

# Virtual SBIR Classroom

## Developing the Business of Technology

**bbc** Entrepreneurial Training & Consulting

1

**mti**  
Maine Technology Institute  
Investing in Innovation

[www.mainetechnology.org](http://www.mainetechnology.org)

## NIH SBIR/STTR Proposal Development

May 6, 2020

Presenter:  
Becky Aistrup  
Managing Partner  
734.930.9741  
[becky@bbcetc.com](mailto:becky@bbcetc.com)  
[bbcetc.com](http://bbcetc.com) / @BBC\_etc

Copyright © BBC Entrepreneurial Training & Consulting, LLC  
DEVELOPING THE BUSINESS OF TECHNOLOGY

2

## NIH SBIR/STTR Proposal Development

To be covered in just 3 hours:

- Assumptions\*
- Strategic Planning (in brief...)
- (Rapid) Review of the Review Criteria
- Tactical Preparation
- Writing the Proposal: Critical Factors for Key Sections



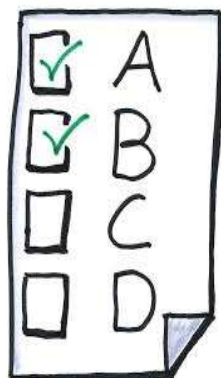
\*Our first assumption is that you're already familiar with overall SBIR/STTR eligibility and rules. If not, please feel free to view a **free** recorded webinar "ABC's of SBIR" (<https://bbcetc.com/training/purchase-webinars/>)



3

3

Our first poll of the day.....



IF YOU'RE NOT  
LIVING IN SWEAT PANTS



YOU'RE NOT LIVING



4

A couple of more polls about you....



5

### The Project: What Does SBIR/STTR Fund?

- PRODUCT Development



- Based on “technological innovation”
  - “high risk”



- Credible Commercialization Strategy



6

6

## The Basics of SBIR: 3 Phases

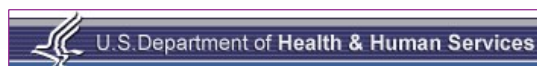
- Phase I Goal = FEASIBILITY
- Feasibility of what? Whatever you hope to accomplish in Phase III!



7

7

## National Institutes of Health




8

8

### HHS SBIR/STTR Program Funding - 2019





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

ACF=Administration for Children and Families  
 ACL=Administration for Community Living  
 NIDILRR=Nat'l Inst. On Disability, Independent Living & Rehabilitation Research  
 \*DOES NOT PARTICIPATE IN THE OMNIBUS SOLICITATION




9

### NIH Mission

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



10

NIH is organized into:   

 **27 Separate Institutes & Centers**  
 (IC) each with different:

-  missions & priorities
-  budgets
-  ways of deciding which grants to fund

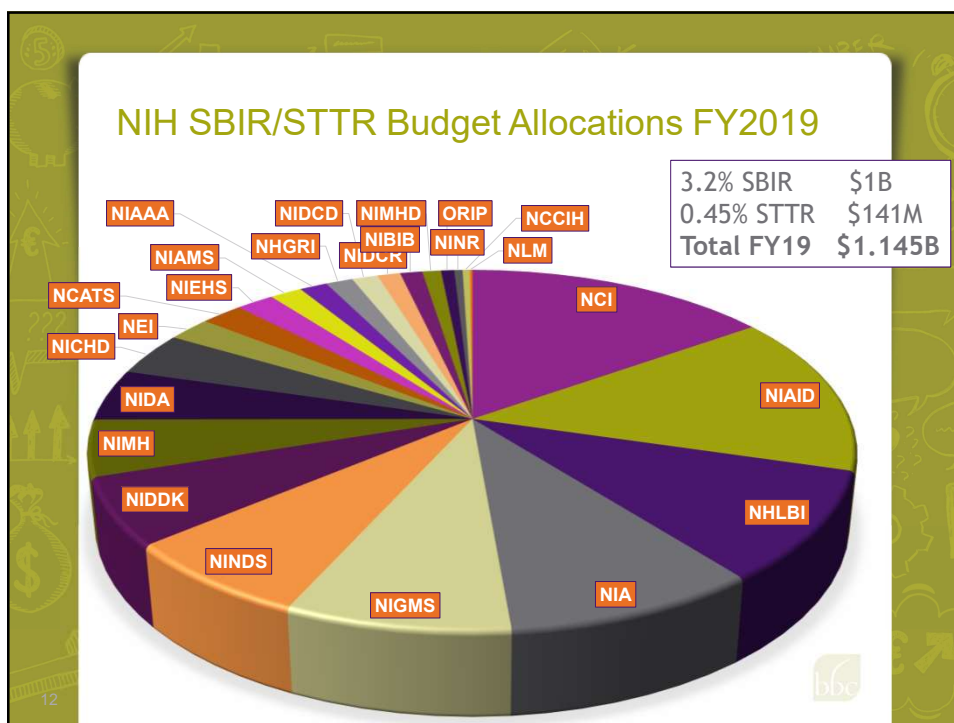
    

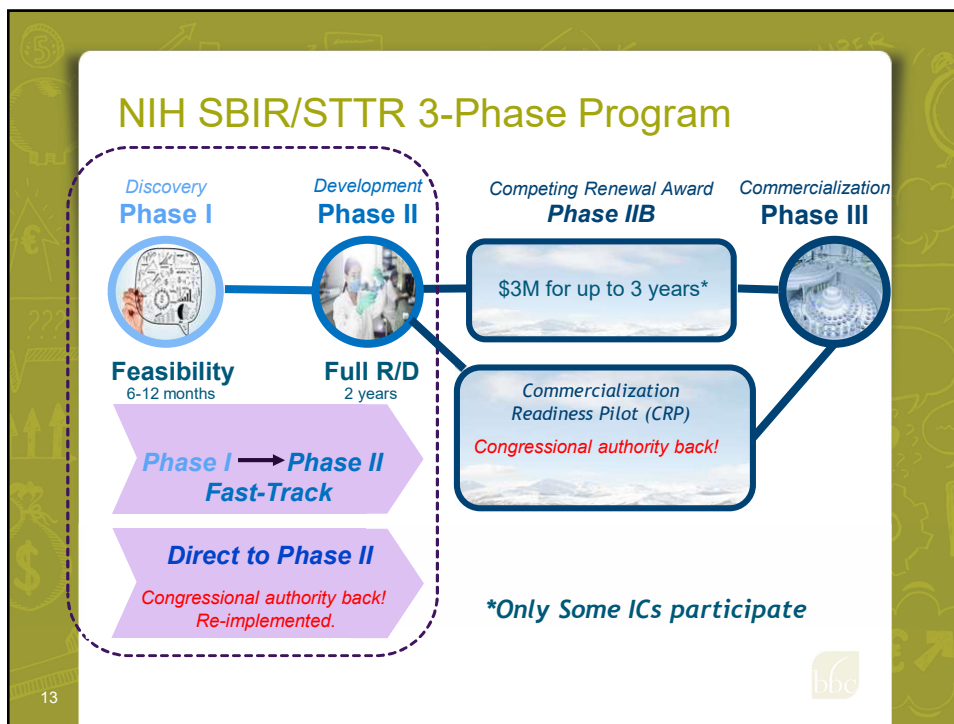
    

11



12



13

### NIH's Contract Solicitation

NIH National Institutes of Health Office of Extramural Research		Differences between contracts and grants
Contracts	Grants	
Acquisition mechanism	Assistance mechanism	
Follows FAR and SBIR Policy Directive	Follows Grants Policy and SBIR PD	
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 PO anytime for anything	
eCPS - New (used to be on paper)	SF424, grants.gov, eRA Commons	

14

14


## Assumptions going into Phase I

- You meet the eligibility requirements
  - There is, or will be, a **small business** with appropriate ownership and control
  - The small business has, or will have, **company-controlled research facilities**
  - The small business has, or will employ, **research personnel**
  - The company will conduct a minimum of **2/3 of the effort in Phase I SBIR** (50% for Phase II)
  - The company will conduct a minimum of **40% of the effort in Phase I and II STTR**; Primary Research Institution will conduct a minimum of **30% of the effort**
- You have determined you have a suitable project
  - The small business is developing **products**
  - The products are based on **technological innovation**
- You have completed the required registrations
- Funding Cycles match your **commercialization** goals

15

15

## Assumptions going into Phase II




- Same as Phase I plus.....
- You have or will have achieved your Phase I aims and demonstrated **feasibility**
- Well-conceived commercialization plan
- Letters of Phase III support/interest

16

16




## Assumptions for Fast-Track



- Same as Phase I plus....
- You have convincing preliminary data
- There is a clear separation of Phase I and II with clear, measurable, achievable milestones & Specific Aims
- You've developed a well conceived Commercialization Plan
- You can include Letters of Phase III support/interest
- Your team has a track record of commercialization
- You've discussed it with NIH program staff

17



17

## Assumptions for Direct to Phase II




- Same as Phase I plus....
- **ONLY** available for SBIR
- You have completed & can provide data proving feasibility/Phase I-equivalent studies are already completed using funds other than SBIR/STTR funds
- You have a well conceived Commercialization Plan and Letters of Phase III support/interest
- Your team has a track record of commercialization on your team
- You've discussed it with NIH program staff

18



18


## Strategic Planning



**BEFORE you start to write your proposal:**


- Understand NIH's structure and solicitation process
- Identify an appropriate solicitation
- Find one or more Institutes/Centers that are a fit for your project
- Identify an appropriate study section and determine the composition of reviewers
- Contact\*\* the relevant Program Director(s) to validate your assumptions
  - *\*\* Prepare your Specific Aims page to facilitate this discussion*

19




19

## Finding a home for your project



20



20

## Is NIH Interested in my project?



- Search *NIH Reporter*
  - Matchmaker
- Read Omnibus Solicitation *Research Topics and Program Descriptions* Document
  - Identify relevant NIH Institute/Center
  - Contact primary SBIR/STTR program director
  - Confirm interest and relevance

21



21

## NIH RePORT



<http://report.nih.gov/>

22

22

NIH RePORTER  
Version: 0.3.0  
03/20/2014 Release Note: New enhancements now available.  
View Release Notes for more information.

