Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

HHS SBIR Contract RFP Informational Webinar PHS 2020-1

August 7, 2019

NIH and CDC SBIR and Contracts Staff

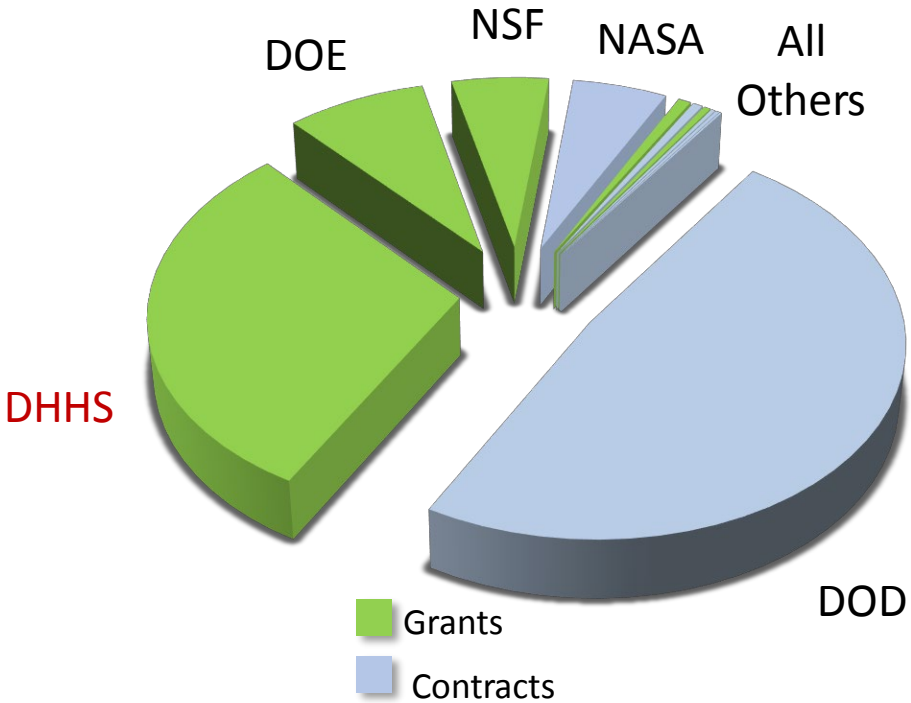
Hosted by Robert Vinson

NIH Office of Small Business, Education, and Entrepreneurship Development

Agenda

1. **Overview of SBIR and Contract RFP**
2. Differences from HHS SBIR grant program
3. Deadlines for Q&A and proposals
4. Electronic proposal submission with eCPS
5. Overview of topics
   - a. NCATS
   - b. NCI
   - c. NHLBI
   - d. NIAAA
   - e. NIAID
   - f. CDC/NCCDPHP
   - g. CDC/NCEH
   - h. CDC/NCEZID
   - i. CDC/NCIRD

SBIR/STTR Budgets by U.S. Agency, FY2018



~ $3.6 Billion in FY2018 across all agencies

SBIR · STTR
America's Seed Fund

5 AGENCIES WITH SBIR & STTR PROGRAMS	APPROX BUDGET
Department of Defense (DOD)	$ 1.750 B
Department of Health and Human Services (DHHS), including the National Institutes of Health (NIH)*	**$1.088 B**
Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)	$291.7M
National Science Foundation (NSF)	$ 202.4 M
National Aeronautics and Space Administration (NASA)	$198.0 M
6 AGENCIES WITH ONLY SBIR PROGRAMS	**APPROX BUDGET**
Department of Agriculture (USDA)	$27.0M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) & Countering Weapons of Mass Destruction Office (CWMD)	$20.8 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) & National Institute of Standards and Technology (NIST)	$14.2M
Department of Transportation (DOT)	$8.5 M
Department of Education (ED)	$7.5 M
Environmental Protection Agency (EPA)	$4.2 M

**DHHS also issues Contracts*

HHS Program Funding

2019 Budget	SBIR	STTR
NIH	$1B	$141M
CDC	~$12M	N/A
ACL (NIDILRR)	~$3M	N/A
FDA	~$1M	N/A

Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH SBIR/STTR 3-Phase Program

Discovery

Phase I

Phase I Feasibility Study

Budget Guide: $150K for SBIR and STTR
Project Period: 6 months (SBIR); 1 year (STTR)

Development

Phase II

Phase II Full Research/R&D

$1M for SBIR and STTR, over two years

Phase IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA
Many, but not all, IC's participate
Varies~$1M per year; up to 3 years

Commercialization

Phase III

Phase III Commercialization Stage

NIH, generally, not the "customer"
Consider partnering and exit strategy early

Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH SBIR/STTR Website

U.S. Department of Health & Human Services | National Institutes of Health

OER HOME | ABOUT GRANTS | FUNDING | FORMS & DEADLINES | GRANTS POLICY | ERA | NEWS & EVENTS | ABOUT OER

Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR·STTR America's Seed Fund

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

New to SBIR/STTR

NIH Technical Assistance Programs

CELEBRATING OVER 11 YEARS

Niche Assessment Program (NAP) | Commercialization Accelerator Program (CAP)

Technical Assistance Programs | Funding | Electronic Submission Process | Success Stories | Contact Us | Engage and Connect

What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.

In Fiscal Year 2016, NIH's SBIR and STTR programs will invest over 870 million dollars into health and life science companies that are creating innovative technologies that align with NIH's mission to improve health and save lives. A key objective is to translate promising technologies to the private sector and enable life-saving innovations to reach consumer markets.

HHS SBIR/STTR COMPONENT PROGRAM LINKS

NEWS

Early Bird Deadline Rapidly Approaching! Register today for the HHS SBIR/STTR Conference NEW
August 10, 2016

The September 6th SBIR/STTR Deadline is less than One Month Away
August 9, 2016

http://sbir.nih.gov

Solicitations and Due Dates

NIH, CDC, & FDA SBIR/STTR Grant Solicitation "Parent" FOAs:

https://sbir.nih.gov/funding#omni-sbir

Clinical Trial Required

SBIR: PA-19-273 **STTR:** PA-19-271

Clinical Trial Not Allowed

SBIR: PA-19-272 **STTR:** PA-19-270

Release Date: May 7, 2019
Standard Due Dates: September 5th (2019)
January 6th, April 6th (2020)

Contracts

SBIR Contract Solicitation (NIH, CDC) - OPEN
Closing Date: October 23, 2019 5:00PM EDT
Program Solicitation PHS 2020-1 (SBIR Only)

R&D Contract Solicitation: SBIR Phase I, Direct Phase II, Fast-Track Contract Solicitation, PHS 2020-1

Closing Date: October 23, 2019, 5:00PM EDT

PHS 2020-1 (PDF - 1 MB)

PHS 2020-1 (MS Word - 373 KB)

Contract Proposal Forms

NIH Guide Notice: NOT-OD-19-121
NIH Guide for Grants and Contracts
Release: Weekly receipt dates specified in each FOA

HHS SBIR Contract RFP Sources

NIH SBIR site: https://sbir.nih.gov/funding#phased1

R&D Contract Solicitation: SBIR Phase I, Direct Phase II, Fast-Track Contract Solicitation, PHS 2020-1

Closing Date: October 23, 2019, 5:00PM EDT

PHS 2020-1 (PDF - 1 MB)

PHS 2020-1 (MS Word - 373 KB)

Contract Proposal Forms

HHS SBIR Contract RFP Sources

NIH OER: Grants & Funding

https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm

NIH and CDC SBIR Contract Solicitation PHS 2020-1	PHS 2020-1	This is the Omnibus (Parent) Small Business Innovation Research Contract (SBIR) Program Solicitation Receipt date: October 23, 2019, 5PM EDT	Program Solicitation: PDF MS WORD **Forms for Phase I** Proposals: Appendices: **A** (PDF - 88 KB or MS Word - 31 KB **B** (PDF - 86 KB or MS Word - 30 KB), **C** (PDF - 124 KB or MS Word - 47 KB), **F** (PDF - 94 KB or MS Word - 26 KB) **H.1** (PDF - 281 KB) - Instructions for the Human Subjects and Clinical Trials Information Form **H.2** (PDF - 1.76 MB) - Human Subjects and Clinical Trials Information Form (*Note: File must be opened directly in pdf reader.) **H.3** (PDF - 1.48 MB) - Study Record Form, Attachment to the Human Subjects and Clinical Trials Information Form (*Note: File must be opened directly in pdf reader.)	Follow all instructions contained within PHS 2020-1 Program Solicitation. Appendices

