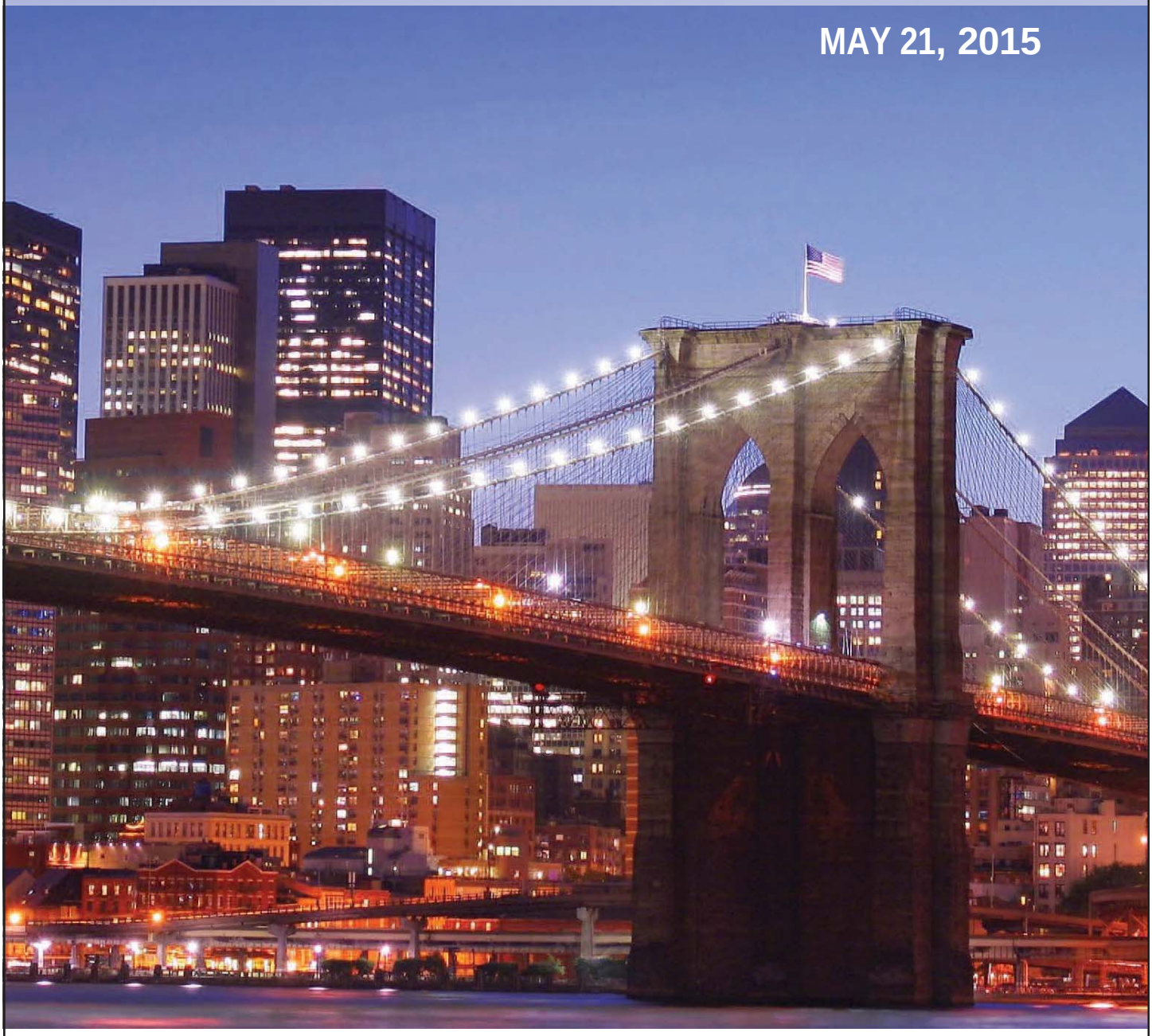
Introduction to SBIR/STTR and NIH Proposal Prep