About RePORTER DATA | FAQ | RePORTER Manual | RSS of Newly Added Projects

QUERY | BROWSE NIH | MATCHMAKER BETA

SUBMIT QUERY | CLEAN QUERY

Fiscal Year (FY) Current FY is 2018 **Active Projects** SELECT

RESEARCHER AND ORGANIZATION

Principal Investigator (PI) / Project Leader: (Last Name, First Name) Use % for wildcard Enter several PIs/Project Leader names

Organization: LOOKUP Please enter at least 3 characters to use Lookup. Contains Begins with Exact

Department: SELECT

Organization Type: SELECT

City: Use % for wildcard

State: SELECT

Country: SELECT

Congressional District: SELECT

DUNS Number:

TEXT SEARCH

Text Search (Logic) **Alzheimers Diagnostic**

Search in:  Projects  Publications  News

Limit Project search to:  Project Title  Project Terms  Project Abstracts

Limit Publication search to: Start Year: 2013 End Year: 2014

PROJECT DETAILS

Project Number/ Application ID: Use % for wildcard in project number, e.g. %R21% Enter multiple project numbers/application IDs

Agency/Institute/Center: Admin Funded

NIH Spending Category: SELECT

Funding Mechanism: **SBRV/STR** SELECT

Award Type: SELECT

Activity Code: SELECT

Study Section: SELECT

Standing CSR study sections only

23

There were 42 results matching your search criteria. Records per page: 25. Show/Hide Search Criteria

Click on the column header to sort the results. Page 1 of 2 Next Last

T: Application Type: Act: Activity Code: Project: Admin IC: Serial No.: Year: Support Year/Supplement/Amendment

Act	Project	Year	Sub #	Project Title	Contact PI/Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
5	R43	AG052271	02	A METHOD FOR EARLY AND EASY DETECTION OF ALZHEIMER'S DISEASE	LIU, GANG et al.	NANOMEDIC, INC.	2017	NIA	NIA	\$198,278	[Icon]
1	R41	AG053149	01A1	MULTI-MODALITY IMAGE DATA FUSION AND MACHINE LEARNING APPROACHES FOR PERSONALIZED DIAGNOSTICS AND PROGNOSTICS OF MCI/DUE TO AD	LURE, FLEMING Y. M.	MS TECHNOLOGIES CORPORATION	2016	NIA	NIA	\$149,936	[Icon]
1	R43	AG057325	01	DEVELOPMENT OF AN ALZHEIMER'S DISEASE SPECIFIC ANTIBODY BIOMARKER FOR A TAU OLIGOMER FRAGMENT	MOE, JAMES G.	OLIGOMERIX, INC.	2017	NIA	NIA	\$302,112	[Icon]
2	R44	GM108137	02	LIVE-CELL ASSAYS OF ER AND GOLGI ENZYME ACTIVITIES	NALEWAY, JOHN J.	MARKER GENE TECHNOLOGIES	2017	NIGMS	NIGMS	\$631,417	[Icon]
1	R43	NS090920	01	THE DEVELOPMENT OF MICROSCOPE FOR THE 3D IMAGING OF EX VIVO CNS TISSUES	RAGAN, TIMOTHY M.	TISSUEVISION, INC.	2015	NINDS	NINDS	\$333,635	[Icon]
1	R43	AI126931	01A1	NANOWIRE SENSOR-BASED ASSAY FOR DETECTING DENGUE AND CHIKUNGUNYA VIRUS	RAY, ANAMIKA	INNOSENSE, LLC	2017	NIAID	NIAID	\$223,251	[Icon]
2	R44	AG048758	03	LASER SPECKLE IMAGING CHIP FOR TELEHEALTH APPLICATIONS	REGE, ABHISHEK	VASOPTIC MEDICAL, INC.	2017	NIA	NIA	\$740,497	[Icon]
5	R44	AG050454	03	DEVELOPMENT OF AN OPHTHALMIC DIAGNOSTIC PROBE FOR NEURODEGENERATIVE DISORDERS	SARRAF, STELLA	AMYDIS DIAGNOSTICS, INC.	2017	NIA	NIA	\$211,174	[Icon]

Page 1 of 2 Next Last

24

DESCRIPTION DETAILS RESULTS HISTORY SUBPROJECTS SIMILAR PROJECTS NEARBY PROJECTS BETA LINKS NEWS AND MORE

Project Number: 1R43AG057325-01  
 Title: DEVELOPMENT OF AN ALZHEIMER'S DISEASE SPECIFIC ANTIBODY BIOMARKER FOR A TAU OLIGOMER FRAGMENT  
 Contact PI / Project Leader: MOE, JAMES G.  
 Awardee Organization: OLIGOMERIX, INC

Contact PI / Project Leader Information: Name: MOE, JAMES G. Email: Click to view Contact PI / Project Leader email address  
 Program Official Information: Name: HSIAO, JOHN Email: Click to view PO email address  
 Other PI Information: Not Applicable

Organization: Name: OLIGOMERIX, INC City: NEW YORK Country: UNITED STATES (US)  
 Department Type/ Organization Type: Unavailable Domestic For-Profits  
 Congressional District: State Code: NY District: 17

Other Information:  
 FOA: PA-16-302  
 Study Section: Special Emphasis Panel IZRG1-ETT-N-P (13/8)  
 Fiscal Year: 2017 Award Notice Date: 1-SEP-2017  
 DUNS Number: 788545130  
 Project Start Date: 1-SEP-2017  
 Budget Start Date: 1-SEP-2017  
 CFDA Code: 866  
 Project End Date: 31-AUG-2018  
 Budget End Date: 31-AUG-2018

Administering Institutes or Centers:  
 NATIONAL INSTITUTE ON AGING

Project Funding Information for 2017:  
 Total Funding: \$302,112

Year	Funding IC	FY Total Cost by IC
2017	NATIONAL INSTITUTE ON AGING	\$302,112

25

25

DESCRIPTION DETAILS RESULTS HISTORY SUBPROJECTS SIMILAR PROJECTS NEARBY PROJECTS BETA LINKS NEWS AND MORE

Project Number: 1R43AG057325-01  
 Title: DEVELOPMENT OF AN ALZHEIMER'S DISEASE SPECIFIC ANTIBODY BIOMARKER FOR A TAU OLIGOMER FRAGMENT  
 Contact PI / Project Leader: MOE, JAMES G.  
 Awardee Organization: OLIGOMERIX, INC

Abstract Text:  
 PROJECT SUMMARY - Phase I SBIR (PA-16-302) Title - Development of an Alzheimer's disease specific antibody biomarker for a tau oligomer fragment The prevalence of Alzheimer's disease (AD) is increasing worldwide due to demographic shifts and an aging population and currently there are no disease-modifying drugs. It is the most costly disease in the US with a financial burden of over \$236 billion annually in direct costs that is estimated to increase to \$1 trillion by 2050. There is an urgent unmet need for the development of blood biomarkers for the early detection and staging of AD. The lack of accurate, sensitive, and well-validated biomarkers for AD is a rate limiting factor for identifying effective treatments. Tau protein, and in particular tau oligomers, have become a high priority target for AD due to 1) their high correlation with diseased regions within the brain of AD patients, 2) their newly discovered extracellular activity that is believed to result in the impairment of synaptic function and loss of memory and 3) their role in the spread of pathology. Oligomerix has developed novel methods to highly purify tau oligomers and has discovered that they undergo autolytic fragmentation at specific sites creating neo-epitopes at the cut ends. Polyclonal antibodies (pAbs) to the neo-epitopes were generated, and one pAb showed a striking specificity for AD specimens. In Aims 1 and 2, monoclonal Abs (mAbs) will be generated that have specificity for this fragment end and specificity for the uncut site. Aim 3 will be to characterize the mAbs and perform a proof-of-concept biomarker study. The overall goal of this project is to produce a blood-based, non-invasive diagnostic test as a biomarker for tau fragment levels from biological specimens for AD. These mAbs can also be used to understand the role of tau autolytic fragmentation in AD, and the ratio of cut to uncut tau at this site may provide greater sensitivity in determining AD stage. Additionally, the tau fragment specific mAb that will be developed under the proposed program could have tremendous commercial utility for any therapeutic program, immuno- or small molecule therapeutics seeking to reduce tau accumulation, enhance clearance, or prevent the formation of tau oligomers. The global CNS biomarker market is projected to reach \$5.1 billion by 2020 from \$3.1 billion in 2015. The proposed study will be enabling for Oligomerix's internal drug discovery programs, and the Company will make these assays available by commercializing them via collaboration with a diagnostic or life sciences company. Thus the proposed program, if successful, will have significant commercial potential and impact. The strong management and scientific team will ensure competencies in mAb production and characterization, as well as assay development and commercialization. Furthermore, the presence of Dr. Peter Davies and Dr. Steven Jacobson on the Scientific Advisory Board provide top notch scientific and business experience to the Company.

Public Health Relevance Statement:  
 PROJECT NARRATIVE There is an unmet need for the development of blood biomarkers for early detection of Alzheimer's disease (AD). A blood-based biomarker would enable more rapid patient recruitment and better retention for clinical therapeutic and diagnostic studies because it is minimally invasive, low cost, and easier to perform. The overall goal of this project is to produce a blood-based, non-invasive diagnostic test as a biomarker for tau fragment levels from biological specimens for Alzheimer's disease (AD).

Project Terms:  
 aging population; Alzheimer disease detection; Alzheimer's Disease; Antibodies; assay development; base; Biological; Biological Assay; Biological Markers; Biological Sciences; Blood; blood-based biomarker; Brain; Brain Diseases; brain tissue; Businesses; Cerebrospinal Fluid; Cleaved celt; Clinical; Collaborations; commercialization; Competence; cost; Cost of illness; Development; diagnostic; diagnostic tests; Direct Costs; Disease; Disease Progression; drug development; drug discovery; early detection biomarkers; effective therapy; Employee Strikes; Ensure; Enzyme-Linked Immunosorbent Assay; Epitopes; experience; extracellular; Goals; Hybridomas; Immunoblotting; Immunohistochemistry; Immunotherapeutic agent; Impairment; in vivo; Laboratories; Legal patent; Liquid substance; loss of function; Memory Loss; Methods; minimally invasive; N-terminal; noninvasive diagnosis; notch protein; novel; Pathologic; Pathology; Patient Recruitments; Patients; Pattern; Peptides; Pharmaceutical Preparations; Phase; phase 1 study; Plasma; polyclonal antibody; Prevalence; prevent; Production; programs; Proteins; Recombinants; Reproducibility; Research; Role; Signal Transduction; Site; Small Business Innovation Research Grant; small molecule therapeutics; Specificity; Specimen; Staging; Structure; success; Surrogate Markers; synaptic function; tau aggregation; tau Proteins; Therapeutic; Therapeutic Studies; Therapeutic Uses

26

26

## Omnibus Solicitation & materials

**2019 SBIR and STTR Omnibus/Parent Grant Solicitations for the NIH, CDC, and FDA, Clinical Trial Not Allowed and Clinical Trial Required**

- ➔ SBIR Omnibus/Parent Clinical Trail Not Allowed Funding Opportunity Announcement (PA-19-272)
- ➔ STTR Omnibus/Parent Clinical Trail Not Allowed Funding Opportunity Announcement (PA-19-270)
- ➔ SBIR Omnibus/Parent Clinical Trail Required Funding Opportunity Announcement (PA-19-273)
- ➔ STTR Omnibus/Parent Clinical Trail Required Funding Opportunity Announcement (PA-19-271)
- ➔ 2019 Program Descriptions and Research Topics Document  
📄 (2.31 MB) 📄 (614 KB)
- ➔ 2019 SBA approved topics list for budget waivers  
📄 (554 KB) 📄 (72 KB)

NIH SBIR/STTR Grant Forms

**Standard Due Dates:**

- January 5
- April 5
- September 5

BDC

27

## SBIR Omnibus Solicitation FOA

Funding Opportunity Title	PHS 2019-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed)
Activity Code	R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II and Fast-Track
Announcement Type	Reissue of PA-18-574
Related Notices	<ul style="list-style-type: none"> <li>• May 07, 2019 - HHS Issues Four (4) PHS 2019-2 SBIR and STTR Omnibus/Parent Grant Solicitations. See Notice NOT-OD-19-105.</li> </ul>
Funding Opportunity Announcement (FOA) Number	PA-19-272
Companion Funding Opportunity	PA-19-270 STTR R41/R42- Phase I, Phase II, and Fast Track PA-19-271 STTR R41/R42- Phase I, Phase II, and Fast Track PA-19-273 SBIR R43/R44- Phase I, Phase II, and Fast Track

bbc

28

## SBIR Omnibus Solicitation

### Key Dates

Posted Date	May 7, 2019
Open Date (Earliest Submission Date)	August 5, 2019
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not Applicable *** SBIR/STTR applications are no longer accepted on Standard AIDS Due dates.
Scientific Merit Review	Standard dates apply
Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	April 7, 2020