HHS SBIR Contract RFP Sources

FedBizOpps:

https://www.fbo.gov/spg/HHS/NIH/NIAID/PHS-2020-1/listing.html

A SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTER FOR DISEASE CONTROL AND PREVENTION (CDC) FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS

Solicitation Number: PHS-2020-1
Agency: Department of Health and Human Services
Office: National Institutes of Health
Location: National Institute of Allergy and Infectious Diseases

Notice Details | Packages | Print

Complete View
- Original Synopsis
  Presolicitation
  Jun 21, 2019
  11:26 am
- Changed
  Jul 10, 2019
  9:21 am
  Solicitation

Return To Opportunities List | Watch This Opportunity | Add Me To Interested Vendors

Solicitation Number: PHS-2020-1

Notice Type: Solicitation

Synopsis:
Added: Jun 21, 2019 11:26 am

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) are soliciting proposals from small business concerns that possess the research and development (R&D) expertise to conduct innovative research that will contribute toward NIH or CDC mission needs and Small Business Innovation Research (SBIR) program objectives.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS), THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS INNOVATIVE RESEARCH (SBIR) PROGRAM SOLICITATION PHS-2020-1 is anticipated to be made **available on or around July 8, 2019**, through both FedBizOpps.gov and the NIH Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) funding web page at https://sbir.nih.gov/funding. This solicitation is anticipated to have **a closing date of October 23, 2019 for receipt of proposals.**

ALL FILES
- Solicitation 1
  Jul 10, 2019
  PHS_2020-1.pdf

GENERAL INFORMATION

Notice Type:
Solicitation

Original Posted Date:
June 21, 2019

Posted Date:
July 10, 2019

Response Date:
Oct 23, 2019 5:00 pm Eastern

Original Response Date:
Oct 23, 2019 5:00 pm

Archiving Policy:
Manual Archive

Original Archive Date:
-

Archive Date:
-

PHS 2020-1

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 2020-1

Closing Date: October 23, 2019, 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 23, 2019, 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 to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.

Overview of RFP

1 INTRODUCTION
2 PROGRAM DESCRIPTION
3 DEFINITIONS
4 PROPOSAL FUNDAMENTALS
5 CONTRACT REQUIREMENTS
6 METHOD OF EVALUATION
7 PROPOSAL SUBMISSION
8 PROPOSAL PREPARATION AND INSTRUCTIONS
9 HHS COMPONENTS ANTICIPATED NUMBER OF AWARDS
10 CONTRACTING OFFICER POINTS OF CONTACT
11 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES
12 COMPONENT INSTRUCTIONS AND TECHNICAL TOPIC DESCRIPTIONS
13 APPENDICES

#1 Piece of Advice

Read the entire RFP several times!!

Section 2.7 Awarding Components

- National Institutes of Health (NIH):
  - NCATS NCI NHLBI
  - NIAAA NIAID
- Centers for Disease Control and Prevention (CDC):
  - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
  - National Center for Environmental Health (NCEH)
  - National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)
  - National Center for Immunization and Respiratory Diseases (NCIRD)

Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

Types of SBIR Proposals Allowed Section 1 and 12

TOPIC NUMBER	PHASE I ALLOWED?	FAST TRACK ALLOWED? (A Phase I proposal and a Phase II proposal submitted simultaneously)	DIRECT TO PHASE II ALLOWED? (Includes only a Phase II Proposal)	TOPIC TITLE
NIH/NCI 408	Yes	Yes	No	Tools and Technologies for Visualizing Multi-Scale Data
NIH/NCI 409	Yes	Yes	No	Software for Automated Analysis of Images for Improved Cancer Health
NIH/NCI 410	Yes	Yes	No	Cancer Clinical Trials Recruitment and Retention Tools for Participant Engagement
NIH/NCI 411	Yes	Yes	No	De-Identification Software Tools for Cancer Imaging Research
NIH/NCI 412	Yes	Yes	No	Software Enabling Data Integration from Wearable Sensors for Cancer Patients
NIH/NHLBI 109	Yes	Yes	Yes	Transcatheter trileaflet tricuspid suture repair system
NIH/NHLBI 110	Yes	Yes	Yes	MRI myocardial biopsy system
NIH/NIAAA 018	No	Yes	Yes	Alcohol Biosensor Development for Continuous Alcohol Consumption Monitoring
NIH/NIAAA 019	Yes	No	No	Data Science Tools for Accelerating Alcohol Research
NIH/NIAID 076	Yes	Yes	No	Co-delivery and Formulation of Adjuvants for HIV Vaccine Development

SBIR Direct Phase II is back

- 2.4 **Direct to Phase II Proposals**

If a Topic notes that Direct to Phase II proposals will be accepted, a small business concern that has already performed Phase I stage-type research through other funding sources (not SBIR/STTR Phase I funding) may submit a Phase II only proposal.

2.5 iCorps at NIH Phase I Option

- Participating Components
  - All NIH awarding components (NCATS, NCI, NHLBI, NIAAA, and NIAID) only.
  - Any offeror submitting a proposal to a Topic falling under the above awarding components may include potential participation in the I-Corps™ at NIH program within its Phase I proposal.
  - To indicate interest, offeror must include a separate "Appendix C – Contract Pricing Proposal," in the Business Proposal. Specify "I-Corps" in the "Title of Proposal" field.
  - This separate budget must not exceed $55,000 in total direct costs – indirect costs may not be included.
    - $22,000 for course registration
    - Estimated 20hrs+/week during 8-week course

2.5 iCorps at NIH Phase I Option

I-CORPS at NIH

Entrepreneurship program for SBIR awardees

COURSE FORMAT

- Curriculum tailored to life sciences
- 3-Day Kick-off Event
- 6 Weekly web classes
- 2-Day Lessons Learned

THERAPEUTICS TRACK

THERAPEUTICS Expert

I-Corps Node Instructor

DIAGNOSTIC TOOLS TRACK

DIAGNOSTICS & eHEALTH Expert

I-Corps Node Instructor

MEDICAL DEVICES TRACK

MEDICAL DEVICE Expert

I-Corps Node Instructor

What is a complete Phase I submission? Section 8.3

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) * New last year

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)

What is a complete Phase II submission? Section 8.4

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) * New last year
- **BUSINESS PROPOSAL (1 PDF)**
- Item 3: Pricing Proposal (Appendix C)
- Item 4: SBIR Application VCOC Certification, if applicable
- Item 5: Proof of Reg. in the SBA Company Registry
- Item 6: Summary of Related Activities (Appendix F)

Human Subjects or Vertebrate Animal Work?

- 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) *

* New last year

Instructions for HS and Vertebrate Animal work

- Section 8.10 Research Involving Vertebrate Animals Instructions

- Section 8.12 – Human Subjects and Clinical Trials Information Form * New required form for ALL Submissions (even if you are **NOT** doing Human Subjects work or Clinical Trials)

Human Subjects and Clinical Trials Information Form

- Appendix H.1. - **INSTRUCTIONS**, HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

- Appendix H.2. – HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM. **This form must be included in every proposal.**

- Appendix H.3. – STUDY RECORD - If your project involves Human Subjects, even if the project is exempt from Federal Regulations H.3 is required.

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**.

- **Prospectively Assigned:** a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

- **Intervention:** a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

- **Health-related Biomedical or Behavioral Outcome:** the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.

Learn more at https://grants.nih.gov/policy/clinical-trials/definition.htm

Determine if Your Study is an NIH-defined Clinical Trial

Does your study…

1. Involve one or more **human participants**?
2. **Prospectively assign** human participant(s) to intervention(s)?
3. Intend to **evaluate the effect of an intervention** on human participants
4. Have a **health-related biomedical or behavioral outcome**?

