



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



HHS SBIR Contract RFP Informational Webinar PHS 2018-1

August 15, 2017

NIH and CDC SBIR and Contracts Staff
Hosted by Matthew Portnoy
NIH SBIR/STTR Program Coordinator



The first part of the document discusses the importance of maintaining accurate records of all transactions. This includes not only sales and purchases but also any other financial activities that may occur. It is essential to ensure that all entries are properly documented and supported by appropriate evidence.

In addition, the document emphasizes the need for regular reconciliation of accounts. This process involves comparing the company's internal records with the bank statements to identify any discrepancies. By doing so, the company can ensure that its financial statements are accurate and reliable.

Furthermore, the document highlights the significance of proper classification of expenses. Each expense should be categorized correctly according to the company's chart of accounts. This allows for more detailed analysis of the company's financial performance and helps in identifying areas where costs can be reduced.

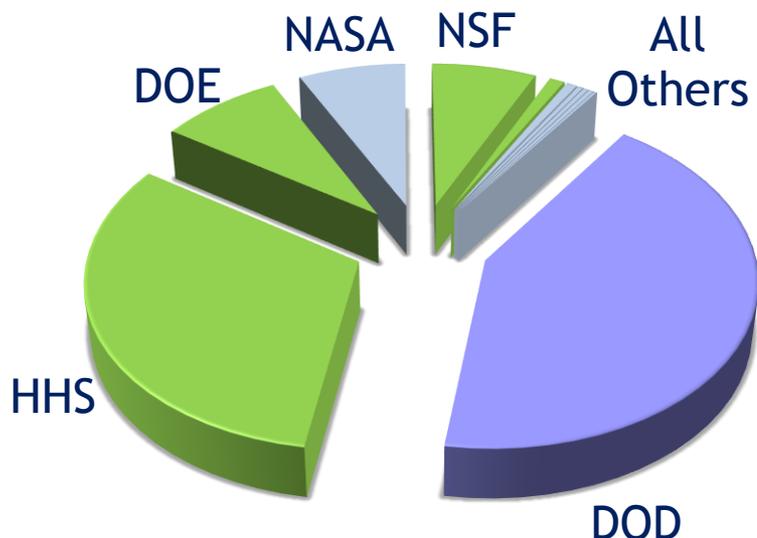
Finally, the document stresses the importance of timely reporting of financial information. Management should receive regular updates on the company's financial status to make informed decisions. This requires a strong system of internal controls and a commitment to transparency.

In conclusion, the document provides a comprehensive overview of the key principles of financial management. By following these guidelines, the company can ensure that its financial records are accurate, complete, and reliable. This, in turn, will enable the company to make sound financial decisions and achieve its long-term goals.



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

SBIR/STTR Budgets by Agency FY15



**~ \$2.5B in FY2015
across all agencies**



Agencies with SBIR and STTR Programs	Budget
Department of Defense (DOD)	\$1.070B
Department of Health and Human Services (HHS), including the National Institutes of Health (NIH)*	\$797.0M
Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)	\$206.1M
National Aeronautics and Space Administration (NASA)	\$180.1M
National Science Foundation (NSF)	\$176.0M
Agencies with SBIR Programs	Budget
U.S. Department of Agriculture (USDA)	\$25.3M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$17.7M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*	\$8.4M
Department of Transportation (DOT)	\$7.9M
Department of Education (ED)	\$7.5M
Environmental Protection Agency (EPA)	\$4.2M

2017 Budget	SBIR	STTR
NIH	\$861M	\$121M
CDC	~\$11.0M	N/A
ACL (NIDILRR)	~\$3M	N/A
FDA	~\$1.4M	N/A

**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

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>



- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation
“Parent” FOAs: [SBIR: PA-17-302](#) [STTR: PA-17-303](#)

Release: June 5, 2017

Standard Due Dates: September 5th, January 5th

- These FOAs are being issued with limited due dates to accommodate the transition from FORMS-D to FORMS-E application packages.
 - **HHS expects to re-issue these Omnibus after the January 5, 2018 due date.**
- SBIR Contract Solicitation (NIH, CDC) - Program Solicitation [PHS 2018-1](#) (SBIR Only)
NIH Guide Notice [NOT-OD-17-089](#)
Release: 7/18/17 Due: 10/20/17
 - [NIH Guide for Grants and Contracts](#)
Weekly receipt dates specified in each FOA



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

**R&D Contract Solicitation:
SBIR Phase I, Fast-Track
Contract Solicitation, PHS
2018-1**

Closing Date: October 20, 2017, 5:00PM EDT



PHS 2018-1 (PDF - 1 MB)



PHS 2018-1 (MS Word - 373 KB)



Contract Proposal Forms



NIH OER: Grants & Funding

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

SBIR Contracts

Format	Description	Date Posted	Form/Instruction File
PHS 2018-1	<p>Competing - SBIR Phase I and II Contract Solicitation</p> <p>Receipt date: October 20, 2017, 5PM EDT</p> <p>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)</p> <p>Forms for Phase II and Fast-Track Proposals: Appendices: B (PDF - 86 KB or MS Word - 29 KB), C (PDF - 124 KB or MS Word - 30 KB), D (PDF - 90 KB or MS Word - 31 KB), E (PDF - 14 KB or MS Word - 31 KB), F (PDF - 94 KB or MS Word - 26 KB), G (PDF - 265 KB or MS Word - 35 KB)</p> <p>Forms for Fast-Track Proposals: ALL Forms (Appendices A-G) are REQUIRED</p>	July 18, 2017	PDF MS WORD





FedBizOpps:

<https://www.fbo.gov/spg/HHS/NIH/NIAID/PHS-2018-1/listing.html>

★ FEDBIZOPPS.GOV
Federal Business Opportunities

Home
Getting Started
General Info
Opportunities
Agencies
Privacy

Buyers: [Login](#) | [Register](#) Vendors: [Login](#) | [Register](#) [Accessibility](#)

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

Solicitation Number: PHS-2018-1
Agency: Department of Health and Human Services
Office: National Institutes of Health
Location: National Institute of Allergy and Infectious Diseases

Print
 Link

Note: There have been modifications to this notice. You are currently viewing the original synopsis. To view the most recent modification/amendment, [click here](#)

[Complete View](#)

Original Synopsis
Jun 29, 2017
11:15 am

Changed
Jul 18, 2017
10:15 am
Solicitation

Return To Opportunities List

Add Me To Interested Vendors

Watch This Opportunity

Solicitation Number: PHS-2018-1 Notice Type: Presolicitation

Synopsis:
Added: Jun 29, 2017 11:15 am

1. National Institutes of Health, Bethesda, MD 20892 and Centers for Disease Control and Prevention, Atlanta, GA 30305 are soliciting proposals from small business concerns that possess the research and edevelopment (R&D) expertise to conduct innovative research that will contribute toward meeting the program objectives of the agencies.