- Sep 5 2019
- Jan 5 2020
- Apr 6 2020

bbc

29

## Department of Health and Human Services

### Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH) Centers for Disease Control and Prevention (CDC) U.S. Food and Drug Administration (FDA)
Components of Participating Organizations	<ul style="list-style-type: none"> <li>National Cancer Institute (NCI)</li> <li>National Eye Institute (NEI)</li> <li>National Heart, Lung, and Blood Institute (NHLBI)</li> <li>National Human Genome Research Institute (NHGRI)</li> <li>National Institute on Aging (NIA)</li> <li>National Institute on Alcohol Abuse and Alcoholism (NIAAA)</li> <li>National Institute of Allergy and Infectious Diseases (NIAID)</li> <li>National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)</li> <li>National Institute of Biomedical Imaging and Bioengineering (NIBIB)</li> <li>Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)</li> <li>National Institute on Deafness and Other Communication Disorders (NIDCD)</li> <li>National Institute of Dental and Craniofacial Research (NIDCR)</li> <li>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</li> <li>National Institute on Drug Abuse (NIDA)</li> <li>National Institute of Environmental Health Sciences (NIEHS)</li> <li>National Institute of General Medical Sciences (NIGMS)</li> <li>National Institute of Mental Health (NIMH)</li> <li>National Institute of Neurological Disorders and Stroke (NINDS)</li> <li>National Institute of Nursing Research (NINR)</li> <li>National Institute on Minority Health and Health Disparities (NIMHD)</li> <li>National Library of Medicine (NLM)</li> <li>National Center for Complementary and Integrative Health (NCCIH)</li> <li>National Center for Advancing Translational Sciences (NCATS)</li> <li>Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)</li> <li>Center for Global Health (CGH/CDC)</li> <li>National Center on Birth Defects and Developmental Disabilities (NCBDDD/CDC)</li> <li>National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP/CDC)</li> <li>National Center for Emerging and Zoonotic Infectious Diseases (NCEZID/CDC)</li> <li>National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP/CDC)</li> <li>National Center for Immunization and Respiratory Diseases (NCIRD/CDC)</li> <li>National Center for Injury Prevention and Control (NCIP/CDC)</li> <li>National Institute for Occupational Safety and Health (NIOSH/CDC)</li> <li>National Center for Environmental Health (NCEH/CDC)</li> <li>Center for Preparedness and Response (CPR/CDC)</li> <li>Center for Biologics Evaluation and Research (CBER/FDA)</li> <li>Center for Drug Evaluation and Research (CDER/FDA)</li> <li>Center for Food Safety and Applied Nutrition (CFSAN/FDA)</li> <li>Center for Devices and Radiological Health (CDRH/FDA)</li> <li>Center for Veterinary Medicine (CVM/FDA)</li> <li>Office of Critical Path Programs (CPP/FDA)</li> <li>Office of Orphan Products Development (OOPD/FDA)</li> </ul>

You must find a fit!

30

## SBIR Omnibus Solicitation CT Required

<b>Participating Organization(s)</b>	National Institutes of Health (NIH) Centers for Disease Control and Prevention (CDC) U.S. Food and Drug Administration (FDA)
<b>Components of Participating Organizations</b>	<p>National Cancer Institute (NCI) National Eye Institute (NEI) National Heart, Lung, and Blood Institute (NHLBI) National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA)</p> <p><i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD) National Institute on Deafness and Other Communication Disorders (NIDCD) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of General Medical Sciences (NIGMS) National Institute of Mental Health (NIMH) National Institute of Nursing Research (NINR) National Institute on Minority Health and Health Disparities (NIMHD) National Center for Complementary and Integrative Health (NCCIH)</p> <p>Center for Global Health (CGH/CDC) National Center on Birth Defects and Developmental Disabilities (NCBDD/CDC) National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP/CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID/CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP/CDC) National Center for Immunization and Respiratory Diseases (NCIRD/CDC) National Center for Injury Prevention and Control (NCIPC/CDC) National Institute for Occupational Safety and Health (NIOSH/CDC) National Center for Environmental Health (NCEH/CDC)</p> <p>Center for Preparedness and Response (CPR/CDC)</p> <p>Center for Biologics Evaluation and Research (CBER/FDA) Center for Drug Evaluation and Research (CDER/FDA) Center for Food Safety and Applied Nutrition (CFSAN/FDA) Center for Devices and Radiological Health (CDRH/FDA) Center for Veterinary Medicine (CVM/FDA) Office of Critical Path Programs (CPIP/FDA) Office of Orphan Products Development (OOPD/FDA)</p>

You must find a fit!

31

31

## Program Descriptions and Research Topics

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PHS 2019-2

OMNIBUS SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, AND FOOD AND DRUG ADMINISTRATION FOR

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND


SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

NIH, CDC, and FDA Program Descriptions and Research Topics

NOTE:

There will be a new Omnibus Solicitation issued by NIH before the September 2020 deadline



WATCH FOR IT!

SUBMISSION DATES

SEPTEMBER 5, 2019, JANUARY 6, 2020, AND APRIL 6, 2020

National Institutes of Health (SBIR and STTR)  
Centers for Disease Control and Prevention (SBIR)  
Food and Drug Administration (SBIR)

bbc

32

32



## Program Descriptions and Research Topics

### TABLE OF CONTENTS

NIH, CDC, AND FDA PROGRAM DESCRIPTIONS AND RESEARCH TOPICS	
NATIONAL INSTITUTES OF HEALTH (NIH)	1
TRANS-NIH RESEARCH PROGRAMS	2
Phase IIB Competing Renewal Awards	2
Research Supplements to Promote Diversity in Health-Related Research	2
TECHNICAL ASSISTANCE PROGRAMS (SUBJECT TO CHANGE)	3
Available to IHS SBIR/STTR Awardees	3
Niche Assessment Program	4
Commercialization Accelerator Program	4
NATIONAL INSTITUTE ON AGING (NIA)	31
Limited Amount of Award	31
NIA-Supported Funding Opportunity A	31
Phase IIB Competing Renewal Award	31
Research Topics of Interest to NIA	31
NATIONAL INSTITUTE ON ALCOHOL ABUSE	35
Limited Amount of Award	35
Phase IIB Competing Renewal Award	35
Commercialization Assistance Program	35
Research Topics of Interest to NIAAA	36
NIAAA Non-Clinical Trials Topics	36
NIAAA Clinical Trials Topics	40
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)	31
Limited Total Amounts for Phase I and Phase II Awards	31
Division of AIDS	31
Division of Allergy, Immunology, and Transplantation	35
Division of Microbiology and Infectious Diseases	36
Other Research Topic(s) Within the Mission of the Institute	40
NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)	49
Limited Amount of Award	49
Research Topics of Interest to NIAMS	49
NIAMS Non-Clinical Trials Topics	50
NIAMS Clinical Trials Topics	51
NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)	52
Research Topics of Interest to NIBIB	52
NIBIB Non-Clinical Trials Topics	53
NIBIB Clinical Trials Topics	56
NATIONAL CANCER INSTITUTE (NCI)	57
Major NCI SBIR/STTR Portfolio Areas	57
Limited Amount of Award	57
Phase IIB Competing Renewal Awards	58
Research Topics of Interest to NCI	58
NCI Non-Clinical Trials Topics	59
NCI Clinical Trials Topics	59

PHS 2019-2, Omnibus Solicitation for SBIR/STTR Grant Applications May, 2019

### NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

NIAID's Division of AIDS (DAIDS), Division of Allergy, Immunology, and Transplantation (DAIT), and Division of Microbiology and Infectious Diseases (DMID) encourage SBIR/STTR applications related to their mission and activities as described below. Questions regarding specific research areas may be addressed to the NIAID Program Officials listed below. General questions about the NIAID SBIR and STTR programs or administrative and business management concerns may be directed to the NIAID Small Business Program Team (<https://www.niaid.nih.gov/grants-contracts/small-business-program-team>).

When possible, applicants are encouraged to use email for communication.

For information about NIAID's Small Business Programs, please visit <https://www.niaid.nih.gov/grants-contracts/small-business>.

#### Limited Total Amounts for Phase I and Phase II Awards

Total funding support (direct costs, indirect costs, fee) normally may not exceed \$252,131 for Phase I awards and \$1,680,879 for Phase II awards. Budget requests at or near these hard caps should be well justified. Phase II/IB applicants should note that NIAID **will not** generally allow awards (of any duration) that exceed \$1,000,000 total costs per year.

NIH has received a waiver from SBA, as authorized by statute, to exceed total award amount hard caps for specific topics. The current list of approved topics can be found in Appendix A of this document or at <https://sbir.nih.gov/funding/omni-sbir>. Approved topics that align with NIAID's priority research areas are listed for each Division, however, a listed topic from any IC is sufficient to consider budget requests that exceed the hard caps. Budget requests exceeding the hard caps must be very well justified in the "Budget Justification" attachment to the Research and Related Budget form and be clearly consistent with the scope of the proposal.

NIAID will allow Phase I applications with budgets of up to \$300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to \$1,000,000 total costs per year for up to 3 years. Requests for these budget levels must be very well-justified. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Applicants are strongly encouraged to contact the NIAID SBIR/STTR Program Team prior to submitting any application in excess of the hard caps. NIAID staff cannot provide prior approval to exceed hard caps.

**Talk to your Program Manager before exceeding the hard caps.**  
**Special Topics may have a different limit**

decrease the length of an award and/or the budget recommended by a review committee.