If "yes" to ALL of these questions, your study is considered a clinical trial

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm

Clinical Trials Changes

Public Website on Clinical Trial Requirements

National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NE

Home » Policy & Compliance » Clinical Trial Requirements for Grants and Contracts

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight
- **Select Policy Topics**
  - Animal Welfare
  - Application Submission Policies
  - Clinical Trial Requirements
    - Clinical Trial Definition
    - Why the Changes
    - Good Clinical Practice
    - Specific Funding Opportunities
    - New Form
    - Single IRB Policy
    - Protocol Template
    - Registration and Reporting

Clinical Trial Requirements for Grants and Contracts

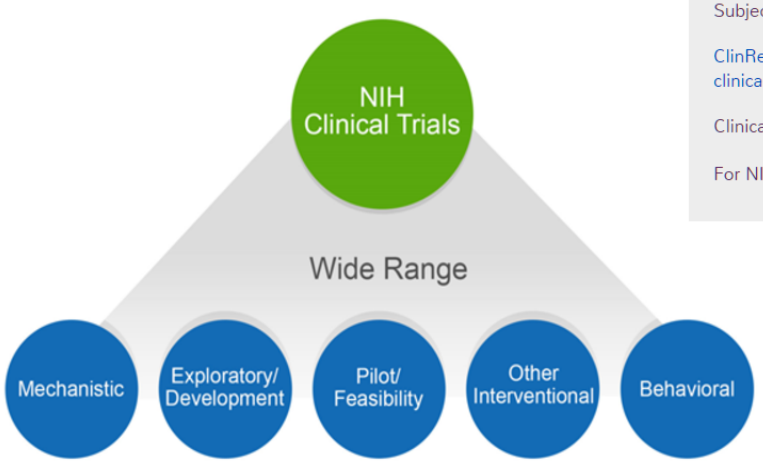
NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will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

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

FIND OUT HERE



Relate

- FAQs
- Training
- Research Subjects
- ClinRegs: clinical tri
- Clinicaltri
- For NIH S

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

HS and CT Form

PHS Human Subjects and Clinical Trials Information

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment | Delete Attachment | View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Page Limits Section 7.3

- **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

Agenda

1. Overview of SBIR and contract RFP
2. **Differences from HHS SBIR grant program**
3. Deadlines for Q&A and proposals
4. Electronic proposal submission with eCPS
5. Overview of topics
   - a. NCATS
   - b. NCI
   - c. NHLBI
   - d. NIAAA
   - e. NIAID
   - f. CDC/NCCDPHP
   - g. CDC/NCEH
   - h. CDC/NCEZID
   - i. CDC/NCIRD

Differences between SBIR Contracts and Grants

Contracts	Grants
Acquisition mechanism	Assistance mechanism
Follows FAR and SBIR Policy Directive	Follows Grants Policy and SBIR Policy Directive
NOT Investigator Initiated	Investigator Initiated
Narrow, well defined topics	Broad or narrow topics
RFP: Offeror: Contractor: Proposal	PA, PAR, RFA: Applicant: Grantee: Application
Only contact is Contracting Officer	Call Program Officer anytime for anything
eCPS – New (used to be on paper)	SF424, grants.gov, eRA Commons

Differences between SBIR Contracts and Grants

	Need to use for Contract?
SBIR Company Registry	Yes – for all offerors
VCOC Certification	Yes – if applicable
DUNS	Yes
SAM	Yes
Grants.gov	No
eRA Commons	No
Electronic Contact Proposal Submission (eCPS)	Yes – required to submit all proposals to PHS 2020-1

Agenda

1. Overview of SBIR and contract RFP
2. Differences from HHS SBIR grant program
3. **Deadlines for Q&A and proposals**
4. Electronic proposal submission with eCPS
5. Overview of topics
   - a. NCATS
   - b. NCI
   - c. NHLBI
   - d. NIAAA
   - e. NIAID
   - f. CDC/NCCDPHP
   - g. CDC/NCEH
   - h. CDC/NCEZID
   - i. CDC/NCIRD

Question Deadline Section 7.1

- Reminder only contact is with Contracting Officer (CO) listed in Section 10
- Questions must be submitted in writing (email) to the Contracting Officer
- **Deadline for Questions is August 27, 2019 - close of business**
- Q&A amendment will be issued in ~ early-mid September in FBO 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

Deadline for receipt of ALL Proposals

Wednesday October 23, 2019

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.

Agenda

1. Overview of SBIR and contract RFP
2. Differences from HHS SBIR grant program
3. Deadlines for Q&A and proposals
4. **Electronic proposal submission with eCPS**
5. Overview of topics
   a. NCATS
   b. NCI
   c. NHLBI
   d. NIAAA
   e. NIAID
   f. CDC/NCCDPHP
   g. CDC/NCEH
   h. CDC/NCEZID
   i. CDC/NCIRD

Electronic Submission of Proposals

- REQUIRED for ALL PROPOSALS
- Paper proposals no longer accepted
- Section 7.4 Submission, Modifications, Revision, and Withdrawal of Proposal

electronic Contract Proposal Submission (eCPS)

https://ecps.nih.gov

Registration for eCPS One Time PIN (OTP)

Want to submit a Proposal?

You must log in to submit proposals through eCPS.

Logging in with an **eCPS account** is recommended.

eCPS Login

If you do not have an eCPS account, you can **register for an eCPS account**.

Sign In

New User ? Register Here

If you are an existing user please enter your registered email below and click on the search button to look up your account.

Enter your registered email address

Having trouble finding your registered email? Contact Admin

Registration for eCPS One Time PIN (OTP)

User Registration

Email	email is required
Confirm Email	confirm email is required
First Name	first name is required
Middle Name	
Last Name	last name is required
Phone	phone number is required
Company	company name is required
Street Address	street address name is required
City	city name is required
State	State name is required
Zip	zip is required
Country	United States of America
i6plyu	enter the exact text as shown in the image

Continue

Back To Login

- Register email address.
- Auto-generated PIN goes to email.
- Enter PIN with email to log in.
- PIN refreshes every 8 hours.

Filter For SBIR

NIH electronic Contract Proposal Submission
National Institutes of Health

Welcome Kapsilis, Michael | Logout

All Active Solicitations | My Submission History | FAQ | How To Submit | About

Note: Lower versions of Internet Explorer are not supported by eCPS system. Please use Internet Explorer version 10 or higher, Google Chrome or Mozilla Firefox.

NIH/SAMHSA Contract Solicitations Available for Electronic Submission

The following table represents NIH/SAMHSA contract solicitations that are available for electronic proposal submission through eCPS. Please Note: Proposals will not be accepted through eCPS after the closing date and time. Potential offerors are instructed to go to FedBizOpps.gov for the full listing of active contract opportunities.

Search by Agency/Project:

○ All ○ NIH/SAMHSA ◉ SBIR/STTR

Search by Institute -- Select All -- Search

Show 100 entries

Search:

FedBizOpps.gov Solicitation	Notice Type	Title	Primary POC	Agency	Closing Date & Time [ET]	Action
PHS-2020-1	Solicitation	CDC/NCCDPHP 043 (Objective Measurement of Opioid Withdrawal in Newborns)	Outley, Jerry	CDC/NCCDPHP	10/23/2019 05:00 PM	Submit
PHS-2020-1	Solicitation	CDC/NCEH 002 (Web-Based Platform for Flooding Vulnerability and HealthCare Access)	Bish, Dale	CDC/NCEH	10/23/2019 05:00 PM	Submit
PHS-2020-1	Solicitation	CDC/NCEZID 021 (Assay to Detect and Quantify E. Coli O157 in Water Samples)	Turner, Priscilla	CDC/NCEZID	10/23/2019 05:00 PM	Submit
PHS-2020-1	Solicitation	CDC/NCEZID 022 (Device Development for Microbial Surface Sampling Field Extraction and Collection)	Turner, Priscilla	CDC/NCEZID	10/23/2019 05:00 PM	Submit
PHS-2020-1	Solicitation	CDC/NCEZID 023 (Diagnostic Testing Platform to Assess Antibiotic Communities of Cystic Fibrosis)	Turner, Priscilla	CDC/NCEZID	10/23/2019 05:00 PM	Submit
PHS-2020-1	Solicitation	CDC/NCIRD 034 (Accelerating Time to Detection of Legionella in Environmental Samples)	Hoxhaj, Pellumbeshe	CDC/NCIRD	10/23/2019 05:00 PM	Submit
PHS-2020-1	Solicitation	NIH/NCATS 019 (Alternatives to commercially	Adams, Jessica	NIH/NCATS	10/23/2019 05:00 PM	Submit

Solicitation Information

Solicitation Number	PHS-2020-1
Solicitation/Topic Title	NIH/NCATS 019 (Alternatives to commercially available cell culture insert membranes and manufacturing techniques)
Closing Date and Time	10/23/2019 05:00 PM [ET]