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 2018-1 with a closing date on or around October 20, 2017, for receipt of proposals, soon will be available electronically through the NIH Small Business

ALL FILES

[Solicitation 1](#)
Jul 18, 2017

[PHS-2018-1.pdf](#)

GENERAL INFORMATION

Notice Type: Presolicitation

Posted Date: June 29, 2017

Response Date: -

Archiving Policy: Manual Archive

Archive Date: -

Original Set Aside: N/A

Set Aside: Total Small Business

**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 2018-1

Closing Date: October 20, 2017, 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 20, 2017, 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_pd_with_1-8-14_amendments_2-24-14.pdf to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.





- 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



Read the entire RFP several times!!



Types of SBIR Proposals Allowed Section 1 and 12

TOPIC NUMBER	PHASE I PROPOSAL ALLOWED?	FAST TRACK ALLOWED? (A Phase I proposal and a Phase II proposal submitted simultaneously)	TOPIC TITLE
NIH/NCI 370	Yes	Yes	Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia
NIH/NCI 371	Yes	Yes	Drugs to Exploit the Immune Response Generated by Radiation Therapy
NIH/NCI 372	Yes	Yes	Development and Validation of Non-Mouse Reagents to Enable Preclinical Development of Novel Therapeutics
NIH/NCI 373	Yes	No	Tools and Technologies for Monitoring RNA Modifications
NIH/NCI 374	Yes	Yes	Novel Approaches for Local Delivery of Chemopreventive Agents
NIH/NCI 375	Yes	Yes	Diagnostic Imaging for Cancer Immunotherapies
NIH/NCI 376	Yes	Yes	Imaging-Based Tools for Longitudinal and Multi-Dimensional Mapping of the Tumor and Its Microenvironment
NIH/NCI 377	Yes	Yes	Bridging the Guideline Implementation Gap: Clinical Decision-Support to Improve Cancer Symptom Management
NIH/NCI 378	Yes	Yes	Mobile Application for Surveillance of Post-Radiation Therapy Health-Related Quality of Life



- 2.4 Direct to Phase II Proposals

This solicitation will **not** accept Direct Phase II proposals. The congressional authority for Direct to Phase II proposals has expired.



- Participating Components
 - All NIH awarding components (NCI, NHLBI, NIAID, and NIDA), CDC NCCDPHP, and CDC NCEZID
 - 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 \$50,000 in total direct costs - indirect costs may not be included.
 - \$20,000 for course registration
 - Estimated 20hrs+/week during 8-week course



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**
ExpertI Corps Node
Instructor**DIAGNOSTIC TOOLS
TRACK****DIAGNOSTICS &
eHEALTH** ExpertI Corps Node
Instructor**MEDICAL DEVICES
TRACK****MEDICAL DEVICE**
ExpertI Corps Node
Instructor



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

BUSINESS PROPOSAL (1 PDF)

- Item 2: Pricing Proposal (Appendix C)
- Item 3: SBIR Application VCOC Certification, if applicable
- Item 4: Proof of Registration in the SBA Company Registry
- Item 5: 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)

• BUSINESS PROPOSAL (1 PDF)

- Item 2: Pricing Proposal (Appendix C)
- Item 3: SBIR Application VCOC Certification, if applicable
- Item 4: Proof of Reg. in the SBA Company Registry
- Item 5: Summary of Related Activities (Appendix F)





- Section 3 - Definitions
- Section 4.9 - Research Involving Human Subjects
- Section 4.10 - Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials
- Section 4.11 - Inclusion of Women, Minorities, and Children in Clinical Research
- Section 4.12 - Care of Vertebrate Animals
- Section 8.10 - Human Subjects Research and Protection from Risk
- Section 8.11 - Inclusion of Women, Minorities, and Children in Clinical Research
- Section 8.12 - PHS Inclusion Enrollment Report(s) for Sex/Gender, Race, and Ethnicity
- Section 8.13 - Research Involving Human Fetal Tissue Instructions
- Section 8.14 - Research Involving Vertebrate Animals Instructions





- Section 8.9 - Enhancing Reproducibility through Rigor and Transparency
- [NOT-OD-15-103](#): View overall NIH Guidance
 - >> Specific instructions in Section 8.9



- **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
- 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



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. NCI
 - b. NHLBI
 - c. NIAID
 - d. NIDA
 - e. CDC/CGH
 - f. CDC/NCCDPHP
 - g. CDC/NCEZID
 - h. CDC/NCHHSTP
 - 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 - (at time of award)
Grants.gov	No
eRA Commons	No - (can use to reg in eCPS)
Electronic Contact Proposal Submission (eCPS)	Yes - required to submit all proposals to PHS 2018-1





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- Reminder only contact is with Contracting Officer listed in Section 10
- Questions must be submitted in writing (email) to the Contracting Officer
- **Deadline for Questions is August 25, 2017 - close of business**
- An 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





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

Deadline for receipt of ALL Proposals

FRIDAY October 20, 2017

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.





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 - g. CDC/NCEZID
 - h. CDC/NCHHSTP
 - i. CDC/NCIRD





- **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/sbirsttr>





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

eCPS Demo

eCPS demo!

<https://ecps.nih.gov/home/howto>





eCPS: Reminders

Please create an account early - do not wait

<https://ecps.nih.gov>





Filter For SBIR

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:

Show entries

Search:

FedBizOpps.gov Solicitation Link	Solicitation Type	Title	Contract Specialist	Closing Date and Time [ET]	Agency
PHS-2018-1	Solicitation	NIH/NCI 370 (Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia)	Chadwick, Tiffany	10/20/2017 5:00:00 PM	NIH/NCI
PHS-2018-1	Solicitation	NIH/NCI 371 (Drugs to Exploit the Immune Response Generated by Radiation Therapy)	Chadwick, Tiffany	10/20/2017 5:00:00 PM	NIH/NCI
PHS-2018-1	Solicitation	NIH/NCI 372 (Development and Validation of Non-Mouse	Chadwick, Tiffany	10/20/2017 5:00:00 PM	NIH/NCI





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, Business or Excel Workbook)
- Technical Proposal sample name
 - XYZ Company_NIAID_TOPIC_050_Technical.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





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 - h. CDC/NCHHSTP
 - i. CDC/NCIRD



NATIONAL CANCER INSTITUTE (NCI)

Questions About NCI SBIR Contracts?