## Budget Limitations 2019 Omnibus

**“Limits” now set at:**

- **\$252,131** Phase I
- **\$1,680,879** Phase II

**UNLESS....**

**2019 SBIR and STTR Omnibus/Parent Grant Solicitations for the NIH, CDC, and FDA, Clinical Trial Not Allowed and Clinical Trial Required**

- SBIR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-272)
- STTR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-270)
- SBIR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-273)
- STTR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-271)
- 2019 Program Descriptions and Research Topics Document  
(234 KB) (644 KB)
- 2019 SBA approved topics list for budget waivers  
(554 KB) (172 KB)
- NIH SBIR/STTR Grant Forms

**Standard Due Dates:**

- January 5
- April 5
- September 5

35

35

## HHS SBIR/STTR Agency Contact Information

Interested in contacting a NIH SBIR/STTR Program Officer? Or have a grants management questions? Use the NIH SBIR and STTR Contact Information Chat below to get in touch! [PDF Version](#)

Awarding Component	Scientific/Research Contact	Financial/Grants Mgmt Contact
National Institute on Aging <a href="http://www.nia.nih.gov">http://www.nia.nih.gov</a>	Dr. Michael-David A.R.R. Kerns Phone: 301-402-7713 Fax: 301-402-2945 Email: Michael-David.Kerns@nih.gov	Ms. Linda Whipp Phone: 301-496-1472 Fax: 301-402-3672 Email: Linda.Whipp@nih.gov
National Institute on Alcohol Abuse and Alcoholism <a href="http://www.niaaa.nih.gov">http://www.niaaa.nih.gov</a>	Megan Ryan, M.B.A. Phone: 301-443-4225 Email: mryan1@mail.nih.gov	Ms. Judy Fox Phone: 301-443-4704 Fax: 301-443-3891 Email: Judy.Fox@nih.gov
National Institute of Allergy and Infectious Diseases <a href="http://www.niaid.nih.gov">http://www.niaid.nih.gov</a>	Dr. Natalia Kruchinin Phone: 240-669-2919 Fax: 240-627-3162 Email: kruchinin@niaid.nih.gov	Ms. Vandhana Khurana, MBA Phone: 240-669-2966 Fax: 301-493-0597 Email: khuranav@niaid.nih.gov  Jason Lundgren Phone: 240-669-2973 Fax: 301-493-0597 Email: Jason.Lundgren@nih.gov
National Institute of Arthritis and Musculoskeletal and Skin Diseases <a href="http://www.niams.nih.gov/">http://www.niams.nih.gov/</a>	Dr. Xibin Wang Phone: 301-451-3884 Fax: 301-480-1284 Email: wangx1@mail.nih.gov	Ms. Aleisha S. James Phone: 301-594-3968 Fax: 301-480-5450 Email: jamesaleisha@mail.nih.gov
National Institute of Biomedical Imaging and Bioengineering <a href="http://www.nibib.nih.gov/">http://www.nibib.nih.gov/</a>	Mr. Todd Merchak Phone: 301-496-8592 Fax: 301-480-1614 Email: merchak@mail.nih.gov	Mr. James Huff Phone: 301-451-4786 Fax: 301-451-5735 Email: huffj@mail.nih.gov

<https://sbir.nih.gov/engage/ic-contacts>

36


36

## How to Contact NIH Program Staff

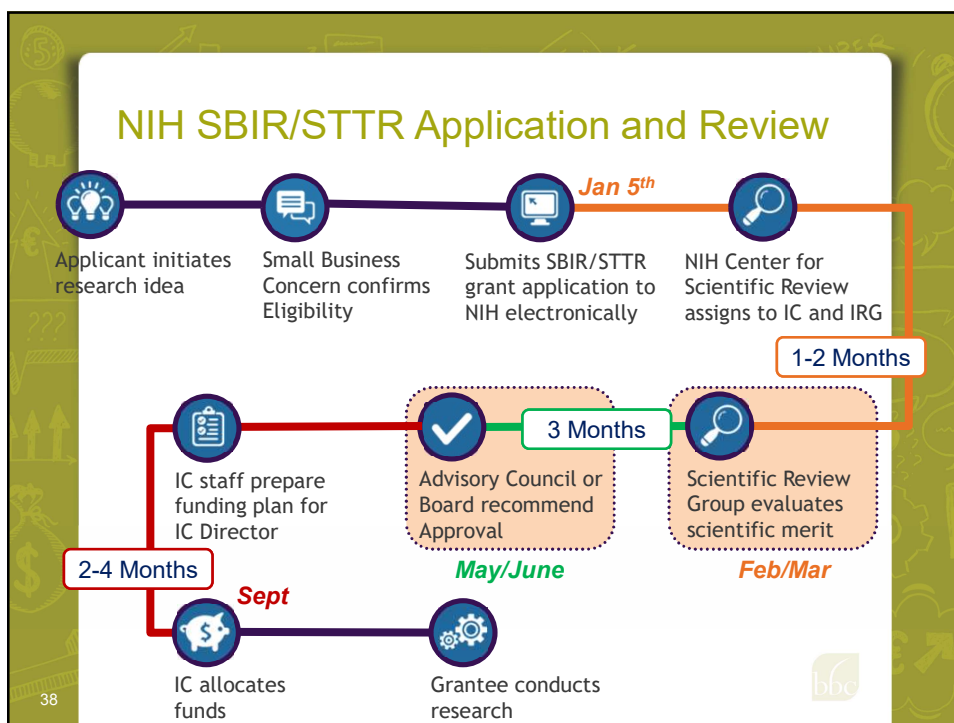


### Before you write your proposal

- Send Program Director an intro email
  - Request a phone call to discuss your SBIR/STTR project and its relevance to their institute
  - Send one-page Specific Aims summary prior to call
- Items to discuss:
  - Relevance to Institute goals & priorities
  - Budget (\$150K guideline? \$251K hard cap? Something greater for topics with a waiver?)
  - SBIR vs. STTR
  - Phase I vs. Fast-track or Direct to Phase II
  - Other special solicitations
  - Other ICs that might be a fit
  - Optional: SBIR/STTR Study Section assignment



37



38



39

### Center for Scientific Review

- Single receiving point for all NIH applications
- Assigns applications to the Scientific Review Groups (aka Study Section)
- Assigns applications to the Institute/Center that is the potential funding component

40

bbc

40

## SBIR /STTR Study Sections

View

Q

Applicants
For Reviewers
News & Policy
Study Sections
Review Panels & Dates
About CSR

### Study Sections

Applications are reviewed in study sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of study sections based on scientific discipline.

Integrated Review Groups

Standing Study Sections

**Small Business & Technology Transfer Fellowship**

Special Emphasis

Small Business & Technology Transfer Fellowship

41

## SBIR/STTR Study Sections

### Small Business and Technology Transfer (SBIR/STTR) Study Section

**Filter Results:**  Q Search

Study Section	Study Section Description	Scientific Review Officer
AARR (10)	Small Business: HIV/AIDS Innovative Research Applications	Dr. Mark Rubert
AARD (11)	Small Business: HIV/AIDS Innovative Research Applications	Dr. Ilanahane Tiso
<b>CVRS (11)</b>	<b>Small Business: Respiratory Sciences</b>	<b>Dr. Eugene Carstea</b>
CVRS (10)	Small Business: Cardiovascular Sciences Activities SEP	Dr. Margaret Chandler
CVRS (11)	Small Business: Respiratory Sciences	Dr. Eugene Carstea
DKUS (10)	Small Business: Digestive Sciences	Dr. Martha Garcia
DKUS (11)	Small Business: Renal and Urological Sciences	Dr. Atul Sahai
EMNR (10)	Small Business: Diabetes, Metabolism, Nutrition and Obesity	Dr. Clara Cheng
EMNR (11)	Reproductive Sciences Small Business SEP	Dr. Clara Cheng
ETTN (10)	Small Business: Clinical Neurophysiology, Devices, Neuroprosthetics and Biosensors	Dr. Cristina Backman
ETTN (11)	Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders	Dr. Aurea De Sousa

42

**CENTER FOR SCIENTIFIC REVIEW SPECIAL EMPHASIS PANEL**  
ZRG1  
11/15/18 - 11/15/18  
Meeting Roster

Home > Study Sections

**CSR –**

**Notice of NIH Policy to All Applicants:** Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in [NOT-OD-14-073](#) and [NOT-OD-15-106](#), including removal of the application from immediate review.

The pro day **CHAIRPERSON**

Reviewer **CHAIRPERSON**


**Reviewer** HOGABOAM, CORY M., PHD  
 PROFESSOR  
 DIVISION OF PULMONARY AND CRITICAL CARE MEDICINE  
 DEPARTMENT OF MEDICINE  
 CEDARS SINAI MEDICAL CENTER  
 LOS ANGELES, CA, 90048

**MEMBERS**  
 ADLER, KENNETH BRUCE, PHD  
 PROFESSOR  
 DEPARTMENT OF MOLECULAR BIOMEDICAL SCIENCES  
 COLLEGE OF VETERINARY MEDICINE  
 NORTH CAROLINA STATE UNIVERSITY  
 RALEIGH, NC, 27607  
 AHSAN, FAKHRUL, PHD  
 PROFESSOR AND PROGRAM ADVISOR  
 DEPARTMENT OF PHARMACEUTICAL SCIENCES  
 TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER  
 SCHOOL OF PHARMACY  
 AMARILLO, TX, 79106

43

43

**Assignment**  
Identify the Appropriate CSR Study Section

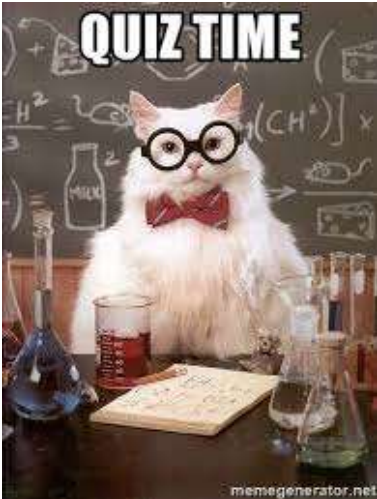
- Start at CSR
  - <https://public.csr.nih.gov/StudySections>
- Use keywords to identify the nest Study Section(s) for your project
- Find the Reviewer Rosters
  - Do they have the necessary skills for your topic
  - Is there anyone you wish to exclude
  - Any skills to be added

**Assignment**


44

44

Poll....




memegenerator.net





45

### NIH Review Criteria



- **Significance**
  - Significant Science
  - Significant Product
  - Significant Commercial Opportunity
- **Investigators**
- **Innovation**
- **Approach**
- **Environment**



46



## Proposal Development

### Tactical Preparation – Phase I

- **Acquire** preliminary data
- **Conduct** scientific literature search and market research
- **Plan** experiments/R&D activities
  - In detail for Phase I
  - In scope for Phase II
- **Convene** the technical team
  - For Phase I, II and beyond...
- **Secure** facilities and other resources
- **Develop** commercialization strategy (yes, even in preparation for Phase II!)

47

47



## Proposal Development

### Tactical Preparation – Phase II


- **Achieve FEASIBILITY** (Phase I)
- **Update** scientific literature search and market research
- Plan experiments/R&D activities
- **Expand/change** the technical team, facilities and other resources
  - For Phase II and beyond...
- **Expand and validate** commercialization strategy

48

48




## Writing the Proposal



### Primary Questions to be Answered

- Why is it worth doing?
- What you are going to do?
- Who is going to do the work?
- Where are you going to do the work?
- How much will it cost?

49



49

## Critical Sections\* of an NIH SBIR/STTR

- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Bibliography and Refs Cited
- **Facilities & Other Resources**
- Equipment
- **Biographical Sketches (5 pg ea.)**
- **Project Budget**
- **Subaward Budget**
- Introduction to Application (resubmission only -1pg)
- **Specific Aims (1 pg)**
- **Research Strategy (6 or 12 pg)**
  - **Significance**
  - **Innovation**
  - **Approach**
- Progress report/Publication List (Phase II only)
- Vertebrate Animals
- Select Agent Research
- Multiple PD/PI Leadership Plan
- **Consortium/Contractual Arrangements**
- **Letters of Support**
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Appendix
- Cover Letter
- **Commercialization Plan** (12 pg; Ph II, DTPH II & Fast Track only)
- PHS Assignment Request
- PHS Human Subjects and Clinical Trials Information

50

\*note that every section is important if relevant to the project




50

Which sections?