Your Contact Information

Vendor	NIH
Name	Kapsilis, Michael
Email	
Phone	

View Contact

** Denotes required fields*

Proposal Name *

Proposal Name

Proposal Documents

Max File Upload Size: 387.19 MB

Technical Document PDF *

Select file

PHS Human Subjects and Clinical Trials Document PDF (Upload the Human Subjects and Clinical Trials Information Form as required in this solicitation. Refer to your solicitation inst more information)

Select file

Business Document PDF *

Select file

Business Document Excel (Upload excel if required by the solicitation instructions. You may upload multiple excel files)

Select file(s)

Submit Proposal | Close

Proposal Names in the eCPS "Proposal Name" field

- The Proposal Name you enter in eCPS shall include:

- Proposal Name Format
  1) The phase the proposal is for
  2) The name of the offeror
  3) The NIH or CDC awarding component
  4) The topic being proposed under

- Name Format Sample: Phase I_XYZ Company_NIAID_Topic 050

Technical and Business File Names

- Shall include
  - Offeror name
  - NIH or CDC awarding component
  - Topic being proposed under
  - Type of proposal (i.e., Technical, Human Subjects and Clinical Trial, Business or Excel Workbook)
- Technical Proposal sample name
  - XYZ Company_NIAID_TOPIC_050_Technical.pdf
- Human Subjects and Clinical Trials Information Form sample name
  - XYZ Company_NIAID_TOPIC_050_HumanSubjectsForm.pdf
- Business Proposal sample name
  - XYZ Company_NIAID_TOPIC_050_Business.pdf
- Excel Workbook (optional)
  - XYZ Company_NIAID_TOPIC_050_Business.xlsx

How do I submit a FAST TRACK Proposal?

For Phase I – include "FAST TRACK" after the Phase. Example:

- Phase I FAST TRACK_XYZ Company_NIAID_Topic_050

Upload the Phase I technical and business proposals and click Submit

After Phase I submission, click "Submit new/alternate proposal" button

For Phase II – include "FAST TRACK" after the Phase. Example:

- Phase II FAST TRACK_XYZ Company_NIAID_Topic_050

Upload the Phase II technical and business proposals and click Submit

Agenda

1. Overview of SBIR and contract RFP
2. Differences from HHS SBIR grant program
3. Deadlines for Q&A and proposals
4. Electronic proposal submission with eCPS
5. **Overview of topics**
   - a. NCATS
   - b. NCI
   - c. NHLBI
   - d. NIAAA
   - e. NIAID
   - f. CDC/NCCDPHP
   - g. CDC/NCEH
   - h. CDC/NCEZID
   - i. CDC/NCIRD

NCATS Topic #019: Alternatives to commercially available cell culture insert membranes and manufacturing techniques

Number of anticipated awards: 1-3

Budget (total costs, per award): Phase I: $225,000 for 9 months; Phase II: $1,500,000 for 2 years

Fast Track proposals will not be accepted

Goal: The goal of this project is to identify potential new biodegradable membranes that can be used to create cell culture insert plates (CCIPs).

Phase I Activities and Expected Deliverables:

- Develop a prototype CCIP that has the following features:
  - Adheres as closely as possible to current ANSI/SLAS Microplate
  - Utilizes membranes that have the following properties:
    - Biocompatibility with tissue culture environments
    - Biodegradability within a time period between 2-6 weeks
    - Suitable for cellular health and function for long term experiments (1+ month)
- Incorporates a ridge or a cap on the underside of the insert such that it extends below the bottom of the membrane and ideally matches the inner diameter of the well wall.
- Has at a minimum a 6 well density as a proof of concept
- Identify a tissue model to use as a standard to validate the functionality of the produced part
- Cost estimates to manufacture a device capable of meeting the specifications listed above
- Provide NCATS with all data resulting from Phase I Activities and Deliverables

Please contact NCATS Contracting Officer, Jeffrey Schmidt (Jeffrey.schmidt@nih.gov), if you have any questions about this topic.

NIH
National Center for Advancing Translational Sciences

NATIONAL CANCER INSTITUTE (NCI)

Questions About NCI SBIR Contracts?

Ms. Tiffany Chadwick

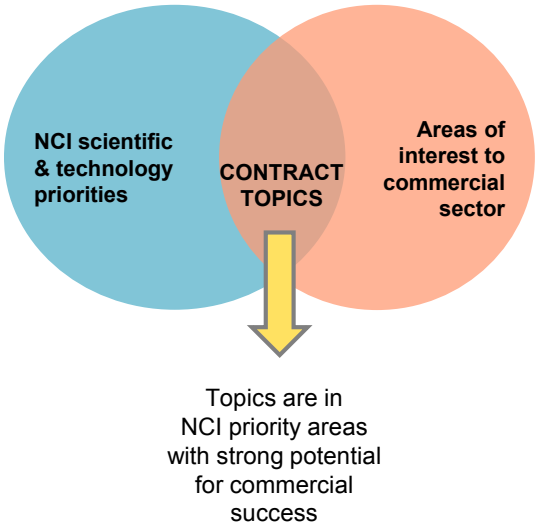
ncioasbir@mail.nih.gov

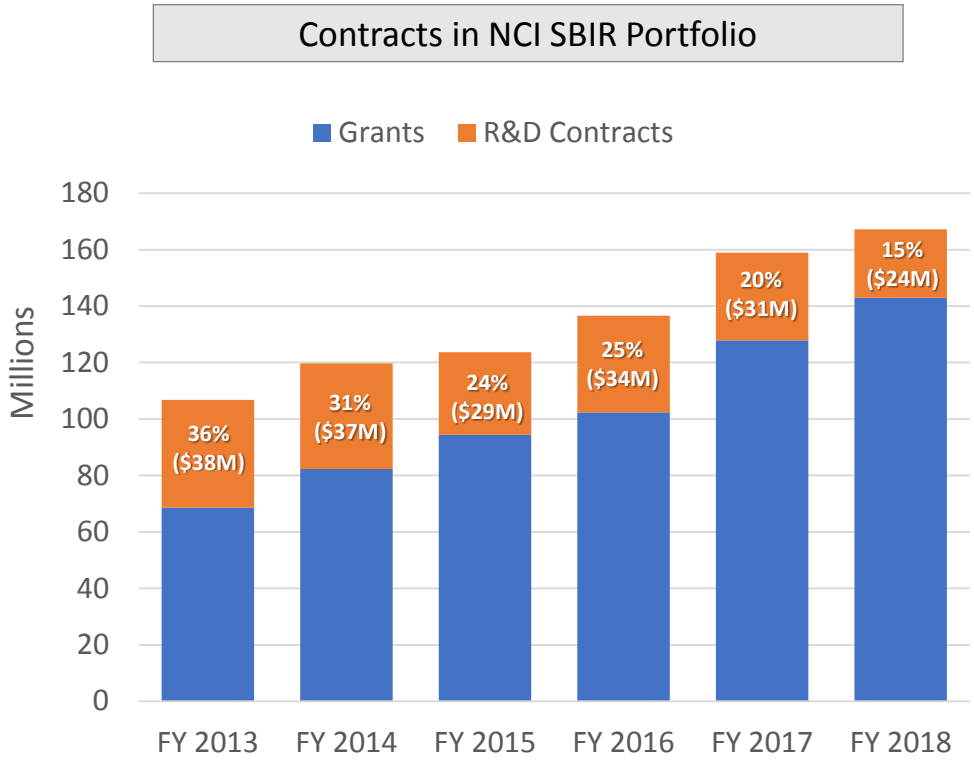
Please reference solicitation PHS 2020-1 and the Topic number with any questions.