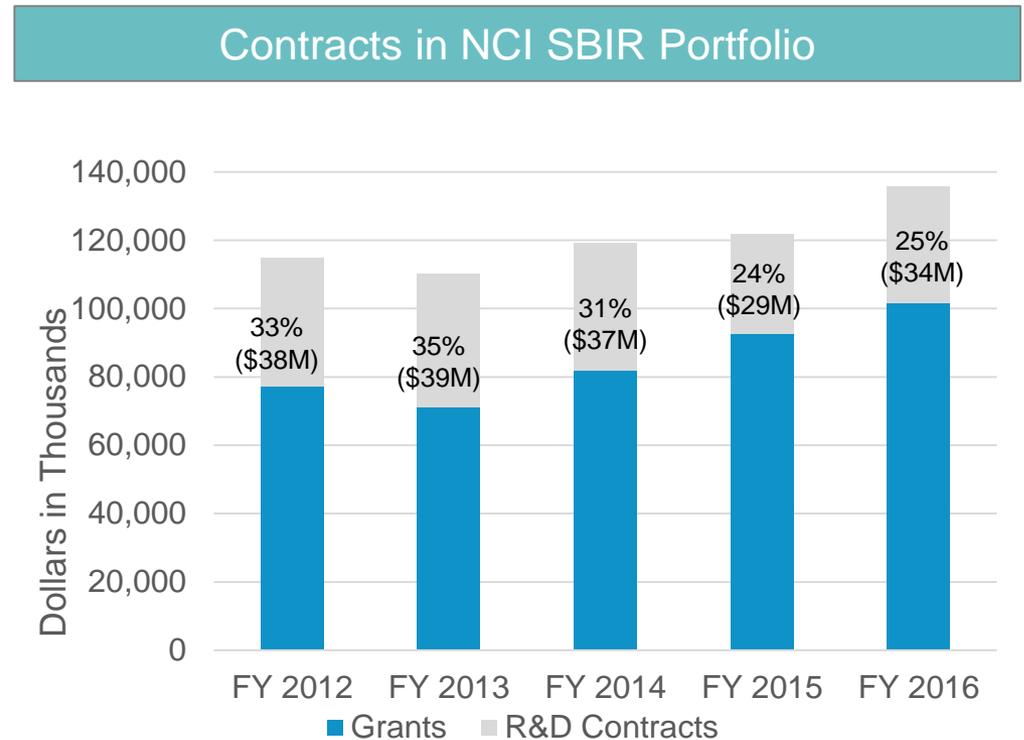
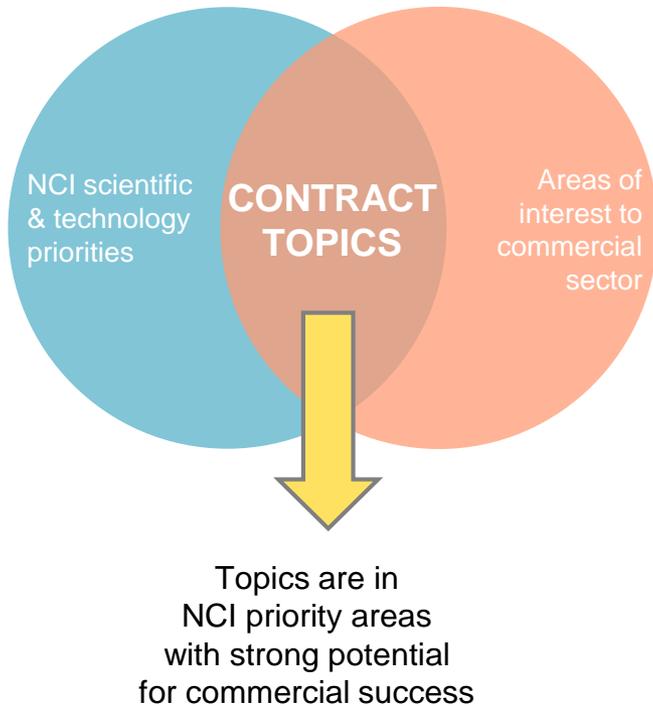
Ms. Tiffany Chadwick

ncioasbir@mail.nih.gov

Please reference solicitation PHS 2018-1 and the Topic number with any questions.

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

CONTRACT TOPICS



FY2018 Funding Opportunity Summary



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

- 370. Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia
- 371. Drugs to Exploit the Immune Response Generated by Radiation Therapy
- 372. Development and Validation of Non-Mouse Reagents to Enable Preclinical Development of Novel Therapeutics
- 373. Tools and Technologies for Monitoring RNA Modifications
- 374. Novel Approaches for Local Delivery of Chemopreventive Agents
- 375. Diagnostic Imaging for Cancer Immunotherapies
- 376. Imaging-Based Tools for Longitudinal and Multi-Dimensional Mapping of the Tumor and its Microenvironment
- 377. Bridging the Guideline Implementation Gap: Clinical Decision-Support to Improve Cancer Symptom Management
- 378. Mobile Application for Surveillance of Post-Radiation Therapy Health-Related Quality-of-Life
- 379. Software Enabling Data Integration from Wearable Sensors to Generate Novel Analytics for Cancer Patients
- 380. Computer Aided Decision Support for Radiation Oncology
- 381. Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts' Radiation Therapy Planning for Prostate Cancer

NIH/NCI 370: TARGETED THERAPY FOR CANCER- AND CANCER THERAPY-RELATED CACHEXIA



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals are accepted.

Goal: Facilitate the commercial development of therapeutic or prophylactic targeted drugs or biologics to prevent, and/or treat cancer and cancer-therapy-related cachexia. Proposals submitted in response to this topic should focus on cancer indications with the highest prevalence of cancer and cancer-therapy-related cachexia. Offerors are expected to have an identified target and sufficient preliminary data to support the mechanism by which their agent will exhibit efficacy in preventing or treating cancer and/or cancer-therapy-related cachexia.

Phase I Activities & Deliverables include:

- Develop and formulate the therapeutic or prophylactic candidate
- Fully characterize the therapeutic or prophylactic candidate including identification of potential obstacles to filing an IND with the FDA
- Proof-of-concept in vitro studies demonstrating therapeutic/prophylactic efficacy
- Proof-of-concept animal studies demonstrating therapeutic/prophylactic efficacy and toxicity profiles using appropriate animal models of cancer cachexia
- Plan and timeline for filing an IND with the FDA
- Phase II studies will focus on generating data to support the IND filing.