**What you are going to do?**

**Why is it worth doing?**

- Specific Aims Section
- Research Strategy
- Project Summary/Abstract



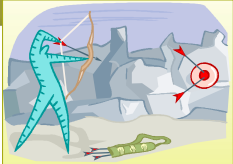
51




51

Specific Aims Section

- Single and most important page of application
- An Executive Summary of the Proposal
- Tells the ENTIRE story in one page
- Articulates the Phase I or II Aims which are CRITICAL to evaluation of the entire proposal





52



52

## Aims vs. Activities

- **Specific Aims = Objectives/Outcomes**
  - Either achieved or not
  - Have measurable, desired end points
  - Do not yield results/data
- **Tasks = Activities**
  - Steps to achieve your aims/objectives
  - Make up your work plan
  - They are performed or carried out
  - Yield results &/or data


53

bbc

53

## Provide quantifiable measures of success

- The criteria for success of the studies conducted should be objective measures.
- These should be measures that would be recognizable as *appropriate endpoints* by reviewers knowledgeable in the specific scientific area.
- They should have *clear success criteria* that can be used for evaluation by NIH.
- Thus, milestones should indicate specific, quantifiable measures of success.



54

bbc

54

## Specific Aims – Phase I Outline

- The Company
- Significance
  - Problem to be solved
  - Gap in knowledge
- The Product
  - Technological Innovation
  - Impact
- Long Term Goal
  - Rationale for the goal
- Phase I Project:
  - Phase I Hypothesis
  - Specific Aim 1...
    - Criteria for acceptance
  - Specific Aim 2...
    - Criteria for acceptance
  - Expected Outcomes
    - Proof of Feasibility
- Plans for Phase II
- Commercial Application

**PAGE LIMIT: One PAGE**



55

55

*“But I can’t get all that on one page!”*

### SPECIFIC AIMS

**Introduction** Lorem ipsum dolor sit amet, consectetur adipiscing elit. Cras vestibulum laconia nunc nec venenatis. Vivamus sem metus, sodales sit amet elementum eget, dictum at magna.

**Significance** Problem to be solved - Nunc trincidunt ultricies viverra. Ut at magna magna, vitae mattis urna. Suspendisse tortor mauris, portitor ut bibendum eu, luctus non arcu. Fusce diam sem, aliquet vitae orname ac, accumsan a magna. Integer vehicula nunc sit amet lectus eleifend vitae scelerisque nisi malesuada. Fusce purus mi, rutrum non auctor et, lobortis vel diam (3,4). Praesent pharetra ultricies suscipit. Nunc quam du, aliquet et malesuada ut, congue ac tellus. Donec ac arcu vel sem commodo auctor. Donec tristique pretium leo ut facilisis. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos.

**Gap in Knowledge** - Etiam ac viverra libero. Donec fets ipsum, ultrices vitae laoreet nec, dignissim in risus. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos (8). Ut scelerisque nulla sed diam volutpat aliquam. Vestibulum du mauns, sollicitudin quis hendrerit eu, laoreet nec dolor. Etiam ut libero enim (12).

**The Product** Donec dignissim posuere est, eget tempus ante eleifend eu. Duis lacus eros, molestie vel portitor vitae, mattis ut neque. Sed non elit ac odio molestie laoreet vitae sit amet tortor. Morbi hendrerit pretium libero, in pharetra felis sodales et.

**The Technological Innovation** - Aliquam fermentum ante vel urna vulputate non pretium nulla dictum. Fusce ullamcorper, elit vel sodales interdum, eros ante luctus mi, in faucibus neque neque ac du. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Ut consectetur sodales urna id trincidunt. Nam viverra odio eu nulla euismod eget ornare tellus ullamcorper.

**Long Term Goal** Maecenas massa ligula, viverra eu pretium eu, bibendum sit amet ipsum. Maecenas eget dignissim dolor. Cras gravida ullamcorper tortor, vel laoreet orci condimentum bibendum. Vivamus ac diam sem. Praesent ullamcorper mi eu nisi sollicitudin in vehicula diam ultrices. Rationale for the Goal: Integer est ipsum, feugiat eu laoreet id, malesuada consequat lorem. Nulla congue odio id lacus varius in faucibus massa vehicula (18). Ut adipiscing hendrerit viverra. Maecenas facilisis nisi a augue luctus nec trincidunt turpis euismod.

**Phase I Hypothesis** Nunc tristique scelerisque nisi, ac porta nulla bibendum ac. Quisque sit amet aliquam lectus. Suspendisse et ligula arcu, eget laoreet lectus.

**Specific Aim 1** - Aliquam erat volutpat. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos. Criteria for Acceptance Mauris non turpis et lectus imperdiet facilisis et et nisi.

**Expected Outcomes** Duis blandit blandit tempus. Donec commodo fringilla ipsum ut volutpat. Aliquam ut mi lectus. Vestibulum nec risus mi.

**Plans for Phase II** Nulla luctus magna ac tellus sollicitudin ut dignissim nisi placerat. Maecenas molestie aliquam du. Praesent id nisi non urna elementum pharetra non vel mi. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos himenaeos.

**Commercial Application** Praesent eget pharetra eros. Phasellus faucibus pharetra erat commodo hendrerit. Nunc eros nunc, suscipit quis dignissim vel, aliquam vitae diam. Ut vitae lacus mi. Quisque trincidunt mi ut du blandit vel euismod nisi scelerisque. Duis consequat, diam at adipiscing semper; ligula lacus feugiat enim, a fermentum tortor metus ac ligula. Praesent placerat sollicitudin nisi quis mollis (20). Quisque eget purus in risa aliquam fringilla eget in tellus. Cras in quam mi. Duis arcu enim, aliquet eu sodales non, luctus in nibh. Nullam vestibulum lacus eu libero sagittis lobortis. Nullam mauris sem, trincidunt sed rhoncus ultrices, egestas lobortis ante.



56

## Specific Aims – Phase II Outline

- The Company
- Significance
  - Problem to be solved
  - Gap in knowledge
- The Product
  - Technological Innovation
  - Impact
- Long Term Goal
  - Rationale for the goal
- Phase I Results (“feasibility”)
- Phase II Project:
  - Phase II Hypothesis
  - Specific Aim 1...
    - Criteria for acceptance
  - Specific Aim 2...
    - Criteria for acceptance
  - Expected Outcomes
    - Enable next steps
- Commercial Application

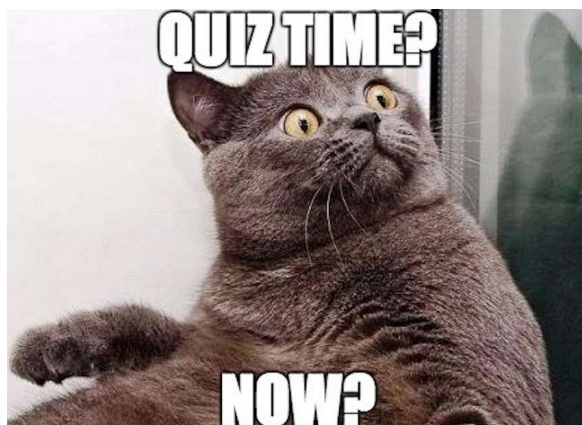
**PAGE LIMIT: One PAGE**



57

57

Poll....



58

## Research Strategy Review Criteria



- Significance
  - Merit of the project
    - Significant science/**technological innovation**
  - Commercial Value of the project
    - Significant **commercial opportunity**
    - **Competitive advantage** over alternatives
- Innovation
  - Clearly state the **technological innovation**
  - Will success improve the “State-of-the-art”, establish new research directions, change clinical practice?
- Approach
  - Do experiments relate to the Specific Aims?
  - Are the end-points/milestones clearly defined?

59



59

## Research Strategy – BBC Outline



### Significance (Phase I)

- Problem to be solved
- Product to be developed
  - Impact of proposed product to provide a solution
  - Impact of product/innovation on state of the science/technology
- Value of the solution to the problem
- Commercial Potential
  - Market analysis
  - Competition (competing technologies and competitors)
  - Commercialization strategy
- Other applications of the technology

60



60

## Research Strategy – BBCetc Outline



### Significance (Phase II)


- Problem to be solved
- Product to be developed
  - Impact of proposed product to provide a solution
  - Impact of product/innovation on state of the science/technology
- Value of the solution to the problem
- Commercial Potential (*summarize.... Detail in commercialization plan*)
- Other applications of the technology

61



61

## Research Strategy – BBC Outline




### Innovation

- The technological innovation (describe)
- Relevance to current state of the science
  - Why is it innovative?
  - How does it move the field forward?
  - What future advancements will this innovation enable?


Phase II – remember to update literature and market searches to reflect CURRENT state of the science and state of the market

62



62


## Research Strategy – BBC Outline



### Approach – Phase I

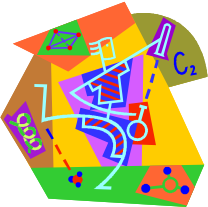
- **Prior work/Preliminary Studies**
  - Rationale
  - Aims of the preliminary studies
  - Results and conclusions
  - Summary (how does the prior work apply to this SBIR/STTR)

63



63

## Research Strategy – BBCetc Outline



### Approach – Phase II

- **Phase I Progress Report**
  - Beginning and ending dates of Phase I
  - Summarize Phase I Aims
  - Results and conclusions (achievement of aims)
  - Describe any significant changes to aims/new directions
  - Summary
    - Demonstration of Feasibility
    - How the outcomes support the Phase II
    - Technology developed, intended use, status of product development

64




64




## Research Strategy - outline

### Approach (continued)



- Restate each Specific Aim
  - Rationale
    - Give the reasoning behind the aim
  - Experimental Design & Methods
    - Lay out what experiments (in detail) will be conducted to complete the aim and methods to be employed in each experiment
  - Data Analysis & Interpretation
    - How will you will analyze the data?
  - Potential Pitfalls / Alternative Approaches
    - What could go wrong and how will you compensate if it does?
  - Expected Outcomes
    - What do you expect to happen?