http://sbir.cancer.gov/funding/contracts/

NATIONAL CANCER INSTITUTE
SBIR
DEVELOPMENT
CENTER

CONTRACT TOPICS





FY2020 NCI CONTRACT TOPICS

Topic Title
NIH/NCI 397: Manufacturing Innovation for the Production of Cell-Based Cancer Immunotherapies
NIH/NCI 398: Development of Senolytic Agents for Cancer Treatment
NIH/NCI 399: Combinatory Treatment Utilizing Radiation to Locally Activate Systemically Delivered Therapeutics
NIH/NCI 400: Sensing Tools to Measure Biological Response to Radiotherapy
NIH/NCI 401: Quantitative Biomimetic Phantoms for Cancer Imaging
NIH/NCI 402: Artificial Intelligence-Aided Imaging for Cancer Prevention, Diagnosis, and Monitoring
NIH/NCI 403: Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research
NIH/NCI 404: Subcellular Microscopy and -Omics in Cancer Cell Biology
NIH/NCI 405: Intra-Tumor Sensing Technologies for Tumor Pharmacotyping
NIH/NCI 406: Software for Patient Navigation Through the Cancer Care Continuum
NIH/NCI 407: Cloud-Based Software for the Cancer Research Data Commons
NIH/NCI 408: Tools and Technologies for Visualizing Multi-Scale Data
NIH/NCI 409: Software for Automated Analysis of Images for Improved Cancer Health
NIH/NCI 410: Cancer Clinical Trials Recruitment and Retention Tools for Participant Engagement
NIH/NCI 411: De-Identification Software Tools for Cancer Imaging Research
NIH/NCI 412: Software Enabling Data Integration from Wearable Sensors for Cancer Patients

*Fast Track proposals **WILL** be accepted for all topics. Direct-to-Phase II proposals will **NOT** be accepted.*

NIH/NCI 397 – Manufacturing Innovation for the Production of Cell-Based Cancer Immunotherapies

Fast Track	# of anticipated awards	Budget (max)	
Accepted	2 - 4	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to facilitate the development of innovative methods and technologies capable of improving and modernizing product manufacturing processes for cell-based cancer immunotherapies. This includes the use of autologous, allogeneic, or pluripotent cells. Offerors are strongly encouraged to establish collaborative relationships with clinical product development companies focused on the development of specific cell-based products. It is expected that offerors will demonstrate the utility of their innovation(s) in the context of at least one cell-based product, which is representative of a particular class of cell-based cancer immunotherapies.

Phase I Activities and Deliverables Include:

- Develop a device/technology/process to improve production of cell-based cancer immunotherapies (e.g., CAR-T cells, adoptive T-cells, NK cells).
- Demonstrate feasibility and reproducibility of the device/technology/process.
- Demonstrate suitability of the device/technology/process to improve manufacturing metrics.
- Conduct pilot beta-testing with appropriate specifications for chosen cell-based immunotherapy.

NIH/NCI 398 – Development of Senolytic Agents for Cancer Treatment

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 4	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to support the pre-clinical development of senolytic agents for use in neoadjuvant and/or adjuvant/combination cancer therapy. Offerors should focus on the optimization of the senolytic agent, or combinations, and demonstrate proof-of-concept by showing selective elimination of senescent cells and benefits in terms of efficacy and/or reduction of side effects when combined with treatments (e.g., chemotherapy or radiotherapy) in human cancer-relevant animal models. Offerors should provide a justification and rationale for their choice of animal model for the proof-of-concept studies.

Phase I Activities and Deliverables include:

- Demonstrate in vitro efficacy for the agent(s) in human cancer-appropriate models.
- Conduct structure-activity relationship studies, medicinal chemistry, and/or lead biologic optimization.
- Optimize formulation of senolytic agent(s) (as appropriate).
- Perform animal efficacy studies in an appropriate animal model for cancer therapy-induced senescence and determine whether senolytic agent(s) confer benefits with respect to side effects and/or cancer therapy efficacy.

NIH/NCI 399 – Combinatory Treatment Utilizing Radiation to Locally Activate Systemically Delivered Therapeutics

Fast Track	# of anticipated awards	Budget (max)	
Accepted	2 - 4	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to stimulate research, development, and commercialization of innovative techniques that could synergistically improve the effectiveness of radiation therapy and therapeutic agents or auger emitters to reduce toxicity to normal tissues. Proposals addressing the following areas are encouraged: new treatment strategies, design/synthesis/evaluation of innovative therapeutic agents, or development of new drug formulations (e.g., nanoformulations). Proposals in the following areas will not be considered responsive: development of radiation sensitizers, new instrumentation for triggering release of therapeutic agent, or treatment strategies that do not involve delivery of external radiation.

Phase I Activities and Deliverables include:

- Demonstrate expected release/activation action in vitro and in vivo by safe doses of radiation.
- Demonstrate (if appropriate) tumor-specific targeting/localization of the therapeutic agent and activation of the therapeutic agent only after exposure to radiation.
- Conduct pilot animal pharmacokinetic/pharmacodynamic studies.
- Significantly characterize the chemistry/purity of the therapeutic agent and chemistry of the reaction.

NIH/NCI 400 – Sensing Tools to Measure Biological Response to Radiotherapy

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to develop in vivo or in vitro sensor tools to measure biologic response to radiation, specifically, to help to redefine dose from solely the traditional physical dose to include the additional dimension of biological response. These sensors should facilitate the development and study of precision radiation oncology, and can be used alone, in combination, in the body, or outside of the body. Ideally, these sensors should generate response via CT or MRI to allow non-invasive dynamic and real-time data collection. The development and evaluation of sensor systems that can measure in a validated fashion biologic response to physical dose from radiation therapy will be preferred. Nanotechnology-based sensors are encouraged.

Phase I Activities and Deliverables include:

- Develop a sensor to measure biologic response to radiation.
- Demonstrate sensor stability in vitro and perform in vitro efficacy studies in relevant cancer cell line(s) and in normal tissue(s).
- Perform a small in vivo efficacy study in animal model systems to evaluate appropriate endpoints.

NIH/NCI 401 – Quantitative Biomimetic Phantoms for Cancer Imaging

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to stimulate growth in development of scalable quantitative tissue-equivalent technologies that would benefit patients who rely on cancer imaging modalities for diagnosis and treatment. Activities that fall within the scope of this solicitation include development and application of Quantitative Biomimetic Phantom (QBP) devices that represent or simulate specific tissue types or organ sites. QBP devices are to provide 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 either single- or multi-modal cancer imaging scanner systems.

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.
- Generate proof-of-concept data and demonstrate feasibility of the QBP device as a calibrated quantitative analysis tool.

NIH/NCI 402 – Artificial Intelligence-Aided Imaging for Cancer Prevention, Diagnosis, and Monitoring

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The goal of this solicitation is to call for development of AI-aided imaging software for cancer prevention, diagnostics, prognostics, and/or response to therapy. The developed AI-system can be used as a stand-alone package or a tool for facilitating clinical decision making. The system may also be used to provide a better mechanistic understanding of tumor development and progress. Data sources can be from conventional X-ray, MRI, PET, CT, ultrasound, optical imaging, and/or other imaging modalities/devices. Cloud-based AI-aided imaging systems are encouraged. Proposals on sharing and archiving imaging information, radiation therapy treatment planning, or mammography will not be considered responsive.

Phase I Activities and Deliverables include:

- Select one modality, or a set of imaging modalities, and data sources associated with the modalities for the AI-aided imaging software that will be developed.
- Perform a software usability study for the prototype software with at least 25 users.
- Demonstrate in a small-scale, proof-of-concept study with animal or human medical image data the feasibility of an algorithm and software package for an AI-aided imaging system.

NIH/NCI 403 – Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to provide research tools to improve cancer early detection, diagnosis, and prognosis for precision medicine. Activities that fall within the scope of this solicitation include the development of technologies that can sequence DNA or RNA within fresh frozen or fixed normal and tumor cells without destroying their spatial context, and can be used to directly link spatial features to particular genetic elements in native tissue or organoid specimens; integration of image modalities with cellular sequencing data; cellular characterization of tumor sequence information without losing the spatial distribution. Projects that propose to integrate image modalities with orthogonal -omics measurement other than sequencing should respond to the topic “Subcellular Microscopy and -Omics in Cancer Cell Biology”.

Phase I Activities and Deliverables include:

- Demonstrate sensitivity, resolution, reliability, robustness, and usability in cancer research.
- For RNA sequencing, technology should reveal RNA splicing and post-transcriptional modifications while preserving spatial context. For DNA sequencing, the proposal should indicate how sequence information is used to determine Single Nucleotide Variation, Copy Number Variation, etc., while preserving spatial context.

NIH/NCI 404 – Subcellular Microscopy and -Omics in Cancer Cell Biology

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The goal of this solicitation is to stimulate innovation that integrates cellular imaging modalities with technologies that provide single cell -omic level data (e.g. proteomic, transcriptomic, etc.) that are relevant to cellular processes and are disabled or exploited in cancer. Projects should enable multidimensional interrogation of cancer cell biology in a manner that combines the spatial-temporal strengths of imaging modalities with complementary orthogonal measurements achieved through -omics and physicochemical approaches. Proposals to integrate sequencing technologies with imaging should respond to the topic “Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research”.