NIH/NCI 371: DRUGS TO EXPLOIT THE IMMUNE RESPONSE GENERATED BY RADIATION THERAPY

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals are accepted.

Goal: Develop agents (e.g., cellular therapies, antibodies, small molecules, or miRNA/siRNA/CRISPR-CAS9 based approaches) that can augment (immune activation) or negate (immune suppression) one or more of the immune modulation events induced by radiation therapy. IR can include conventional clinically relevant radiation; hypofractionated radiation; and high-dose, hypofractionated radiation.

Phase I Activities & Deliverables include:

- Selection of cancer type(s), organ site(s), immune modulation agent(s), and radiation dose & fractions, with adequate justification
- Proof of concept animal (e.g., mice or rat) studies demonstrating augmentation or inhibition of radiation-induced immune activation or suppression respectively with the combination of radiation and the agent
 - Demonstrate augmentation of immune activation in irradiated environment with appropriate standard markers showing an increased influx of positive effector immune cells (e.g., T-cells, macrophages, dendritic cells, etc.) in the tumor micro environment.
 - Demonstrate negation of immune suppression in irradiated environment with standard appropriate markers showing reduction in the influx of negative effector immune cells (e.g., neutrophil, T-reg, and MDSCs) in the tumor micro environment.
- Proof of concept animal (e.g., mice or rat) studies demonstrating tumor regression in a syngeneic contra-lateral tumor model whereby regression is observed in both the irradiated primary tumor as well as distal non-irradiated tumor when the agent is combined with radiation.

NIH/NCI 372: DEVELOPMENT AND VALIDATION OF NON-MOUSE REAGENTS TO ENABLE PRECLINICAL DEVELOPMENT OF NOVEL THERAPEUTICS



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals are accepted.

Goal: The short-term goal of this topic is the creation of a set of reagents that will enable additional preclinical testing of novel therapeutics. In addition, the development of reagents for clinical testing in companion animals (such as canines) will facilitate additional market opportunities. The long-term goal is to enable better demonstration of the utility of novel therapeutics for administration in both humans and companion animals. Reagents that enable the use of models for the testing of immunotherapy are of particular interest, but proposals to develop reagents for the testing of other therapeutic approaches, such as chemotherapy and radiation, with a strong rationale for the need of such reagents, will be considered.

Phase I Activities & Deliverables include:

- Analytically validate and characterize the reagent(s) for a number of parameters including, as appropriate, but not limited to: purity, concentration, storage conditions, reference standards, specificity, linearity, limits of detection (LOD), range, accuracy, and precision.
- Develop pertinent controls and reference standards.
- Conduct tests to characterize the developed reagents to ensure rigor and reproducibility
- Provide a proof-of-concept SOP for the reagents and assays. The SOP should include necessary information on the required equipment, operating parameters, sample preparation, standards control solution preparation, procedure, system suitability, calculations, data reporting, and statistics.
- Demonstrate renewability and reproducibility of the developed reagents.

NIH/NCI 373: TOOLS AND TECHNOLOGIES FOR MONITORING RNA MODIFICATIONS



Budget: Phase I \$300,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals are not accepted.

Goal: Develop approaches for monitoring modified eukaryotic RNA, including mRNA and regulatory RNA. Potential tools, technologies, or products may include affinity-based assay kits for detecting RNA modifications; kits for sequencing based detection of RNA modifications; products to enable *in vitro* or *in vivo* imaging of modified RNAs; and software tools.

Phase I Activities & Deliverables include:

- Identify and justify development of a tool or technology for monitoring a specific RNA modification or set of RNA modifications.
- Develop and characterize the tool or technology for monitoring the specific RNA Modification(s).
- Specify and justify quantitative milestones that can be used to evaluate the success of the tool or technology being developed.
- Develop an assay or system for testing and benchmarking the specificity and sensitivity of the tool or technology
- Demonstrate the reliability and robustness of the tool, technology, or product.
- Provide justification that the tool, technology, or product can be scaled up at a price point that is compatible with market success and widespread adoption by the basic research community.
- Provide proof-of-concept data demonstrating the monitoring of the specific RNA modification(s) in relevant cell or animal models with the potential to benchmark data across a variety of cancer models.

NIH/NCI 374: NOVEL APPROACHES FOR LOCAL DELIVERY OF CHEMOPREVENTIVE AGENTS

Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals are accepted.

Goal: Advance the development and/or application of local delivery devices or formulations for chemoprevention. The technology should be designed for effective delivery of agent to a specific organ, while minimizing systemic toxicities. Acceptable toxicities will depend on the agent and target population.

Phase I Activities & Deliverables include:

- Select cancer type(s), organ site(s), chemoprevention agent(s), and method(s) of local delivery with adequate justification.
- Demonstrate that the chemoprevention agent is:
 - Stable in local formulation and/or when incorporated with the local delivery device/technology
 - Released at the organ(s) of interest when incorporated into a local delivery device/technology
- Perform preliminary proof-of-concept of the local delivery approach in a suitable animal model and demonstrate:
 - Accumulation/presence (>90% higher concentration) of the agent at the organ/tissue of interest than in the circulation
 - At least 90% reduction in agent concentration in the blood compared to systemic delivery/administration
 - Efficacy of the agent with relevant standard tests based on MOA of the agent (e.g., proliferation assay, apoptosis assay)
 - Significant reduction in toxicity with the local approach compared to systemic administration; relevant organ observed toxicity could be used with appropriate justification

NIH/NCI 375: DIAGNOSTIC IMAGING FOR CANCER IMMUNOTHERAPIES



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 3-4

Fast-Track proposals are accepted.

Goal: Provide much needed support for the development of diagnostic imaging technologies to identify patients who are likely to respond to cancer immunotherapies, evaluate the efficacy and potential toxicities of the treatment, and/or monitor cancer patients' prognosis. The cancer immunotherapies for this topic will include the ones that either have been approved by the FDA, or are still under clinical development. This topic is intended specifically to address cancer immunotherapies that depend upon eliciting an immune response.

Phase I Activities & Deliverables include:

- Demonstrate proof-of-concept for the development of a diagnostic imaging technology to identify patients who are likely to respond to immunotherapies, and/or evaluate efficacy and toxicities of immunotherapy, and/or monitor tumor prognosis under immunotherapy using the imaging technology.
- Quantify sensitivity and specificity of the imaging technology.
- Conduct preliminary biosafety study for the imaging technology.