SBIR IMPACT
BIO AND HEALTH TECH NYC

MAY 21, 2015



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An initiative of

NYCEDC
New York City Economic Development Corporation

THIS EVENT IS AN INITIATIVE OF:

NEW YORK CITY ECONOMIC DEVELOPMENT CORPORATION

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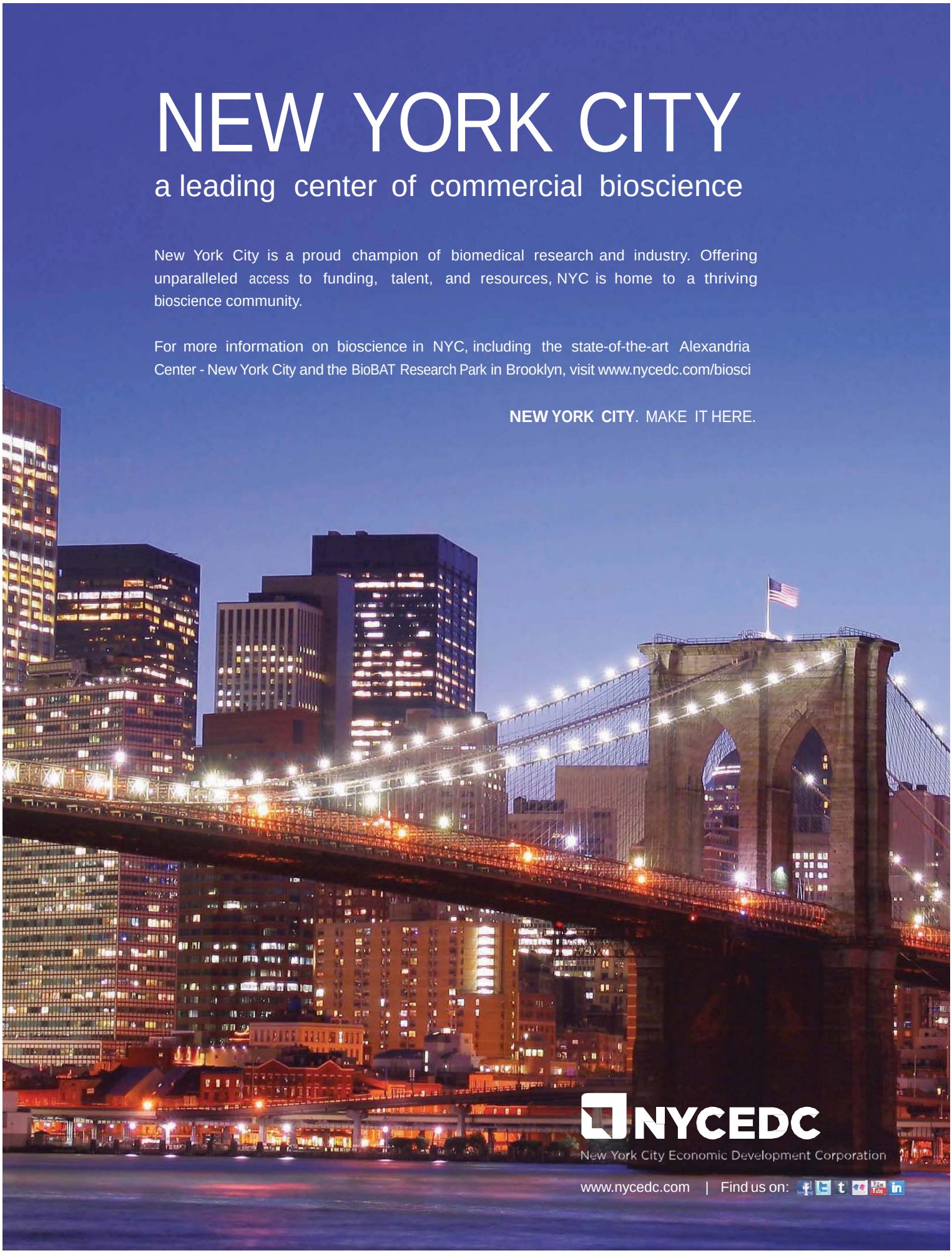
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a leading center of commercial bioscience
New York City is a proud champion of biomedical research and industry. Offering unparalleled access to funding, talent, and resources, NYC is home to a thriving bioscience community.
For more information on bioscience in NYC, including the state-of-the-art Alexandria Center - New York City and the BioBAT Research Park in Brooklyn, visit www.nycedc.com/biosci
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NYCEDC
New York City Economic Development Corporation
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NEW YORK GENOME CENTER AT A GLANCE