Phase I Activities and Deliverables include:

- Generate proof-of-concept data in an accepted cancer cell model system that demonstrates the ability to sense, interrogate, detect or resolve and map spatial cellular anatomy and/or dynamics using microscopy or other imaging modalities with nano- to micro-scale resolution.
- Demonstrate feasibility of combining the imaging modality(ies) with orthogonal assessments at the molecular scale (e.g. genomic, proteomic, metabolomic, or epigenomic analyses), physicochemical scale (e.g. redox, pH, force/stiffness), and/or functional scale to generate multidimensional data.

NIH/NCI 405 – Intra-Tumor Sensing Technologies for Tumor Pharmacotyping

Fast Track	# of anticipated awards	Budget (max)	
Accepted	2 - 3	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The primary goal of this topic is to expand the capabilities that can enable emerging pharmaco-typing approaches by developing intra-tumoral sensing technologies. Proposals must involve in vivo measurements of specific intra-tumoral markers of anti-cancer activity that are triggered by the delivery of sub-therapeutic doses of candidate therapeutic agents, and offer approaches that can eventually report on patient-specific efficacy from a variety of potential treatment options while maintaining patient safety. Offerors may utilize any route of administration to deliver candidate therapeutic agents; however, the sensing technology and/or process must enable sufficient throughput to evaluate an appropriate number of therapeutic agents needed to inform clinical decision-making within a relevant timeframe.

Phase I Activities and Deliverables include:

- Demonstrate intra-tumoral sensing capabilities using at least one solid tumor animal model.
- Conduct proof-of-concept experiments using appropriate anti-cancer agents, combinations, and/or doses (at least four) to demonstrate throughput capability to support clinical decision-making.
- Conduct preliminary safety studies in the chosen animal model to provide early evidence that the technology is likely to support human testing.

NIH/NCI 406 – Software for Patient Navigation Through the Cancer Care Continuum

Fast Track	# of anticipated awards	Budget (max)	
Accepted	2 - 4	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The overall goal is to develop new software tools that support patient navigation. The short-term goals are to develop, deploy, and evaluate IT tools that: 1) reduce the cognitive or time burden (or both) of navigation-related tasks performed by either Patient Navigators (PNs) or patients; 2) are well-integrated in the work flow of PNs and existing IT architecture; 3) securely transmit information across a variety of IT systems. The tool design approach must account for integration within existing IT systems, interoperability, cyber-security, and protecting patient's privacy.

Phase I Activities and Deliverables include:

- Conduct a needs assessment of PNs and cancer patients in at least one cancer care delivery site.
- Develop prototype software tool(s) to support two or more patient navigation tasks. Tasks include, but are not limited to, providing education to patients, scheduling or coordinating appointments, communicating with clinicians, coordination care planning, referring patients to appropriate resources to meet their financial or transportation needs.
- Conduct at least one usability study of the IT tool(s) with the participation of ≥25 users.

NIH/NCI 407 – Cloud-Based Software for the Cancer Research Data Commons

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $252,131 for 9 months	Phase II - $1,680,879 for 2 years

Goal:
The goal of this contract topic is to provide support for development and implementation of innovative solutions for continued advancement and evolution of cloud-based informatics tools to integrate with the Cancer Research Data Commons (CRDC) for broader user community engagement. Activities that fall within the scope of this contract topic include delivery of design specification for the development/ extension of informatics tools and demonstration of early phase prototype that shows successful integration with CRDC. Proposals for the development of big data analysis tools without consideration for integration with the CRDC will not be considered.

Phase I Activities and Deliverables include:

- Design the specifications for the development/extension of cloud-based informatics tools to operate in the CRDC, and develop an early software prototype.
- Demonstrate the feasibility of CRDC integration through the Data Commons Framework.
- Conduct a pilot software usability study with the participation of ≥25 users.

NIH/NCI 408 – Tools and Technologies for Visualizing Multi-Scale Data

Fast Track	# of anticipated awards	Budget (max)	
Accepted	2 - 3	Phase I - $400K for 9 months	Phase II - $2M for 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 409 – Software for Automated Analysis of Images for Improved Cancer Health

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The goal of this topic is to stimulate development of software for automated analysis of physical activity, performance, and behavior in still and video images for clinical, home monitoring, and public health applications. Examples include: automated assessments of gait, walking speed, and other parameters in the clinic; enabling in-home monitoring of compliance with medication and physical therapy regimens; improved evaluation of physical activity in transportation or park settings. Proposals addressing medical images such as MRI scans, microscopy, or DEXA scans will not be considered.

Phase I Activities and Deliverables include:

- Create or identify an open access image data source (e.g., cell phone images, SenseCam data, the AMOS archive of webcam images, Photovoice collected image libraries, security video).
- Develop a functional prototype system that includes capacity to:
  - Extract data from ≥1 image type involving human physical activity, performance, or behavior.
  - Combine automatic and manual detection, and counting of intended aspects of physical activity, performance, and behavior via a graphical user interface.
- Conduct a usability study with ≥15 users not affiliated with the study team.

NIH/NCI 410 – Cancer Clinical Trials Recruitment and Retention Tools for Participant Engagement

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 4	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The goal of this topic is to advance the development of tools for clinical trials recruitment, retention, or both. The tool could be clinic-facing or participant-facing or both. The tool should incorporate best practices for recruitment and retention (see full solicitation for list of best practices). Preference will be given to projects that are easily adaptable between trials.

Phase I Activities and Deliverables include:

- Develop and characterize a prototype tool/technology and demonstrate that the tool addresses specific recruitment and/or retention concern(s).
- Specify and justify quantitative milestones to evaluate the success of the tool or technology.
- Provide a proof-of-concept SOP for the tool or technology.
- Demonstrate feasibility and usability with a pilot user testing.
- Demonstrate that the tool, technology, or product can be adapted to multiple clinical trials at a price point compatible with market success and widespread adoption by the clinical research community.

NIH/NCI 411 – De-Identification Software Tools for Cancer Imaging Research

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 5	Phase I - $400K for 9 months	Phase II - $2M for 2 years

Goal:
The goal of this solicitation is to support development and sustainment of software tools and pipelines for image de-identification, especially for but not exclusive to CT patient data sets and images produced by whole slide imagers (WSI) for digital pathology applications. These tools will selectively remove Protected Health Information (PHI) while retaining other metadata fields that help provide interoperability with other image formats and other data types, such as genomic data and proteomic data. Brute force methods for de-identification (e.g., erasing of all header information) are not acceptable. Retention of data and metadata necessary for downstream applications (population studies, segmentation training) is required. Solutions should not compromise the biomedical use of data files.

Phase I Activities and Deliverables include:

- Identify different WSI vendor file types and the fields that contain PHI.
- Ability to recognize and open multiple WSI file formats, display PHI field variable values, remove or alter PHI field values from fields labeled with PHI.
- Identify the data sets and file types required to demonstrate software capability.

NIH/NCI 412 – Software Enabling Data Integration from Wearable Sensors for Cancer Patients

Fast Track	# of anticipated awards	Budget (max)	
Accepted	2 - 3	Phase I - $400K for 9 months	Phase II - $1,680,879 for 2 years

Goal:
The goal is to develop scalable informatics tools and resources for their broad adoption across clinical cancer research applications that use continuous, passive monitoring of multiple biological parameters via wearable platform technologies. Offerors should execute project plans that will eventually lead to commercially viable solutions for: 1) sustained development and evolution of passive continuous monitoring platform informatics tools and resources; and 2) their broad adoption in clinical cancer research. Tools that do not allow the integration and subsequent interpretation of a myriad of current wearable sensor platforms simultaneously, or that use only data from inertial sensing wearables, will not be considered.

Phase I Activities and Deliverables include:
Phase I activities should culminate in the development of a functional prototype system that follows the planned compatibility matrix (see full solicitation for list of requirements). Wireframes and user workflows for the proposed Graphical User Interface should be provided.