NIH/NCI 376: IMAGING-BASED TOOLS FOR LONGITUDINAL AND MULTI-DIMENSIONAL MAPPING OF THE TUMOR AND ITS MICROENVIRONMENT



Budget: Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

Number of Anticipated Awards: 3-5

Fast-Track proposals are accepted.

Goal: The goal of this solicitation is to develop non-invasive, *in vivo* imaging-based platforms that can repeatedly generate three-dimensional molecular and cellular maps of the tumor and its TME at different time points for diagnosis and treatment prediction/response.

Phase I Activities & Deliverables include:

- Optimize detection scheme to demonstrate *in vitro* signal specificity
- Establish calibration curves correlating *in vivo* signal changes to concentration of molecular
- Demonstrate robust signal changes in response to *in vivo* perturbation.
- Demonstrate feasibility in generating maps of measurable parameters as a function of time.
- If new molecular targets are proposed, demonstrate specific binding/targeting capabilities of the agent/probe
- Determine optimal dose and detection window through proof-of-concept small animal studies
- Benchmark experiments against currently state-of-the-art methodologies.

For successful completion of benchmarking experiments, demonstrate a minimum of 5x improvement against comparable methodologies.

NIH/NCI 377: BRIDGING THE GUIDELINE IMPLEMENTATION GAP: CLINICAL DECISION-SUPPORT TO IMPROVE CANCER SYMPTOM MANAGEMENT



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 1-2

Fast-Track proposals are accepted.

Goal: Develop an electronic, rule-based, clinical decision-support system for symptoms (CDS-Sx) that leverages national CPGs to improve the evaluation and management of symptoms during and following cancer treatment.

Phase I Activities & Deliverables include:

- Develop a replicable consensus-based methodology to synthesize and transform evidence-based guideline recommendations from their narrative prose formulation into algorithms for symptom assessment and treatment
- Develop algorithms for evidence-based evaluation and management of constipation and fatigue
- Identify the approach and specific standards (e.g., CDISC, SDTM, and ICD) for standardization and encoding of data points in the algorithms
- Pilot test the CDS-Sx algorithms with a multidisciplinary panel of clinicians

NIH/NCI 378: MOBILE APPLICATION FOR SURVEILLANCE OF POST-RADIATION THERAPY HEALTH-RELATED QUALITY OF LIFE



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 3-4

Fast-Track proposals are accepted.

Goal: Develop mobile applications for reporting toxicities after radiation therapy either alone or in combination with other modalities in accordance with Patient Reported Outcomes Common Terminology Criteria for Adverse Events (PRO-CTCAE).

Phase I Activities & Deliverables include:

- Establish a project team with expertise in: mobile app development, radiation oncology specific to the treatment of at least one anatomical tumor location/site, and relevant adverse effects related to a specific tumor site or all sites
- Conduct a focused workshop with appropriate key opinion leaders
- In consultation with NCI, develop requirements for mobile application(s)
- Develop a prototype mobile application on the iOS and/or Android platforms
- Perform small scale usability testing with at least 25 cancer patients

NIH/NCI 379: SOFTWARE ENABLING DATA INTEGRATION FROM WEARABLE SENSORS TO GENERATE NOVEL ANALYTICS FOR CANCER PATIENTS



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals are accepted.

Goal: Advance the development, and subsequent commercialization, of scalable informatics tools and resources for their broad adoption across clinical cancer research applications such that continuous, passive monitoring of multiple biological parameters via wearable platform technologies may be used

Phase I Activities & Deliverables include:

- Establish a project team including proven expertise in sensor technology for physiological monitoring, wireless sensor integration with mobile devices, etc.
- Provide wireframes and user workflows for proposed Graphical User Interface (GUI) and software functions
- Develop a functional prototype system
- Include funds in the budget to present Phase I findings in a detailed report and demonstrate the final prototype to an NCI evaluation panel

NIH/NCI 380: COMPUTER AIDED DECISION SUPPORT FOR RADIATION ONCOLOGY



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals are accepted.

Goal: Develop new approaches and refine existing “radiomics” tools for radiotherapy treatment planning images to enable more accurate decision making support for radiation therapy treatment planning.

Phase I Activities & Deliverables include:

- Select radiomic features that are suitable for the proposed organ site and imaging modality (such as treatment planning CT) for improving treatment plans and/or their modification during therapy
- Develop appropriate tools and algorithms to extract the features from the images, characterize the data and assess the stability of the features
- Use the obtained radiomics data from treatment planning CTs (and other scans) to develop models for treatment plans and predict outcomes in radiation oncology
- Obtain feedback from radiation oncologists at a minimum of 3 different institutions regarding user specifications and clinical need
- Testing and validation of the software tool on a small subset of clinical images to demonstrate feasibility

NIH/NCI 381: DEVELOPMENT OF ARTIFICIAL INTELLIGENCE (AI) TOOLS TO UNDERSTAND AND DUPLICATE EXPERTS' RADIATION THERAPY PLANNING FOR PROSTATE CANCER



Budget: Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

Number of Anticipated Awards: 2-3

Fast-Track proposals are not accepted.

Goal: See if Artificial Intelligence (AI) technology can be used to improve treatment planning for prostate cancer by developing algorithms to “read” standard Computerized Tomography (CT) images in context with clinical information and recommend suitable treatment plan approaches.

Phase I Activities & Deliverables include:

- Establish a project team to develop an AI tool to understand and improve treatment planning for prostate cancer, comprising of cross disciplinary expertise.
- Identify criteria used by an expert planner to develop each treatment plan for each risk group (i.e., low, intermediate, and high NCCN).
- Design and develop computational algorithms/methods aimed at improving treatment planning for prostate cancer patients.
- At a minimum, apply this technology to standard 3D CT datasets. Use of additional imaging is at the preference of the planning team.



- 103 Devices for Transcatheter Surgery
- Fast-Track proposals will be accepted.
- Number of anticipated awards: 1-2 Phase I, 1 Phase II
- Budget (total costs):
 - Phase I: \$400,000 for 12-18 months
 - Phase II: \$3,000,000 for 24-36 months
- To develop an ensemble of devices to enable a broad array of novel catheter treatments for structural heart disease in adults and children. These devices will deliver and secure sutures inside the beating heart without surgery and promise a dramatic impact on cardiovascular therapeutics.





