions related to the contract topics  
Contact: Joanna Magginas : [magginaj@nhlbi.nih.gov](mailto:magginaj@nhlbi.nih.gov)



## Topic 111 Oxygen Delivery Device Innovations

- Fast-Track proposals will be accepted.
- Direct to Phase II proposals will be accepted
- Number of anticipated awards: 2 Phase I, 1 Phase II
- Budget (total costs):
  - Phase I: \$300,000 for 12 months
  - Phase II: \$2,000,000 for 24 months

### Project Goals

The goal of this project is to develop a lightweight, Portable Oxygen Device, with a continuous flow of oxygen of at least 5 liters per minute and provide pulsed oxygen at a rate equivalent to 5 liters per minute of continuous flow. Remote control of the device to allow adjustments without taking the POC off and allow for use on domestic and international travel.



## Topic 112 : Intramyocardial Suture Annuloplasty System (“MIRTH” and “SCIMITAR” devices)

Amended

- Fast-Track and Direct to Phase II proposals will be accepted.
- Number of anticipated awards: 1 Phase I; 1 Phase II
- Budget (total costs):
  - Phase I: \$400,000 for 12 months
  - Phase II: \$3,000,000 for 36 months

### Project Goals

- The project goal is to develop MIRTH (Mycocardial Intramural Restraint by endovenous interstitial ther) and SCIMITAR (Suture via Coronary sinus with Interstitial Mycocardial navlgation for Mitral and Tricuspid Annular Reduction) system implants and delivery catheters. The goals are to develop and commercialize specific catheter tools to accomplish a MIRTH and SCIMITAR annuloplasty. The tools work together as a suite of catheters.



National Institute of Allergy and Infectious Diseases

PROGRAM SOLICITATION PHS 2021-1

# FY21 SBIR Contract Topics

Presented By: Brigitte Sanders, DVM, PhD  
SBIR/STTR Coordinator  
Division of AIDS

NIAD



National Institute of  
Allergy and  
Infectious Diseases

# Summary of FY21 SBIR Contract Topics

- 087 Point-of-Care HIV Viral Load, Drug Resistance, and Adherence Assays**
- 088 Therapeutic Targeting of Intracellular HIV-1 Proteins or Nucleic Acids**
- 089 Particle-based Co-delivery of HIV Immunogens as Next-generation HIV Vaccines**
- 090 Sequence-based Assays to Quantify the Replication-Competent HIV Reservoir**
- 091 Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases**
- 092 Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases**
- 093 Production of Adjuvants Mimics**
- 094 Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models**
- 095 Improving Technologies to Make Large-scale High Titer Phage Preps**
- 096 Development of Priority Diagnostics for Chagas Disease**
- 097 Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis**
- 098 Group A Streptococcus Vaccine Development**
- 099 Rapid, Point-of-Care Diagnostics for Hepatitis C Virus**
- 100 Informatics Tools (Data Science Tools) for Infectious, Immune, and Allergic Research**



- **DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES (DMID)**

**095 Improving Technologies to Make Large-scale High Titer Phage Preps**

**096 Development of Priority Diagnostics for Chagas Disease**

**097 Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis**

**098 Group A Streptococcus Vaccine Development**

**099 Rapid, Point-of-Care Diagnostics for Hepatitis C Virus**



- **DIVISION OF AIDS (DAIDS)**

**087 Point-of-Care HIV Viral Load, Drug Resistance, and Adherence Assays**

**088 Therapeutic Targeting of Intracellular HIV-1 Proteins or Nucleic Acid**

**089 Particle-based Co-delivery of HIV immunogens as Next-generation HIV Vaccines**

**090 Sequence-based Assays to Quantify the Replication-Competent HIV Reservoir**

## **OFFICE OF DATA SCIENCE AND EMERGING TECHNOLOGIES**

**100 Informatics Tools (Data Science Tools) for Infectious, Immune, and Allergic Research**



- **DIVISION OF ALLERGY, IMMUNOLOGY, AND TRANSPLANTATION (DAIT)**
  - 091 Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases**
  - 092 Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases**
  - 093 Production of Adjuvants Mimics**
  - 094 Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models**



# NIAID Contracting Officer Contact

Please direct **all** inquiries regarding NIAID topics included in this solicitation to:

Charles H. Jackson, Jr.

Contracting Officer

Office of Acquisitions, DEA, NIAID

Phone: (240) 669-5175

Email: [Charles.Jackson@nih.gov](mailto:Charles.Jackson@nih.gov)



## SBIR Contract RFP Informational Webinar



Sean David Griffiths, MPH  
Small Business Innovation Research Program Manager  
Office of Science  
(SBIR Contract RFP PHS 2021-1)

August 11, 2020



## CDC - SBIR Contract RFP Informational Webinar (PHS 2021-1)

- Please read the contract solicitation and any future amendments to the solicitation.
- If you have questions after the 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 2021-1](#), and the CDC topic number, along with your specific question(s). Please also Cc: the CDC [SBIR@cdc.gov](mailto:SBIR@cdc.gov) e-mail address.



## 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 SBIR Program Overview

- Budget - CDC SBIR set-aside approximately \$10 million (FY20)  
Awards:  $\approx$  15-20 Phase I's up to \$243,500 each and  $\approx$  2-6 Phase II's per year up to \$1.0 M each
- CDC participates in both the SBIR HHS Omnibus Grant Solicitations ([PA-20-260 & 262](#)) and the HHS SBIR Contract Solicitation ([PHS 2021-1](#))
- CDC does not participate in the Small Business Technology Transfer (STTR) Program
- CDC does not participate in Fast Track, Direct to Phase II, Phase II B or CRP

## CDC's SBIR Program Overview

- Center for Preparedness and Response ([CPR](#)) –
  - (006) Developing Innovative Specimen Packaging Approaches to Improve Transit Success Rates
  
- National Center for Emerging Zoonotic and Infectious Diseases ([NCEZID](#)) –
  - (24) Device Development for Microbial Surface Sampling, Field Extraction and Collection
  - (25) Development of a Diagnostic Testing Platform to Assess Antibiotic Activity on Microbial Communities
  - (26) Intradermal Delivery of Human Rabies Vaccine Using Dissolvable Microneedles
  - (27) Interactive Phone-Based Video Game to Promote Handwashing Behavior Among Children
  
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention ([NCHHSTP](#)) –
  - (50) Agnostics Computer Vision Solution for Highly Integrated Robotic Platforms
  - (51) Microfluidics for Genetic and Serological Characterization of hepatitis C virus Infection



PROTECTING AMERICA'S SAFETY, HEALTH, AND SECURITY

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](mailto:SBIR@cdc.gov)  
OTI: 404-639-1330 or OTI@ CDC.gov  
[www.cdc.gov](http://www.cdc.gov); [www.cdc.gov/sbir](http://www.cdc.gov/sbir)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



**Wednesday, October 26, 2020**

**5:00 PM Eastern Daylight Time**

**Electronic submission must be complete**

**No paper submissions**