NHLBI topics

NHLBI FY2020 SBIR Contract topics

To learn more about the SBIR program at NHLBI
Contact: Dr. Mike Pieck NHLBI_SBIR@mail.nih.gov
Or visit our website: sbir.nih.gov/NHLBI

For technical questions related to the contract topics
Contact: Dr. Robert Lederman ledermar@nhlbi.nih.gov

Topic 109 **Transcatheter trileaflet tricuspid suture repair system**

- Fast-Track proposals will be accepted.
- Direct to Phase II proposals will be accepted
- Number of anticipated awards: 2
- Budget (total costs):
  - Phase I: $400,000 for 12 months
  - Phase II: $3,000,000 for 36 months

Project Goals

The goal of this project is to develop a catheter system to achieve a non-surgical off-pump tricuspid valve LEAFLET repair that allows 3 or more sutures to reappose 3 or more tricuspid valve leaflets to repair secondary or primary tricuspid valve regurgitation, sometimes described as “clover-leaf repair.” This project should generate an Early Feasibility Study (EFS) IDE for clinical evaluation in the United States, towards commercialization through a mechanism such as Phase IIb bridge-to-commercialization.

Topic 110 : **MRI myocardial biopsy system**

- Fast-Track proposals will be accepted.
- Direct to Phase II proposals will be accepted
- Number of anticipated awards: 2
- Budget (total costs):
  - Phase I: $400,000 for 12 months
  - Phase II: $3,000,000 for 24-36 months

Project Goals

- The goal of the project is to develop a myocardial biopsy catheter of materials safe for MRI operation yet sufficiently sharp to extract myocardial tissue effectively. First a prototype would be developed and tested in animals, and ultimately a clinical-grade device would undergo regulatory development for clinical testing.
- This project should generate an Early Feasibility Study (EFS) IDE for clinical evaluation at NIH or another suitable medical center, towards commercialization through a mechanism such as Phase IIb bridge-to-commercialization. Alternatively it is possible that 510(k) market clearance can be achieved depending on the selected technologies.

NIAAA topics

NIH/NIAAA: **Alcohol Biosensor Development for Continuous Alcohol Consumption Monitoring**

Budget (total costs): Phase I (of FastTrack): up to $500,000 for 9 months; Phase II: up to $2,000,000 for up to 2 years

Number of Anticipated Awards: 1-3

Objective: To develop and produce a wearable alcohol biosensor to measure, record and store blood alcohol levels in real-time. Technologies measuring alcohol in sweat or sweat vapor will be considered non-responsive.

Phase I: Demonstration of the ability of the technology to detect alcohol, detection signal is proportional to amount or concentration of alcohol, specificity of alcohol detection.

Phase II: Incorporation the alcohol sensor into a discreet, attractive, wearable device, refinements of functionality, accuracy, security, and integration of data collection, data transmission and data storage, accuracy of quantitation of blood alcohol concentration, output of detection signal as blood alcohol concentration, … (see solicitation for additional objectives). Evidence of a functional, marketable, alcohol biosensor is the specific deliverable of the Phase II portion of the contract.

NIH/NIAAA:

Data Science Tools for Accelerating Alcohol Research

Budget (total costs): Phase I: up to $225,000 for 6-12 months. FAST track not accepted.
Number of Anticipated Awards: 1-2

Objective: The goal is to develop data science analysis algorithms, mathematical models, and software tools for currently NIAAA-funded alcohol researchers

Phase I:

- New algorithms for integrative analysis of current NIAAA and public 'big data' sets
- Software applications (including API) for data aggregation, harmonization, or visualization of current and future NIH data sets
- Algorithms and/or software tools for improving data collection and validation
- Computational and/or systems biology models of alcohol exposure and use, that include multiscale models and/or data from clinical and basic science research.

Activities and deliverables are expected to use currently available data sets and databases. Offerors should discuss potential deliverables with NIAAA-supported researchers to determine research needs and goals. The generation of new primary data is not supported by this topic.

National Institute of Allergy and Infectious Diseases

PROGRAM SOLICITATION PHS 2020-1

FY20 SBIR Contract Topics

Presented by: Wolfgang Leitner, PhD
Chief, Innate Immunity Section
Basic Immunology Branch
Division of Allergy, Immunology and Transplantation

NIAID

Summary of FY20 SBIR Contract Topics

076 Co-delivery and Formulation of Adjuvants for HIV Vaccine Development

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

078 Sequence-based Assays to Quantify the Replication-Competent HIV Reservoir

079 Small Molecule Targeting of HIV RNA

080 Adjuvant Discovery for Vaccines against Infectious or Immune-mediated Diseases

081 Adjuvant Development for Vaccines against Infectious or Immune-mediated Diseases

082 Production of Adjuvants

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

084 Antiviral drugs to cure chronic hepatitis B virus infection

085 Broad spectrum antibody against human enteroviruses

086 Development of rapid fungal diagnostics for select endemic dimorphic fungi

NIAID

FY20 SBIR Contract Topics

076 Co-delivery and Formulation of Adjuvants for HIV Vaccine Development

Project Goals

- Co-delivery of adjuvants with HIV antigens is not mutually exclusive and should converge to accelerate the development adjuvanted HIV vaccine candidates capable B/T-cell activation, enhanced antibody avidity or broadening of effector immune responses while minimizing reactogenicity and preserving the protective immune responses against HIV.

- The primary goal of this project to support, accelerate and advance early stage and/or pre-clinical development and optimization of a promising HIV antigen-adjuvant formulation or select combination-adjuvant(s) for co-delivery for a preventative HIV vaccine.

FY20 SBIR Contract Topics

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

Project Goals

- Tailored immunogens (such as Envs, monomers, native and/or native-like trimers, mRNAs, or self-amplifying RNAs) combined with an effective multivalent antigenic display on nanoparticles for delivery may provide a strategy to promote strong and long-lived neutralizing antibody responses against HIV and direct affinity maturation toward HIV neutralizing antibodies.

- This project may include a range of development, evaluation/validation and manufacturing activities in support of this strategy.

FY20 SBIR Contract Topics

078 Sequence-based Assays to Quantify the Replication-Competent HIV Reservoir

Project Goals

- Despite effective antiretroviral therapy, HIV-1 persists in all infected individuals as proviral DNA within long-lived memory CD4+ T cells. This reservoir constitutes the primary barrier for curing HIV infection.
- The goal of this project is to develop and commercialize sequence-based HIV reservoir assays for clinical HIV cure interventions. The assay should be designed as an analytical tool to monitor the size of the replication-competent HIV reservoir in clinical research.
- An additional goal of this project is to develop secondary assays that are not tissue culture-based and discriminate between actively transcribed and latent full-length proviruses.

FY20 SBIR Contract Topics

079 Small Molecule Targeting of HIV RNA

Project Goals

- The identification of detailed RNA structures now allows the design of small molecules which are capable of binding to RNA with high selectivity and specificity.

- This project should focus on the discovery and/or design of RNA-targeted small molecules which specifically bind to HIV RNA transcripts to prevent RNA processing and translation into protein.

FY20 SBIR Contract Topics

080 Adjuvant Discovery for Vaccines against Infectious or Immune-mediated Diseases

Project Goals

- The objective of this program is to support:
  - the screening for new adjuvant candidates for vaccines against infectious diseases or for immune-mediated diseases (autoimmune and allergic diseases or transplant tolerance);
  - adjuvant characterization; and
  - early-stage optimization of adjuvant candidates

FY20 SBIR Contract Topics

081 Adjuvant Development for Vaccines against Infectious or Immune-mediated Diseases

Project Goals

- The goal of each project will be to accelerate the pre-clinical development and optimization of a single lead adjuvant candidate or a select combination-adjuvant for prevention of human disease caused by non-HIV infectious pathogens, or for autoimmune or allergic diseases, or organ/tissue transplantation tolerance.

- The adjuvant products supported by this program must be studied and further developed with currently licensed or new investigational vaccines (no stand-alone agents).

FY20 SBIR Contract Topics

082 Production of Adjuvants

Project Goals

- NIAID supports the discovery and development of novel adjuvants through different mechanisms; this topic is intended to address the limited availability of adjuvants that mimic the functionality of those with a favorable clinical track record.

- The goal of this project is development, validation, and production of adjuvants that are based on, or similar to, compounds or formulations successfully used in clinical trials or part of licensed vaccines, for use by the broader research community, either as commercial products or through licensing agreements.

FY20 SBIR Contract Topics

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

Project Goals

- Development and validation of reliable antibodies and reagents for identification and tracking of primary immune cells or analysis of immune function/responses (e.g., cytokines, chemokines, intracellular signaling) in non-mammalian models or underrepresented mammalian models.
- Non-mammalian models are limited to arthropods, amphibians, fish (e.g., jawless, sharks, zebrafish), nematodes, and marine echinoids.
- Underrepresented mammalian models are limited to guinea pig, ferret, cotton rat, pig (including minipigs), rabbit and marmoset.