- 104 Tapered Guidewires for Transcatheter Electrosurgery
- Fast-Track proposals will be accepted.
- Number of anticipated awards: 1 Phase I, 1 Phase II
- Budget (total costs):
 - Phase I: \$200,000 for 12 months
 - Phase II: \$2,000,000 for 24 months
- To support the development of specific guidewire devices to ease and simplify transcaval access to the aorta, to make the procedure available to a wider range of patients and operators.





- 105 Reagent Development for Small Cell Number ChIC-seq
- Number of anticipated awards: 1 Phase I only
- Budget (total costs):
 - Phase I: \$150,000 for 1 year
- To develop reagents that can be used for mapping genome-wide epigenetic changes during normal development and disease process in rare primary and patient cells. Because conjugating proteins could result in inactivation of the proteins, it will be important to achieve efficient conjugation between antibodies and MNase while preserving the activities of both.





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SBIR Contract Solicitation PHS 2018-1 NIAID Topics

SBIR Contact Solicitation PHS 2018-1 contains opportunities to submit a proposal under a variety of different NIAID topics

- **050** Methods Improving HIV Protein Expression: Cell Substrate and Protein Purification
- **051** Inhaled Delivery of Clofazimine (CFZ) – An Important Anti-tuberculosis Drug
- **052** High-Throughput Assay Platform for Quantifying Latent HIV Reservoirs
- **053** Effective Targeted Delivery of RNA-based Vaccines and Therapeutics
- **054** Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases
- **055** Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases
- **056** Reagents for Immunologic Analysis of Non-mammalian Models
- **057** Development of Sample Sparing Assays
- **058** Bioinformatics tools to make data FAIR (Findable, Accessible, Interoperable, and Re-usable)
- **059** Diagnostics to Enable Malaria and Neglected Tropical Diseases (NTDs) Elimination
- **060** Computational Software Development to Advance Translational Research for Infectious Diseases
- **061** Induction of Mucosal Immune Response to Parenterally Delivered Vaccines
- **062** Novel Vaccine Technologies and Strategies to Promote Sustained Vaccine Efficacy

050 Methods Improving HIV Protein Expression: Cell Substrate and Protein Purification

Primary Goal:

- evaluate and modulate molecular pathways involved in regulating and enhancing HIV envelope/antigen expression in mammalian cell lines
- accelerate development of purification platforms in a cGMP manufacturing setting.

051 Inhaled Delivery of Clofazimine (CFZ) – An Important Anti-tuberculosis Drug

Primary Goal:

Develop an inexpensive, easy-to-use, inhaled delivery system for clofazimine to be used with combinations of systemic anti-TB drugs to improve treatment of MDR and DS TB.

052 High-Throughput Assay Platform for Quantifying Latent HIV Reservoirs

Primary Goal:

Design a high-throughput assay platform to reproducibly quantify changes in the size of the replication-competent latent HIV reservoir in resting CD4+ memory T cells from individuals on highly effective antiretroviral therapy.

053 Effective Targeted Delivery of RNA-based Vaccines and Therapeutics

Primary Goal: Encourage small businesses to develop improved platform technologies for delivery of RNA into specific cells and tissues to improve efficacy of HIV vaccines or therapeutics.

- **Long-term Goal:** Enable a small business to bring fully developed delivery systems for RNA-based HIV vaccines and therapies to the clinic and eventually to the market.
- **Short-term Goal:** Perform feasibility studies for development and use of delivery mechanisms for RNA-based HIV vaccines and therapies.

054 Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases

Primary Goal:

- Support screening for new adjuvant candidates for vaccines
 - against infectious diseases or
 - for autoimmune or,
 - for allergic diseases;
- Support characterization of newly discovered adjuvants;
- Support early-stage optimization of newly discovered adjuvants.

055 Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases

Primary Goal:

Accelerate pre-clinical development and optimization of a single lead adjuvant candidate (or a select combination-adjuvant) for

- prevention of human disease caused by infectious pathogens,
- or for autoimmune diseases, or
- allergic diseases.

056 Reagents for Immunologic Analysis of Non-mammalian Models

Primary Goal:

Development and validation of

- reliable antibodies against non-mammalian immune cell markers, or
- other reagents that allow for the identification and tracking of primary immune cells.

057 Development of Sample Sparing Assays

■ Primary Goal:

Accelerate commercial development of novel, standardized sample sparing assays that improve monitoring of the immune system using limited amounts of biological sample. Assays of interest may include, but are not limited to monitoring or assessments of the following:

- Antigen-specific immune responses
- Distinct immune cell populations
- T-cell and B-cell regulatory networks
- Innate immune responses
- Markers of T-cell turnover & homing to lymphoid tissue
- Cytokine & signaling networks
- Gene & protein expression/regulation
- Mucosal inflammatory & innate immune response

058 Bioinformatics tools to make data FAIR (Findable, Accessible, Interoperable, and Re-usable)

Primary Goal:

- Support development of new and/or improved methods that make data FAIR (for popular search engines to index) and provide relevant search results for research data sets available for public use.
- Tools will complement capabilities of more specialized search interfaces or services such as those provided by DAIT-funded data repositories.

059 **Diagnostics to Enable Malaria and Neglected Tropical Diseases (NTDs) Elimination**

Primary Goal:

Develop low-cost, diagnostic platforms with appropriate sensitivity and specificity for detection of subclinical malaria or select NTD infections (leprosy, lymphatic filariasis, trachoma, onchocerciasis, HAT) for use in disease elimination campaigns.

060 Computational Software Development to Advance Translational Research for Infectious Diseases

Primary Goal:

- Development of software that provides sensitive tools to enable translational research on high priority infectious disease pathogens by analyzing massive amounts of existing data.
- Use of novel cognitive computational strategies that combine large complex data sets and machine learning algorithms to translate information into knowledge that can help drive more informed decision-making.

The scope is limited to :

- Analyzing large-scale ncRNA data to identify expression patterns associated with flu, Mtb, or HIV infection and/or disease progression to guide future mechanistic and translational studies.
- Predicting flu virus evolution to improve vaccine strain selection & vaccine efficacy.

061 Induction of Mucosal Immune Response to Parenterally Delivered Vaccines

Primary Goals:

- Determine the best vaccine: adjuvant formulation(s) of current enteric vaccine candidate(s) that induce both mucosal and systemic immune responses .
- Characterize systemic and mucosal immune responses to parenterally-delivered enteric vaccine candidates.
- Encourage collaboration between academic institutions and small business entities to determine the optimal formulation for such vaccines.