65



65


## Which Sections?

### Who, Where and How Much?



- Biographical Sketches
- Consortium/Contractual Arrangements
- Letters of Support
- Budget & Budget Justification


66




66

## Key Personnel: Build a Strong TEAM!

- Your (the SBC's) employees
  - Includes the PI if SBIR
  - If STTR should have at least 1 (may include PI)
- Subcontractor's employees
- Consultants
- Other Significant Contributors
  - e.g. "advisors"; 0% effort on project (think ahead to Phase II and commercialization)





67

## Biographical Sketches

OMB No. 0625-0001 and 0625-0002 (Rev. 09/17 Approved Through 03/31/2020)

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: \_\_\_\_\_

eRA COMMONS USER NAME (credential, e.g., agency login): \_\_\_\_\_

POSITION TITLE: \_\_\_\_\_


EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions and Honors

C. Contributions to Science




68

## Biosketches - Key Personnel


- PD/PI is always considered a senior/key person
  - Technical lead
- Key personnel on subaward
- Consultants
- Other Significant Contributors
  
- Key persons - role on the project (Sr. Scientist, Programmer, Co-investigator) - not company title
  
- Other Personnel – Do NOT have biosketch
  - Technicians, junior staff

69



69

## Sections of the Biosketch




- Name, eRAcommons, Position. Education & Training
- A. Personal Statement
- B. Positions and Honors
- C. Contributions to Science
- D. Research Support

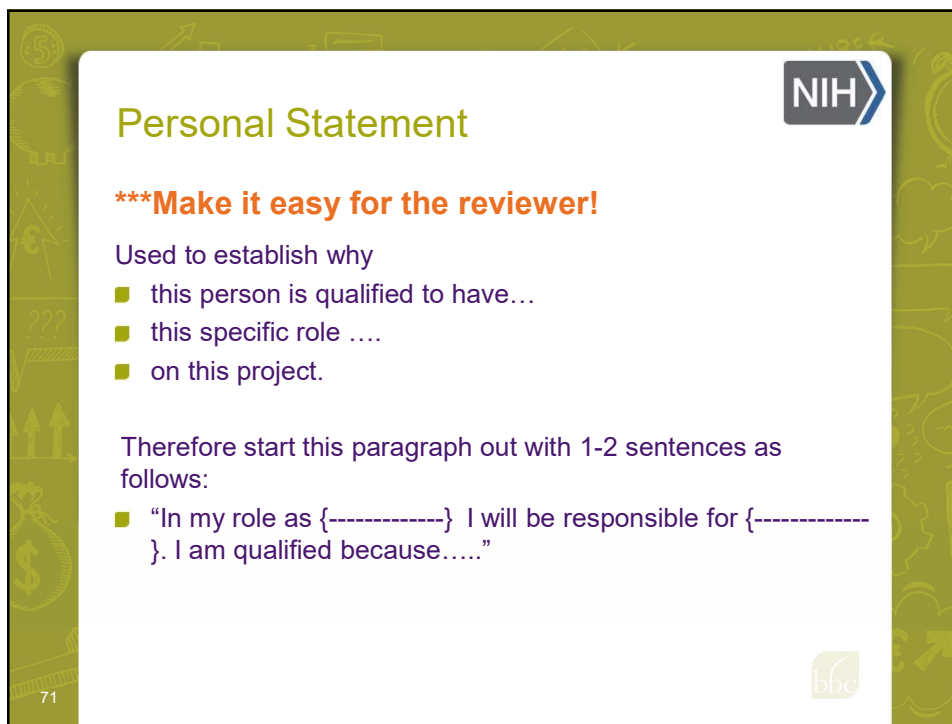
Follow format  
5-page limitation


Template, instructions and samples can be found at:  
<http://grants.nih.gov/grants/forms/biosketch.htm>

70



70



**Personal Statement** 


**\*\*\*Make it easy for the reviewer!**

Used to establish why

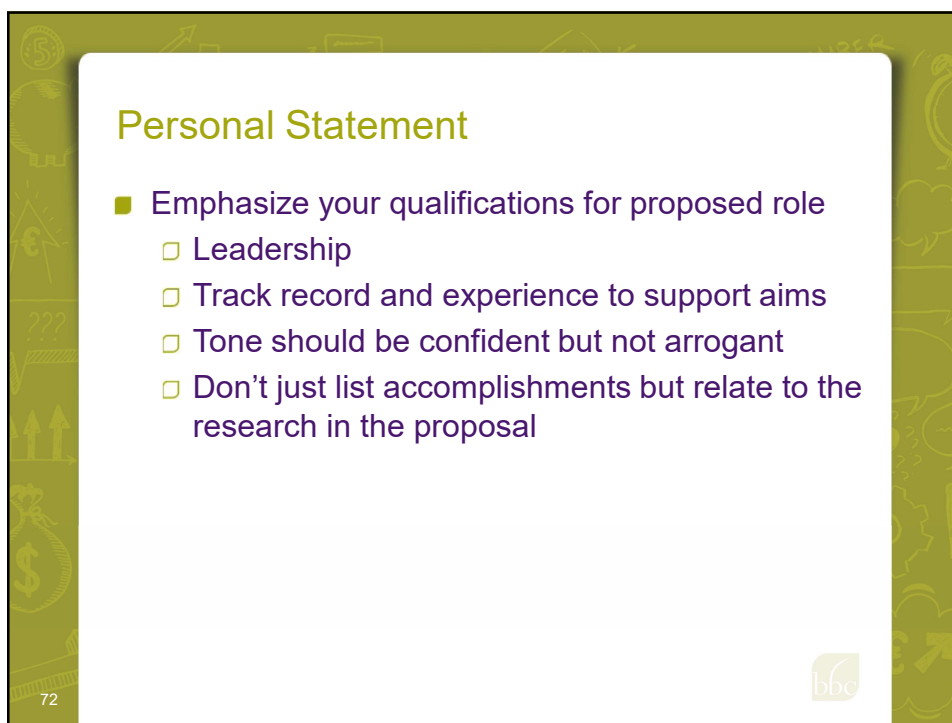
- this person is qualified to have...
- this specific role ....
- on this project.

Therefore start this paragraph out with 1-2 sentences as follows:

- “In my role as {-----} I will be responsible for {-----}. I am qualified because.....”


 71

71



**Personal Statement**

- Emphasize your qualifications for proposed role
  - Leadership
  - Track record and experience to support aims
  - Tone should be confident but not arrogant
  - Don't just list accomplishments but relate to the research in the proposal

 72

72

OMB No. 0925-0047 (002) (Rev. 09/12 Approved Through 9/31/2019)

**BIOGRAPHICAL SKETCH**  
Provide the following information for the SeniorKey personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Hunt, Morgan Casey

PI/COMMUNICATOR NAME (preference, e.g., agency logo, Twitter):

POSITION TITLE: Associate Professor of Psychology

EDUCATION (begin with baccalaureate or other initial professional education, such as nursing; include postdoctoral training and residency training if applicable; include dates as appropriate)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date (MM/YYYY)	FIELD OF STUDY
University of California, Berkeley	B.S.	05/1990	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

**A. Personal Statement**

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neurophysiological changes associated with addiction. As PI or co-investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Mermle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
3. Hunt, M.C., Mitchell, S.A. & Mermle, R. (2009). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC912304
- Hunt, M.C., Newell, D.B. & Flaherty, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.

**B. Positions and Honors**

**Positions and Employment**

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Cogswell Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO

Position where you will be doing the work

**CRITICAL!\*\*\***

- Make sure to list the small business for all personnel that will be working there at the time of award
- If not already employed add "to be implemented at time of award"

73

that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.

- a. Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. *Journal of the Geriatrics*, 60(4), 45-51.
- b. Hunt, M.C. & Pout, B. (2004). Methadone treatment and personal assessment. *Journal Drug Abuse*, 45(5), 15-26.
- c. Mermle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. *Journal of Ageing*, 54(1), 24-41. PMID: PMC912304
- d. Hunt, M.C., Jensen, J.L. & Mermle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY: NY: W. W. Norton & Company.

**Complete List of Published Work in My Bibliography:**  
<https://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PqT7IEFIAJBGMRDdWFmiWAO/?sort=date&direction=ascending>

**D. Research Support**

**Ongoing Research Support**

R01 DA942367	Hunt (PI)	09/01/08-08/31/16
Health trajectories and behavioral interventions among older substance abusers		
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.		
Role: PI		
R01 MH922731	Mermle (PI)	12/15/07-11/30/15
Physical disability, depression and substance abuse in the elderly		
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.		
Role: Co-Investigator		
Faculty Resources Grant, Washington University		08/15/09-08/14/15
Opiate Addiction Database		
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.		
Role: PI		

**Completed Research Support**

Template, instructions and samples can be found at:  
<http://grants.nih.gov/grants/forms/biosketch.htm>

abuse among older

74

## Contributions to Science

**Topic #1 (use an explanatory subheading)**

- Brief narrative (1<sup>st</sup> person)
- Up to 4 publications (bold your own name)

**Topic #2 (use an explanatory subheading)**

- Brief narrative (1<sup>st</sup> person)
- Up to 4 publications (bold your own name)

[Etc. up to 5]

75

## Contributions to Science

- In your previous research experiences, what did the team do and what did you do? What did you learn from what you did?
- Focus on 2-5 strong contributions that you did not discuss in the Personal Statement.
- Relevant citations do not have to be authored by you
- Research citations can include:
  - audio or video products
  - conference proceedings
  - posters or other presentations
  - Patents
  - data and research materials
  - Databases
  - educational aids or curricula
  - instruments or equipment
  - Models
  - Protocols
  - software or netware.

76

## Common Biosketch Mistakes 1

- Not explaining your **role** on the project in the Personal Statement.
  - We can't judge whether you're qualified for your role if we don't know what your role is.
- Citing more than four publications under your Personal Statement. The limit is **four**
- Not including a Contributions to Science Section.
  - This section is required for every Key Person (on every biosketch). It should be a short paragraph.
- Citing more than four publications or research products after each Contribution to Science.
  - The limit is **four**.

mistake



77

## Common Biosketch Mistakes 2

- Inventing your own formatting. Follow the format.
  - Do I need to explain this any further?
- Including Completed Research that goes back further than 3 years.
  - The instructions say to limit this section to the past 3 years.
- Not fixing your collaborators and your team's biosketches to make them all look beautiful and consistent.
  - Take the time to do this. Look professional.

bbc

78

## Review Comments on Investigators

### Weaknesses

- The proposed PI ██████ is currently a graduate student, supposedly defending his PhD soon and joining the company
- The nature / details / scope of the company operations are not well described

### 2. Investigator(s):

#### Strengths

- PI is excellent and has established expertise in all phases of this study. PI has R01 with similar

#### Weaknesses

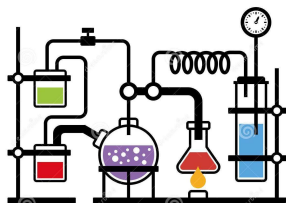
- ██████ appears to complete work done as a PhD candidate by joining the company. While technically enabled, it is unclear what the company brings to the project apart from a vessel for hosting the grant. It is unclear what the nature of the company is, apart from a shell to continue work done under a R01.
- Needs clinicians from ██████ on board to provide input on design.



79

## Facilities and Other Resources

- More than a cut-and-paste list.
- Not just facilities
- Address how the (scientific) environment will contribute to probability of success, unique features of environment, etc.



80

80



## Facilities and Other Resources

- Company's Research Facility(s)
- Subcontractors' Research Facilities
- Other R&D Resources
  - Other Significant Contributors (e.g., Scientific Advisory Board)
- Commercialization Resources
  - Management
  - Strategic Partners
  - Funding
  - Regulatory/Reimbursement



81


81

## Contractual Arrangements & Letters of Support \*\*

(1 of 2)

**Start sections with brief introductions explaining role of organization/participant and what they bring to the project.**

- Subcontractors should describe commitment to project (note special language if STTR)
- Consultants (required); must include:
  - Role on project
  - Amount of time committed
  - Rate to be charged
- Other Scientific Resources
  - Other Significant Contributors
  - Scientific/Technical/Facilities



\*\*contingent commitment

bbc

82

82

## Contractual Arrangements & Letters of Support \*\*

(2 of 2)

**Validate your resources and opportunity**

**Critical for Phase II:**

- Commercialization Resources, e.g.:
  - Investors
  - Strategic Partners
  - Key Customers
  - Regulatory/Reimbursement Experts



**VALIDATED**

**\*\*contingent commitment**

83

bbc

83

## Phase I Letters of Support – Typical Content

*Single page*

*Use official letterhead*

***Addressed to the Principal Investigator***

- **Paragraph #1:** Description of the author or the organization
  - Who/what are they?
  - Why/how are they knowledgeable about this market sector?
- **Paragraph #2:** How do they view the problem?
  - Why is it significant?
  - Why does it present a commercial opportunity?
- **Paragraph #3:** What would be the impact of a viable solution?
  - Who would benefit and how?