Incorporated in 2010 and launched in 2011, the New York Genome Center is an independent nonprofit at the forefront of transforming biomedical research and clinical care with the mission of saving lives. As a consortium of renowned academic, medical and industry leaders, NYGC focuses on translating genomic research into clinical solutions for serious disease. Our member organizations and partners are united in this unprecedented collaboration of technology, science, and medicine.

NYGC has extensive in-house bioinformatics support, the fastest gene sequencing technology available and a large IT infrastructure for data storage and high-performance computation, empowering researchers to access best-in-class analysis, to perform research in a clinically relevant and cost-effective timeframe, and to consolidate resources. Member institutions include: Albert Einstein College of Medicine, American Museum of Natural History, Cold Spring Harbor Laboratory, Columbia University, Cornell University/Weill Cornell Medical College, Hospital for Special Surgery, The Jackson Laboratory, Memorial Sloan Kettering Cancer Center, Icahn School of Medicine at Mount Sinai, NewYork-Presbyterian Hospital, The New York Stem Cell Foundation, New York University, North Shore-LIJ, The Rockefeller University, Roswell Park Cancer Institute, Stony Brook University and IBM.

NYGC is led by President, Chief Executive Officer and Scientific Director Robert B. Darnell, M.D., Ph.D., a leading physician-scientist, Howard Hughes Medical Investigator and member of the National Academy of Sciences. Our board of directors consists of a senior representative from each of our Institutional Founding Members, as well as a number of independent directors. In addition to our staff of leading bioinformaticians, software engineers, high performance computing experts and sequencing personnel, we have a growing list of faculty members who are leading their own innovative research at the Center. Each faculty member holds a joint appointment at a Member Institution. Our capacities and expertise reflect our commitment to being a vital resource – and driver – for the advancement of translational genomics. Our current core activities include:

- providing best-in-class sequencing and bioinformatics services to our members and the genomics research community at large;
- building our clinical laboratory, which is offering Next Generation Sequencing (NGS)-based exome testing for constitutional disorders, and is in the process of getting NY State approval to offer cancer testing and whole genome clinical sequencing;
- leading innovative research and methods development and improvement; we have several multi-institutional projects currently underway in cancer, autoimmune disease and neurological disorders – including a personalized medicine trial that includes Watson, IBM's artificial intelligence technology;
- developing the systems and infrastructure to enable researchers from New York and beyond to carry out large-scale, collaborative genomics research; and
- hosting and supporting a number of educational and outreach initiatives, including two lecture series that are free and open to the public.

Since its inception, NYGC has raised over $200 million from a number of sources, including grants, corporate and private philanthropic support, and other funding – including a matching grant from the State of New York for $55.75 million. We invite you to visit our website, www.nygenome.org, to learn more about the work we have underway, and our vision for the future.

SBIR IMPACT
BIO AND HEALTH TECH NYC

Program Overview

Mission

An initiative of New York City Economic Development Corporation, SBIR Impact – Bio & Health Tech NYC is a competitive SBIR/STTR application assistance program for life sciences and healthcare technology companies in New York City. The Program will help participants compete for over $2.6 billion in non-dilutive federal R&D funding through the government's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Description

Each year, SBIR Impact will offer 20 select companies specialized assistance through a combination of advanced training workshops and 20 hours each in one-on-one expert proposal-development assistance. In addition, the Program will offer a series of introductory workshops to prospective applicants and the public. Participants for intensive training and one-on-one assistance are identified through a competitive application process held three times per year.