062 Novel Vaccine Technologies and Strategies to Promote Sustained Vaccine Efficacy

Primary Goals:

- Identify or develop novel vaccine technologies (e.g., delivery platforms, formulations) that induce long-term protection against malaria or pertussis.
- Develop new vaccines or vaccine strategies using technologies that induce long-term immunity & sustainable efficacy against malaria or pertussis.



NIH/NIDA 163: Digital Markers for Marijuana

Budget: Phase I \$225,000 for 6 months; Fast Track \$1,725,000 for 2.5 years

Number of Anticipated Awards: 3-4

Fast-Track proposals accepted

Goals: Develop digital markers for detection of acute marijuana intoxication using, exclusively, Apple Inc.'s ResearchKit or/and Android ResearchStack frameworks. It is envisioned that the proposed and validated digital markers be consolidated into a tool for clinical research or law enforcement procedures.

Phase I Activities & Deliverables Include:

- Identify and describe selected digital markers. Present the conceptual framework.
- Customize the variables to be highly specific to the detection of marijuana-dependent dysfunction.
- Develop an app prototype and produce the video to clearly demonstrate the app functionality.
- Demonstrate the capability of the app in the pilot clinical study.
- Determine the feasibility of the app to achieve reproducible, highly sensitive measurements of psychomotor impairment.





NIH/NIDA 164: Development of Portable Neuromodulatory Devices for the Treatment of Substance Use Disorders (SUDs)

• Project Goals

- To build on published studies by developing viable portable neuromodulatory devices to treat SUDs or pain (i.e., result in opioid sparing).
- Develop new or existing technologies used for other indications into FDA-approvable commercial products to treat SUDs or pain.

• Phase I Activities and Expected Deliverables (focus on the neuromodulatory device characterization)

- Build a prototypic and appropriately-sized device; demonstrate feasibility
- Ensure the portable device has a refractory period or ‘prescription’ mechanism
- Show bio-equivalency based on prototypic measure and demonstrate device capability by comparing effects using other techniques (fMRI, EEG, etc.)
- Complete initial safety studies and proof-of-concept clinical trial

• Phase II Activities and Expected Deliverables (involves clinical studies on the effects of the portable device to the user and device usability)

- Lab test of devices followed by improvement finalization
- A test on SUD or pain (opioid sparing) w/ a minimum of 15 enrolled participants
- File an IDE, complete IDE-enabling studies, and retesting of device in a Phase I condition
- Detailed commercialization plan, including cost analysis, market strategy to extend treatment effects and reduce relapse, device sales and reimbursement possibilities

Budget (total costs)

Phase I: **\$225,000** for 8 months

Phase II: **\$1,500,000** for 1 year

No Fast-Track or Direct-to-Phase II proposals will be accepted.

Anticipated awards: 4



Centers for Disease Control and Prevention (CDC)



Presented by:

Sean David Griffiths, M.P.H.

SBIR Program Manager

Office of Technology and Innovation (OTI)

Office of the Associate Director for Science (OADS)

August 15, 2017



CDC SBIR Program

- The Office of the Associate Director for Science (OADS) manages CDC's SBIR Program and works with CDC Centers/Institutes/Offices (CIO) to determine where SBIR funds would best be used to support high quality, high impact SBIR projects
- CDC participates in the SBIR/STTR HHS Omnibus Grant Solicitation and contract solicitations
 - CDC does not participate in the STTR Program (at this time)
 - CDC has opted to participate in the Majority VC ownership authority (FY15')
- Budget - CDC SBIR set-aside approximately \$11.0 million (FY17')



CDC SBIR Program

- **Uniqueness of CDC's SBIR Program** – life sciences; public health; emergency response; – domestic & international
- **Awards** - ≈ 25 Phase I's up to \$150,000 each and ≈ 5-6 Phase II's per year up to \$1.0 M each
- **Grants vs. Contracts** –
 - FY13 – 58% grants & 42% contracts
 - FY14 – 25% grants & 75% contracts
 - FY15 – 30% grants & 70% contracts
 - FY16 – 56% grants & 44% contracts



CDC Strategic Priorities

- Strengthen surveillance, epidemiology, and laboratory services;
- Improve the ability to support state, tribal, local and territorial public health;
- Improve global health impact;
- Increase policy impact; and,
- Better prevent illness, injury, disability and death.



Where CDC's SBIR Program Intersects with Small Business Concerns/VCs/Entrepreneurs

- Help CDC confront public health challenges through the SBIR Program:
 - CDC supports groundbreaking health and medical research and real-time emergency response activities to keep the U.S. safe, healthy, and secure;
 - CDC will promote and fund research and development that supports our mission and/or strategic priorities;
 - CDC has roles at the local, state, federal and global levels; an,
 - The SBIR program is a way for innovators and entrepreneurs to contribute to making not only the U.S., but the world a healthier and safer place.



Modular, End-user-assembled Biosafety Cabinets for Sustainable Biocontainment

- Number of anticipated awards: 1-2
 - Budget: Phase I up to \$ 150,000 for up to 6 months
- Project goal(s):
 - To offer sustainable biocontainment to global laboratories by developing an inexpensive cabinet with modular components that are easy to assemble, disassemble and transport.
- Phase I Activities and Deliverables:
 - To engineer the biosafety cabinet (BSC) modules so that all motor parts and filters are easily accessible and can be replaced or repaired by laymen as needed. Modular BSC cabinets will be designed with robust, multi-membrane filter components that are durable and easy to maintain.



(039) Finding Human Carriers of Taeniasis to Prevent Neurocysticercosis Associated Epilepsy

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - To develop a human taeniasis coproantigen detection assay using capture reagents that are species-specific and heat-stable and have minimal batch-to-batch variation.
- Phase I Activities and Deliverables:
 - Find monoclonal antibodies/aptamers that will bind to *T. solium* adult worm extracts but not to Phosphate buffered saline or normal stool samples
 - Submit to CDC, 5 monoclonal antibody clones or 5 aptamers (sequences and aptamer products) that bind with high affinity to *T. solium* adult worm extracts but NOT to normal stool samples
 - Submit to CDC, a detailed report of the strategy and the analysis of the monoclonal antibodies or aptamers which include the sequences of the 5 aptamers selected



(040) Web-based Application to Enable Healthy Behaviors Through Behavioral Design