*For Phase II, add what is specifically being committed by the writer and any contingencies for that commitment*

84

bbc

84

## Letters of Commitment – Phase II

- From prospective investors, strategic partners, customers, licensees, etc.
- Commitment of tangible resources (e.g., funding, services, business agreements)
- Estimate dollar value
- Describe achievements necessary to secure the commitment



85




COFFEE?



86

86

Polls...



bbc

87

How important is the budget?



bbc

88

## The Facts

- The budget is not a factor in an SBIR/STTR impact score BUT the appropriateness and detail are always evaluation factors.
- An appropriate budget is one that is in harmony with the proposed work.
- Inappropriate budget is not consistent with the proposed work.
  - Example: 1-month salary for 6-month project or visa versa



89

## Project Budget Approach



- Build the budget as you build the project.
- Determine the task or milestone and then consider:
  - Who will do the work?
  - How long will it take?
  - What materials or supplies will be needed?
  - What equipment will be used and is it available?
  - Will a portion need to be done by a collaborator?
  - Where will the work be performed?
  - Are there special services needed?
  - Is travel required?



90

90

## Budget Limitations 2019 Omnibus

- “Limits”\* now set at:
  - \$252,580 Phase I
  - \$1,710,531 Phase II
- UNLESS....

**2019 SBIR and STTR Omnibus/Parent Grant Solicitations for the NIH, CDC, and FDA, Clinical Trial Not Allowed and Clinical Trial Required**

- SBIR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-272)
- STTR Omnibus/Parent Clinical Trial Not Allowed Funding Opportunity Announcement (PA-19-270)
- SBIR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-273)
- STTR Omnibus/Parent Clinical Trial Required Funding Opportunity Announcement (PA-19-271)
- 2019 Program Descriptions and Research Topics Document (2.31 MB) (614 KB)
- 2019 SBA approved topics list for budget waivers (554 KB) (72 KB)
- NIH SBIR/STTR Grant Forms

**Standard Due Dates:**  
📅 January 5  
📅 April 5  
📅 September 5

\*See NOT-OD-20-080

91

## NIAID

**NATIONAL INSTITUTE OF DIVISION OF AIDS (DAIDS)**

- A. Development of anti-HIV and in vivo evaluation of infection.
- B. Development and evaluation of alternate HIV disease prevention strategies in the absence of daily therapy.
- C. Development of method competent latent HIV in vivo.
- D. Development and evaluation of resistance to monitor development of basic to determine HIV response.
- E. Development of long-acting products (PEP, post (MPT) products that can be used for HIV prevention.
- F. Development of rapid tests (e.g., blood, urine, hair).
- G. Development of process manufacturing, formulae related constructs/products, such as self-synthetic, lipid and poly-combination-adjuvants/delivery-co-administrative neutralizing, (e) deliver viral vectors, and (g) DN...
- H. Improving cell line development and novel cell lines for expression platforms for viral vectors.
- I. Development of formulae associated co-infections.
- J. Allergy, Asthma and A conditions of interest, as to food allergy, atopic diseases but is not limited and epidemiologic research diagnostic markers, particularly of immunologic interventions such as...

PHS 2019-2, Omnibus Solicitation for SBIR/STTR Grant Applications May, 2019

**NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)**

NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

NIAID's Division of AIDS (DAIDS), Division of Allergy, Immunology, and Transplantation (DAIT), and Division of Microbiology and Infectious Diseases (DMID) encourage SBIR/STTR applications related to their mission and activities as described below. Questions regarding specific research areas may be addressed to the NIAID Program Officials listed below. General questions about the NIAID SBIR and STTR programs or administrative and business management concerns may be directed to the NIAID Small Business Program Team (<https://www.niaid.nih.gov/grants-contracts/small-business-program-team>).

When possible, applicants are encouraged to use email for communication.

For information about NIAID's Small Business Programs, please visit <https://www.niaid.nih.gov/grants-contracts/small-business>.

**Limited Total Amounts for Phase I and Phase II Awards**

Total funding support (direct costs, indirect costs, fee) normally may not exceed \$252,131 for Phase I awards and \$1,680,879 for Phase II awards. Budget requests at or near these hard caps should be well justified. Phase II/IB applicants should note that NIAID **will not** generally allow awards (of any duration) that exceed \$1,000,000 total costs per year.

**Talk to your Program Manager before exceeding the hard caps  
Special Topics may have a different limit  
Ask if TABA is included in the hard caps**

NIAID will allow Phase I applications with budgets of up to \$300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to \$1,000,000 total costs per year for up to 3 years. Requests for these budget levels must be very well-justified. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Applicants are strongly encouraged to contact the NIAID SBIR/STTR Program Team prior to submitting any application in excess of the hard caps. NIAID staff cannot provide prior approval to exceed hard caps. Compliance with a pre-approved topic will be confirmed at time of award by the applicant's Grants Management Specialist and Program Officer.

NIAID will generally not fund applications at budget levels exceeding these budget guidelines. For budgetary, administrative, or programmatic reasons, NIAID may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

92

## Budgets

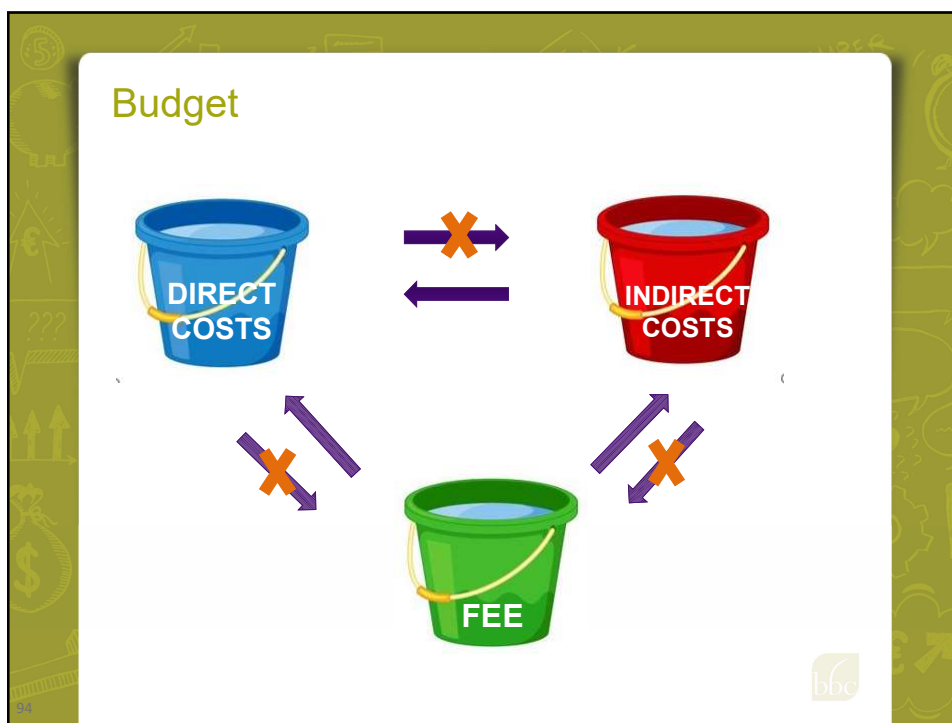


- **Direct Costs\*\***
  - E.g., Salaries, supplies, equipment, travel, consultants fees, subcontract costs
- **Indirect Costs (F&A)**
  - ≤ 40% of TOTAL direct costs for Phase I (Includes fringe benefits)
  - OR
  - Request higher rate IF you can support it through a negotiation with DFAS
- **Fee**
  - 7% of total costs (direct and indirect)
- **Unallowable Costs**

**\*\*Make sure to justify your direct costs extremely well.**

93

93



94

## Before you begin.....

### Understand the different roles on the project.

- Senior/Key persons
- Other personnel
- Consultant or contract employee
- Sub award vs. fee for service



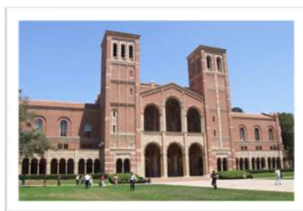
95

95

## SBIR vs. STTR: Who does the work?

### 'Outsourcing' limits:

- SBIR: Must be >67% of the budget at the small business in Phase I; 50% in Phase II
- STTR: Must be >40% at the small business; > 30% at partner non-profit research institution (30% 'floating')



The applicant is *always* the small business

bbc

96



## Salaries/Wages

- Salary for Senior/Key Persons and Other Personnel
  - Who will do the work?
  - What will be their role?
  - What amount of time will they commit?
  - Is the proposed labor cost appropriate for the scope of the work?



97

97

## Roles - Contract Employee

**Self-employed individuals, paid by the hour.**

- Set their own schedule
- Not managed by a supervisor
- Use their own equipment, maintain their own benefits and licenses



98

98

## Roles - Consultants

- Individual or organization retained to provide professional advice or services for a fee but usually not an employee of the company.
  - Rate must be reasonable in relation to the service rendered
  - Rate comparable to other consultants in the industry
  - Consulting agreement includes individual/organization name, nature of service, relevance to project, period of service, rate per hour.



99

99

## Roles - Subcontractor

- Conducts work with their employees in their facilities
- Whose award it is?
  - Make sure to agree to scope of work and deliverables
- Why use a subcontractor?
  - Specialized facilities
  - Complimentary expertise
- Potential for jointly developed IP
  - Discuss any IP contingencies up front



100

100

## Subaward

### What do you need from the sub award?

- Biosketches of all key persons
- Budget and budget justification
- Facilities description and equipment lists
- Letter(s) of commitment

101



101

## Roles - Fee for Service

- A fee for service is an arrangement between the primary organization and another organization
- Vendor provides a routine service to the primary organization.
- No shared IP



102



102

## SBIR/STTR Programs

### Subcontracting Guidelines

	Phase I		Phase II	
	Company	Collaborator	Company	Collaborator
SBIR	≥67%	≤33%	≥50%	≤50%
STTR	≥40%	≥30%	≥40%	≥30%

- Based on percentage of budget allocated
- For STTR projects the remaining 30% can be allocated to either party or to a 3<sup>rd</sup> party



103

103

Poll....



It depends.....