Overview of Application Process

Interested participants submit an online application by one of three deadlines: January 14, April 22 or September 9, 2015.

1. Applicants will be asked to participate in an assessment call with our Program Team to discuss eligibility and interest in submitting an SBIR/STTR application.
2. Selected participants will be notified on a rolling basis by dates that will be announced depending upon the cycle in which their applications were received.
3. Twenty participants will be selected per year. Once 20 companies are selected, a waiting list will be established and additional companies may be accepted based on availability.
4. In addition to receiving 20 hours of expert assistance, selected participants will be expected to participate in one of our Intensive Training workshops.

Presenter

Becky Aistrup

Principal Consultant
BBC Entrepreneurial Training & Consulting

Becky joined BBC Entrepreneurial Training & Consulting as a Principal Consultant in July 2012. Prior to that, she was with the Minnesota Science and Technology Authority as SBIR/STTR Program Director. In addition to her work for the State of Minnesota, Becky's professional background includes over 20 years of experience working within the medical, biotech, advanced materials and electronics industries and as a consultant to technology companies helping them successfully win SBIR/STTR funding. In the 1990's, she served as VP of Business Development & Licensing for a successful SBIR firm, helping them strategically target proposals, develop & write Phase II Commercialization Plans, and successfully commercialize resulting technologies. The company, Surmodics, is now a successful public firm.

Becky has presented numerous workshops beginning in the 1993 for NSF, state organizations and private clients about the SBIR program and SBIR commercialization. She holds a Bachelor's degree in Chemistry from the University of Kansas, postgraduate work in Biochemistry and an MBA in Marketing Management from the University of Minnesota, and a Master's Certification in Interactive Marketing from the University of San Francisco.

About BBC Entrepreneurial Training & Consulting (BBCetc)
BBCetc works with technology-based entrepreneurs and companies on strategies to advance R&D efforts to commercialization. In particular, the BBCetc team is nationally recognized for its success in helping clients secure federal funding through the Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. BBCetc services include commercialization planning, research grant assistance, SBIR/STTR training and proposal development assistance, and grants and contract management. With expertise in all 11 participating federal agencies, BBCetc has trained thousands of entrepreneurs and coached hundreds one-on-one in how to prepare compelling SBIR/STTR proposals and how to integrate SBIR/STTR funding into their overall funding strategy.

Intro to SBIR/STTR &
NIH Proposal Preparation
May 21, 2015

Agenda

8:30 – 9:00 a.m.	**Registration**
9:00 – 9:10 a.m.	**Welcome and Introduction** *Lenzie Harcum* Director, Bioscience and Health Tech, NYCEDC *Emily Gantman* Engagement Associate & Outreach Scientist, NY Genome Center
9:10 – 10:15 a.m.	**Overview of SBIR Impact NYC** **Introduction to SBIR/STTR** *Lisa Kurek* SBIR Impact NYC Program Director
10:15 – 10:30 a.m.	**Networking Break**
10:30 – 11:45 a.m.	**Introduction to SBIR/STTR (cont'd)** *Lisa Kurek*
11:45 a.m. – 12:45 p.m.	**Networking lunch**
1:00 – 2:30 p.m.	**National Institutes of Health SBIR Program** *Lisa Kurek*
2:30 – 2:45 p.m.	**Networking Break**
2:45 – 4:00 p.m.	**NIH SBIR Program (cont'd)** *Lisa Kurek*
4:00 – 4:30 p.m.	**Review of SBIR Impact NYC** **Q & A**
4:30 – 5:30 p.m.	**Informal Networking**

SBIR IMPACT
BIO AND HEALTH TECH NYC

Assistance for NYC Bio & Health Tech Ventures

Portfolio of initiatives for Life Sciences & Healthcare Technology

In addition, the City and NYCEDC have been backing significant efforts to grow the early-stage ecosystem for life sciences and healthcare technology