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - Design and build a web-based tool that demonstrates how each concept/aspect of the environment and resulting human experience can be modified to enable healthier behaviors.
- Phase I Activities and Deliverables:
 - Collaborate with an innovative design/architectural firm that can use architectural modelling, design thinking, and industry insights to layout a basic web-platform assisting those in the building and design community to understand the potential health impacts of their work.
 - Develop checklists and guide (i.e., toolkits) for application for each setting and venue, with subject matter expert input
 - Create a framework to guide design choices by how they influence behaviors or actions with health outcomes



Antifungal-Containing Solution for Corneal Tissue Storage and Transport

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - The specific research aim is to develop a liquid solution for corneal tissue storage and transport that contains an antifungal drug that inhibits growth of contaminant fungi for at least 14-days following donor tissue extraction. The solution must be usable in compliance with current corneal tissue storage, evaluation and transport procedure guidance and regulations.
- Phase I Activities and Expected Deliverables:
 - Assemble list of viable antifungals (e.g., Amphotericin B) and design *in vitro* and *in vivo* studies to demonstrate effectiveness against *Candida* and other fungi, optimize antifungal concentration, and demonstrate that the product does not adversely affect corneal tissue quality and health.
 - Present preliminary data on efficacy and safety, showing effective antifungal properties without compromise of corneal tissue health and quality.
 - Present data supporting optimized antifungal and ingredient concentrations, and advanced evidence of product suitability for further development and ultimate regulatory evaluation.



Bacterial Amplicon Subtyping

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - The offeror will provide an innovative bioinformatics algorithm in their software platform that allows the user to design amplicons that can be sequenced to determine the subtype of a pathogen. Specifically, the software must identify heterogeneous regions which are useful for strain typing and also flanked by conserved sites suitable for primers. The resolution of strain subtyping must be equivalent to current whole genome sequencing-based subtyping techniques for isolates and can distinguish isolates associated with an outbreak from background cases. (see solicitation for more)
- Phase I Activities and Expected Deliverables:
 - The contractor will design the algorithm to meet the above specifications and perform in silico validation of amplicons. The contractor will use epidemiologically relevant sequence data from the relevant pathogen groups for testing their algorithm and will be expected to provide preliminary results upon completion of Phase I. The results must include primers, fasta files for amplicons, in silico PCR results, annotated bedgraphs and coverage histograms.



Identification of *Brucella canis* Seroreactive Proteins and Serology Assay Development

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - The goal of this project is to develop assays for detection of antibodies against rough *Brucella* strains such as *B. canis* and bovine vaccine strain *B. abortus* RB51, which are known human pathogens. Presently, we are not able to offer serological diagnosis to infected patients, or monitoring to exposed individuals.
- Phase I Activities and Expected Deliverables:
 - Screen entire proteome of *Brucella* species using sera from canine and human infections to identify specific *B. canis* and *B. abortus* RB51 antigens that are recognized by antibodies.



Multiplex Pan_lyssavirus/ β -actin Real-time RT-PCR Assays for Rabies Diagnostics

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - Develop a reaction kit combining the LN34/ β -actin real-time RT-PCR assays into a single reaction. Select enzymes and reaction volumes to further reduce the cost for the assay. Develop a dry-bead format and optimize the reaction conditions for diagnostic laboratories.
- Phase I Activities and Expected Deliverables:
 - Utilize artificial positive control RNA and rabies-negative brain samples to optimize the multiple assay combining LN34/ β -actin real-time RT-PCR assays
 - Test low cost enzymes to further reduce the cost of the reaction kit, develop a dry-bead format for the reaction kits to improve the stabilities of the reaction kits.
 - Optimize the reaction in a low volume format to further reduce the cost of the reaction



Tools for Combined Analysis of Optical Mapping and Sequencing Data

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 12 months
- Project goal(s):
 - Although optical mapping (OM) is currently used as a quality control tool for next generation sequencing (NGS) assemblies, if an efficient tool were available to combine both datasets, OM data could be used to accelerate or automate genome assemblies. Development of a tool would allow users to integrate OM and sequencing data from any platform, thereby reduce investigation response time and increase sequence data quality.
- Phase I Activities and Expected Deliverables:
 - Import OM and NGS data from any platform
 - Develop algorithms to scaffold sequence data using optical mapping data
 - Develop algorithms to compare optical maps with NGS assemblies
 - Develop graphical interface and reporting



(048) – Development of a Benchtop Laboratory Platform for Amplicon Deep Sequencing

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 6 months
- Project goal(s):
 - The aim of this proposal is to develop and evaluate a new, small footprint, benchtop automated nucleic acid extraction, amplification and sequencing system that fundamentally improves laboratory safety and quality control (QC) (See solicitation).
- Phase I Activities and Expected Deliverables:
 - The unit design and industrial diagrams with the final layout will be generated. Computer modeling of the final design is required for testing virtual laboratory protocols and fine tuning of individual processes and steps.
 - The workstation is expected to perform the entire laboratory protocol starting from clinical samples to the next generation sequencing library within a few hours (between 8-12 hours) without any user intervention.



(049) – Risk Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 6 months
- Project goal(s):
 - The primary goal of this project is to develop a toolkit for pharmacies to implement risk reduction services targeting person who inject drugs (PWID) who access syringes through pharmacies. Pharmacists should be provided training and tools to implement pharmacy-based syringe programs and risk reduction services in order to improve the health of their local communities (See Solicitation).
- Phase I Activities and Deliverables / Specific project goal(s):
 - Develop a prototype for a pharmacy-based syringe program and toolkit to implement risk reduction services for pharmacy-based risk reduction services associated with non-prescription syringe sales. Tools can include products that provide safer methods for injection and for safe syringe disposal (See solicitation).



Stable Sabin-based Inactivated Polio Vaccine

- Number of anticipated awards: 1
 - Budget: Phase I up to \$ 150,000 for up to 6 months
- Project goal(s):
 - Proposals are solicited for the development of a heat-stable, Sabin-based inactivated polio vaccine administered by needle and syringe. Heat stability is defined as no loss in antigenicity (as measured by standard vaccine potency tests) and no reduction in immunogenicity (as measured in accepted animal models for IPV potency) following heat challenge.
- Phase I Activities and Deliverables / Specific project goal(s):
 - Develop a formulation and process for dry-preserving polio vaccines.
 - Generate a Sabin-IPV by inactivating dry-preserved oral polio vaccine (OPV).
 - Assess heat stability by in vitro potency tests, at several storage conditions.
 - Prepare vaccine formulations for in vivo IPV potency assay using Wistar rat model





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

Deadline for receipt of ALL Proposals

FRIDAY October 20, 2017

5:00 PM Eastern Daylight Time

Electronic submission must be complete.

No paper submissions.





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