104

## Materials/Supplies

- Direct cost when used directly on the project
- Indirect supplies – those that can be used on multiple projects
- Office supplies are an indirect
- General supplies are an indirect:
  - Gloves
  - Screws
  - Wires
  - Beakers



bbc

105

105

## Travel

- Direct cost where such travel will provide direct benefit to the project
- No foreign travel
- When the company does not have an established policy use government travel policy found at [www.gsa.gov](http://www.gsa.gov) varies by state
- Must be related to the needs of the project



bbc

106

106

107

NIH

## Technical & Business Assistance (TABA)

- Increase Technical & Business Assistance
  - Up to \$6,500 per year per Phase I (up from \$5K/year)
  - Up to \$50,000 per Phase II **project** (up from \$5K/year)
  - Request at time of APPLICATION
  - Request in F. Other Direct Costs lines 8-10 on SBC budget
  - Label as “Technical Assistance”
  - May not count towards hard cap (confirm with Program Manager)

bbc

107

108

NIH

## Technical & Business Assistance (TABA)

- To provide small business concerns engaged in SBIR or STTR projects with technical and business assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, product sales, IP protections, market research, market validation, development of regulatory plans, manufacturing plans, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in:
  - making better technical decisions concerning such projects;
  - solving technical problems which arise during the conduct of such projects;
  - minimizing technical risks associated with such projects; and
  - **developing and commercializing new commercial products and processes resulting from such projects, including intellectual property protections.**

bbc

108

## Indirect costs

- Any item, service or labor that is used to “support or complete” the project but also benefits other projects/activities. E.g.
  - Utilities
  - Rent
  - Benefits



109

109

## Indirect Costs (Overhead)

- Fringe Benefits
  - Payroll taxes
  - Insurance – health, disability, workers compensation
  - Retirement plan contributions
  - Paid leave – vacation, sick, holiday
- General & Administrative (overhead)
  - Office supplies
  - Rent
  - Phone
  - Technology – web, email
  - Administrative wages



110

110

## Unallowable Costs

- Costs necessary for a business but can not be paid with federal dollars.
  - Patent costs
  - Interest expense
  - Advertising/Marketing

[www.acquisition.gov/far/html/subpart%2031\\_2.html](http://www.acquisition.gov/far/html/subpart%2031_2.html)



111

111

## SBIR Preliminary Budget (\$150K budget)

	# Hours	Who	Where	Cost
Objective #1				
Task A	800	Company	In-house	\$68,000
Task B	600	Subcontract	Out-source	\$36,000
Objective #2				
Task A	200	Company	In-house	\$17,000
Consultant	160	AJ Burns	Out-source	\$12,000
Supplies	-	-	-	\$5,000
Other	-	-	-	\$12,000

= \$48K

\$48k/\$150K

= 32%

**Total \$150,000**



112

112



## Estimate Your Budget

### Plan For This

	Phase I	Phase II
<b>Total Budget</b>	<b>\$252,000</b>	<b>\$1,680,000</b>
(Indirect@40% of total Direct Cost)	\$67,000	\$450,000
(Fee@7% Total Direct + Indirect)	\$17,000	\$110,000
<b>Direct Cost</b>	<b>168,000</b>	<b>1,120,000</b>

Formula approximation: Total Budget x 0.67 = Direct Cost



113

113

## Budget Best Practices

- Develop your budget **early**
- Make sure that your direct costs are consistent with the work proposed
- Request indirect costs
- Request fee
- Understand the difference between direct costs, indirect costs and fee



114

114

## Other Sections

### Beware....

- Read the instructions carefully
- Just because it is there doesn't mean it is there for you
- For example -



115

## Critical Sections\* of an NIH SBIR/STTR

- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Bibliography and Refs Cited
- **Facilities & Other Resources**
- Equipment
- **Biographical Sketches (5 pg ea.)**
- **Project Budget**
- **Subaward Budget**
- Introduction to Application (resubmission only -1pg)
- **Specific Aims (1 pg)**
- **Research Strategy (6 or 12 pg)**
  - **Significance**
  - **Innovation**
  - **Approach**
- Progress report/Publication List (Phase II only)
- Vertebrate Animals
- Select Agent Research
- Multiple PD/PI Leadership Plan
- **Consortium/Contractual Arrangements**
- **Letters of Support**
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Appendix
- Cover Letter
- **Commercialization Plan (12 pg; Ph II, DTPH II & Fast Track only)**
- PHS Assignment Request
- PHS Human Subjects and Clinical Trials Information

116

\*note that every section is important if relevant to the project



116

## SBIR/STTR Long Term Goal - Commercialization



The diagram shows a central green circle labeled "Business PLAN" surrounded by eight smaller colored circles: Timeline (orange), Competition Analysis (yellow), SWOT Analysis (red), Mission Statement (purple), Marketing Plan (blue), Product Description (light blue), Financial Planning (green), and Operations (dark green).

### What is Commercialization?

- Ability to provide a solution to a problem in exchange for money
  - Targeted and Differentiated Solution
  - Important Problem
  - Viable Business Model

117



117

## Agency Expectations

- **Credible Commercialization Strategy**
  - Demonstrates an understanding of the market
  - Recognizes the Company's strengths & limitations
  - Integrated into the product development plan
  - Internally consistent



The word cloud features the words "MARKET" and "RESEARCH" in large yellow letters. Other words include: individuals, advantage, insight, products, trial, competitors, business, strategy, opinions, information, discover, identify, statistics, analyze, customers, marketing.

118



118

## Commercialization

There is no such thing as the “*Build it and they will come*” Business Model



bbc

119

## NIH Commercialization Plan Elements

### What to include in NIH Phase I

- No special section for commercialization
- Reviewed under the Significance criteria
- Reviewers need to know you have a plan
- Suggested outline under “Significance” section
  - Commercial Potential (1/2 to 1 page)
    - IP status and issues
    - Market opportunity
    - Competing technologies & competitors
    - Business model for commercialization
    - Other technology applications

120

bbc

120

## NIH Commercialization Plan Elements

### NIH Required Outline for Phase II (12-page limit)

- Value of SBIR/STTR project, Expected Outcomes, and Impact
- Company
- Market, Customer, Competition
- Intellectual Property Protection
- Finance Plan
- Production and Marketing Plan
- Revenue Stream

Additional review criteria:

121



121

## Grant Writing 101


### Be Kind to the Reviewer

a.k.a.- make the reviewers job easy...



**BEST PRACTICE**

122



122

## Grantsmanship

*“There is no grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise a good one.”*



123

123

## Be Kind to the Reviewer


*Make the reviewer's job easy*



124


124

The quick brown fox jumps over the lazy dog" is a pangram that has been used to test typewriters and computer keyboards because it is coherent, short, and contains all the letters of the English alphabet. It was often used for testing the teletype services (a procedure known as "foxing") when these machines were still used [citation needed] in the age of computers, it is often used as a sample text in font selection contexts. The phrase is frequently misquoted as "The quick brown fox jumped over the lazy dog", which does not contain all the letters of the alphabet since it lacks the letter "s". For this reason, the word "slow" or "sleeping" is sometimes inserted into the phrase, or the word "dog" is made plural. The quick brown fox jumps over the lazy dog" is a pangram that has been used to test typewriters and computer keyboards because it is coherent, short, and contains all the letters of the English alphabet. It was often used for testing the teletype services (a procedure known as "foxing") when these machines were still used [citation needed] in the age of computers, it is often used as a sample text in font selection contexts. The phrase is frequently misquoted as "The quick brown fox jumped over the lazy dog", which does not contain all the letters of the alphabet since it lacks the letter "s". For this reason, the word "slow" or "sleeping" is sometimes inserted into the phrase, or the word "dog" is made plural. The quick brown fox jumps over the lazy dog" is a pangram that has been used to test typewriters and computer keyboards because it is coherent, short, and contains all the letters of the English alphabet. It was often used for testing the teletype services (a procedure known as "foxing") when these machines were still used [citation needed] in the age of computers, it is often used as a sample text in font selection contexts. The phrase is frequently misquoted as "The quick brown fox jumped over the lazy dog", which does not contain all the letters of the alphabet since it lacks the letter "s". For this reason, the word "slow" or "sleeping" is sometimes inserted into the phrase, or the word "dog" is made plural. The quick brown fox jumps over the lazy dog" is a pangram that has been used to test typewriters and computer keyboards because it is coherent, short, and contains all the letters of the English alphabet. It was often used for testing the teletype services (a procedure known as "foxing") when these machines were still used [citation needed] in the age of computers, it is often used as a sample text in font selection contexts. The phrase is frequently misquoted as "The quick brown fox jumped over the lazy dog", which does not contain all the letters of the alphabet since it lacks the letter "s". For this reason, the word "slow" or "sleeping" is sometimes inserted into the phrase, or the word "dog" is made plural. The quick brown fox jumps over the lazy dog" is a pangram that has been used to test typewriters and computer keyboards because it is coherent, short, and contains all the letters of the English alphabet. It was often used for testing the teletype services (a procedure known as "foxing") when these machines were still used [citation needed] in the age of computers, it is often used as a sample text in font selection contexts. The phrase is frequently misquoted as "The quick brown fox jumped over the lazy dog", which does not contain all the letters of the alphabet since it lacks the letter "s". For this reason, the word "slow" or "sleeping" is sometimes inserted into the phrase, or the word "dog" is made plural.




**It's about more than just following the rules**

125



125



**Let's eat grandma!**

**Even commas matter**

**Let's eat, grandma!**

**PUNCTUATION SAVES LIVES!**

126

## Keep it simple

### Avoid acronyms

- They confuse
- Not everyone reading your proposal is an expert
- They destroy the flow
- The story gets lost



bbc

127

## Writing tips (from NIH)

- **Don't wait until the last minute**
- Organize to communicate
- Follow instructions EXACTLY
- Proof a hard copy
- Get a critique
- **Ask people at NIH for help**
- Submit again
- Analyze the critique
- Don't give up




bbc

128



*I love deadlines. I like the whooshing sound they make as they fly by.*

*-Douglas Adams*



129

bbc

129

Where's my money?


- Just-in-time Information
- Assurances
- Financial Information
- 3rd party involvement
  - Subcontracts, consultants



bbc


130

## JIT – Just in Time Information





**This is NOT a notice of grant award**

- Financial Statements
- Line of Credit
- Chart of accounts
- Demonstrate the ability to record costs by project
- Time & Reporting
- Internal Controls
- Procurement Policy
- Travel Policy
- Conflict of Interest
- Lab notebooks
- Update Other Support (all key persons)
- Human Subjects Assurance Number
- IRB Approval
- Document of required education of human subjects
- IACUC verification/letter
- SBIR/STTR Verification
- Budget
- Signed lease



131

132

132

## About BBCetc

BBCetc works with technology-based entrepreneurs and companies on strategies to advance R&D efforts to commercialization. We are nationally recognized for our success in helping clients win federal funding through the SBIR/STTR programs and use it tactically to propel growth. Services include training courses and one-on-one counseling in:

- Commercialization Planning
- SBIR/STTR and Other Research Grant Assistance
- SBIR/STTR and Commercialization Training
- Grants/Contracts Management
- Tech-Based Economic Development Programs

[www.bbcetc.com](http://www.bbcetc.com) / 734-930-9741 / @BBC\_etc



133

133

## Contact Us

info@bbcetc.com  
734.930.9741  
www.bbcetc.com

Social:

-  @BBC\_etc
-  BBCetcllc
-  BBC Entrepreneurial Training & Consulting LLC

Copyright © BBC Entrepreneurial Training & Consulting, LLC  
DEVELOPING THE BUSINESS OF TECHNOLOGY



134

134

# Developing the Business of Technology

**bbc** Entrepreneurial Training & Consulting

Copyright © BBC Entrepreneurial Training & Consulting, LLC

DEVELOPING THE BUSINESS OF TECHNOLOGY

135