FY20 SBIR Contract Topics

084 Antiviral drugs to cure chronic hepatitis B virus infection

Project Goals

- Research on candidate drugs and mechanisms of action different from that of existing licensed drugs, and pre-clinical development of such candidates, with the express purpose of advancing them commercially.
- **Objective**: functional cure of HBV - defined as loss of virus, loss of hepatitis B surface antigen (HBsAg) and seroconversion, which rarely occurs with current regimens.
- As the intent of this project is to obtain potentially curative drugs, it may be necessary to develop, in parallel, additional determinants of post-treatment efficacy.

FY20 SBIR Contract Topics

085 Broad spectrum antibody against human enteroviruses

Project Goals

- Goal: develop broad-spectrum prophylactic and therapeutic monoclonal antibody therapeutics against human enteroviruses.
- Final product can be monoclonal antibodies specific to multiple medically-relevant enteroviruses, a combination of multiple monoclonal antibodies with a narrow specificity, or both.
- The final product should target different strains of a single family, e.g. multiple EV-D68 strains, multiple members in one species (e.g. Enterovirus A species), or members in multiple species (e.g. coxsackie viruses in A and B species).

FY20 SBIR Contract Topics

086 Development of rapid fungal diagnostics for select endemic dimorphic fungi

Project Goals

- Timely recognition and treatment of invasive fungal diseases (IFDs) is necessary to reduce the morbidity, mortality and inappropriate antibiotic usage commonly associated with IFDs.

- **Purpose**: support the development of rapid, sensitive, specific, simple, and cost-effective diagnostics for primary health-care settings (hospitals and point-of-care (POC)) to detect IFDs.

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

Centers for Disease Control and Prevention (CDC)

Presented by:
Barbara Stewart, Deputy Director
Extramural Research Program Office
Small Business Innovation Research (SBIR) Program

August 7, 2019

SAFER · HEALTHIER · PEOPLE™

CDC's SBIR Program

- Please read the solicitation and any future amendments to the solicitation very carefully.

- If you have questions after the webinar, during the open question/answer period, please contact CDC's Office of Financial Resources (OFR/OAS). Please also Cc: the CDC SBIR@cdc.gov e-mail address. Reference the responsible contracting officer/specialist, the solicitation PHS 2020-1 and the CDC topic number along with your specific question(s).

CDC's SBIR Program

- The CDC Office of Science (OS) manages CDC's SBIR Program. The Office of Science works across the agency and with CDC Centers/Institutes that have a SBIR set-aside to help ensure that SBIR funds support high quality, high impact SBIR projects

- CDC participates in both the SBIR HHS Omnibus Grant (PA-19-272 & 273) Solicitations and the HHS SBIR Contract Solicitation (PHS 2020-1)
  - CDC does not participate in the STTR Program (at this time)
  - CDC does not participate in Fast Track, Direct to Phase II or Phase II B
  - CDC has opted to participate in the Majority VC ownership authority

CDC's SBIR Program

- Budget - CDC SBIR set-aside approximately $10 million (FY19)

- Awards - ≈ 30 Phase I's up to $150,000 each and ≈ 5-7 Phase II's per year up to $1.0 M each

- SBIR Technical Assistance - CDC participates in SBIR Technical Assistance Programs – (e.g., Niche Assessment Program, Commercialization Accelerator Program, I-Corps @ NIH, etc.)

CDC / National Center for Chronic Diseases Prevention and Health Promotion (NCCDPHP) – (043) Objective Measurement of Opioid Withdrawal in Newborns

- Number of anticipated awards: 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - To create a wearable device that objectively measures a newborn's withdrawal symptoms.
- Phase I Activities and Deliverables:
  - Build upon existing technology to create a device that not only captures body temperature, movement, and sleep, but also sound (crying frequency, duration, pitch) and muscle tone (degree of rigidity)
  - Ensure the device is small enough and safe for newborn wear
  - Create a user-friendly interface to view symptoms and guide diagnosis, treatment, and management of opioid withdrawal in newborns.

CDC / National Center for Environmental Health – (NCEH)

(002) Web-Based Platform for Flooding Vulnerability and Healthcare Access

- Number of anticipated awards: 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - The launch of an online data portal or platform, providing high-resolution spatial information on baseline flood risk and real-time inundation information. The proposed data platform, intended to receive updated data feeds from federal agencies and private partners, can protect human health during flooding disasters by facilitating access to healthcare and emergency care.
- Phase I Activities and Deliverables:
  - Collection and synthesis of publicly available baseline flood risk information.
  - Creation of a national dataset of critical healthcare facilities.
  - Merging of two datasets into a single pilot web-based platform that overlays flooding maps with healthcare facilities, demonstrating potential facilities at risk from flooding.

CDC / National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) - (021) Assay to Detect and Quantify *E. Coli* O157 in Water Samples

- Number of anticipated awards: 1-2
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - To develop an assay that can detect and quantify *E. coli* O157 in water samples.
- Phase I Activities and Expected Deliverables:
  - Develop or adapt a method to detect and quantify *E. coli* O157 in water samples; the assay must be able to detect 1 cfu/100 ml.
  - Determine the sensitivity and specificity of the test against E. coli O157, other STEC serotypes, and non-STEC *E. coli*.
  - Conduct matrix evaluation to understand the assay performance using different water types (e.g., varied mineral or chemical composition, pH, etc. of the water source being tested).

CDC / National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) - (022) Device Development for Microbial Surface Sampling, Field Extraction and Collection

- Number of anticipated awards: 1-2
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - To develop a novel sampling device that is able to efficiently collect microorganisms from a solid surface and to extract and concentrate the organisms from the device into a vial or tube in the field.
- Phase I Activities and Expected Deliverables:
  - Develop prototype sampling, elution and concentration device.
  - Test efficiency of recovery by placing known quantities of *Staphylococcus aureus*, and *Acinetobacter baumannii* cells and *Clostridioides difficile* spores (or *Bacillus* spp. Spores, if anaerobe chamber is not available) onto surfaces, then use the device to recover the cells and spores. Efficiency will be determined by a quantitative microbial culture and qPCR, and then compared to number of cells and spores placed on surface.

CDC / National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) - (023) Diagnostic Testing Platform to Assess Antibiotic Activity on Microbial Communities of Cystic Fibrosis Patients

- Number of anticipated awards: 1-2
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - To support the development of a standardized diagnostic platform for use in a clinical laboratory to determine the microbial community susceptibility/antibiogram of an infection using primary cystic fibrosis (CF) clinical specimens (i.e., sputum).
- Phase I Activities and Expected Deliverables:
  - Establish a laboratory-developed in vitro test methodology/model that can test clinical sputum specimens for microbial community-susceptibilities or yield a microbial community-antibiogram.
  - Apply the method/model from deliverable #1 to sputum from an existing set or bank of clinical specimens to track sequential sputum community composition following treatment with one or more antibiotics.
  - Proof of concept: Compare these in vitro community changes to microbial community changes observed in clinical sputum specimens from the same patient during/following antibiotic treatment.

CDC / National Center for Immunization and Respiratory Health (NCIRD) – (034) Accelerating Time to Detection of Legionella in Environmental Samples

- Number of anticipated awards: 1
  - Budget: Phase I up to $ 150,000 for up to 6 months
- Project goal(s):
  - To develop a test that can rapidly detect viable Legionella bacteria in water samples collected from environmental sources.
- Phase I Activities and Expected Deliverables:
  - Demonstrate proof of principle by comparing results with traditional Legionella culture methods.
  - Determine ranges of sensitivity and specificity for all water sample sources tested.
  - Develop a protocol to validate the assay in the field.

CDC 24/7™

Saving Lives.
Protecting People.™

LEARN MORE ABOUT HOW
CDC WORKS FOR YOU.

Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Web: www.cdc.gov

Deadline for receipt of ALL Proposals

Wednesday October 23, 2019

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.

More Information

Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: **subscribe SBIR-STTR your name**
- NIH Guide for Grants and Contracts (weekly notification) http://grants.nih.gov/grants/guide/listserv.htm
- Follow us on Twitter: @NIHsbir
- Submit your SBIR/STTR Success Story at: http://sbir.nih.gov
- Email: sbir@od.nih.gov