NYCEDC
New York City Economic Development Corporation

City of New York and NYCEDC initiatives launched in 2013

Harlem Biospace: Incubator facility with affordable wet-lab bench stations, access to shared equipment and mentorship for new biotech firms: ***www.harlembiospace.com***
Entrepreneurship Lab NYC: Intensive training & mentorship program for early-career scientists and engineers starting new ventures from NYC-based academic medical centers: ***www.elabnyc.com***
SBIR Impact NYC: Competitive program awarding 20 hrs. of one-on-one assistance to each of 20 select companies actively preparing SBIR/STTR proposals: ***www.sbirnyc.com***
PILOT Health Tech NYC: Program to give up to $100K in matching funds to each of 10 NYC-based health tech firms conducting pilot programs in a healthcare provider setting: ***www.pilothealthtechnyc.com***
City of New York Early-Stage Life Sciences Fund: $100M+ initiative to launch new life sciences ventures in partnership with industry leaders GE Ventures, Celgene and Eli Lilly, academical medical centers and top-tier venture capital firms: ***www.nycedc.com/lifesciences***

Hb

ENTREPRENEURSHIP LAB
BIO AND HEALTH TECH NYC

SBIR IMPACT
BIO AND HEALTH TECH NYC

PILOT
health tech NYC

NYC LIFE SCIENCES FUND

Note: These programmatic initiatives complement NYCEDC and City investments in prior years (e.g., Alexandria Center for Life Sciences – NYC)

SBIR IMPACT
BIO AND HEALTH TECH NYC

Assistance for NYC Bio & Health Tech Ventures

Intro to SBIR/STTR & NIH Proposal Prep Workshop

May 21, 2015

Becky Aistrup

www.sbirnyc.com

734.930.9741

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SBIR Impact NYC

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An initiative of NYCEDC and the City of New York, SBIR Impact NYC is designed to enhance the competitiveness of SBIR/STTR proposals among NYC-based life sciences and healthcare technology companies. The program features:

- Introductory workshops and "How to Apply for SBIR Impact" webinar open to the public.
- 20 hrs. of one-on-one assistance for each of 20 select companies actively preparing SBIR/STTR proposals.

http://www.sbirnyc.com/

SBIR IMPACT

Thank You to Today's Host and Sponsors

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SBIR IMPACT

Outline

- Who are we?
- Who are you, your technology and/or company?
- What is the SBIR program and who is eligible?
- Participating Agencies
- SBIR vs. STTR
- Introduction to the NIH
- How to write a great NIH SBIR proposal
- Intro to Electronic Submission

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BBC Team

- **Lisa M. Kurek**, MS – Managing Partner
- **Michael P. Kurek**, PhD, MBA – Partner
- **Andrea Johanson**, PhD – Principal Consultant
- **Becky Aistrup**, – Principal Consultant
- **Kris Bergman** – Consultant, Grants and Contract Management
- **Jayne Berkaw** – Director, Marketing and Outreach

SBIR IMPACT BIO AND HEALTH TECH NYC

What We Do

bbc Entrepreneurial Training & Consulting

BBC works with technology-based entrepreneurs and companies on strategies to advance R&D efforts to commercialization. Through training courses and one-on-one counseling, the BBC team coaches clients in:

- Commercialization Planning
- Research Grant Assistance
- SBIR/STTR Training
- Grant/Contract Management
- Tech-Based Economic Development Programs

The BBC team is nationally recognized for its success in helping clients win federal funding through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, and use it tactically to propel growth.

SBIR IMPACT BIO AND HEALTH TECH NYC

Now about you…

- Where are you from….
  - University? Industry? Government? Other?
- What is your technology?
- How will your technology become a product?
- Who will purchase this product when commercialized?
- Already submitted grants or contracts
  - SBIR/STTR? R0I? NIH, NSF, Other?
- Planning to submit?

SBIR IMPACT

Why SBIR/STTR?

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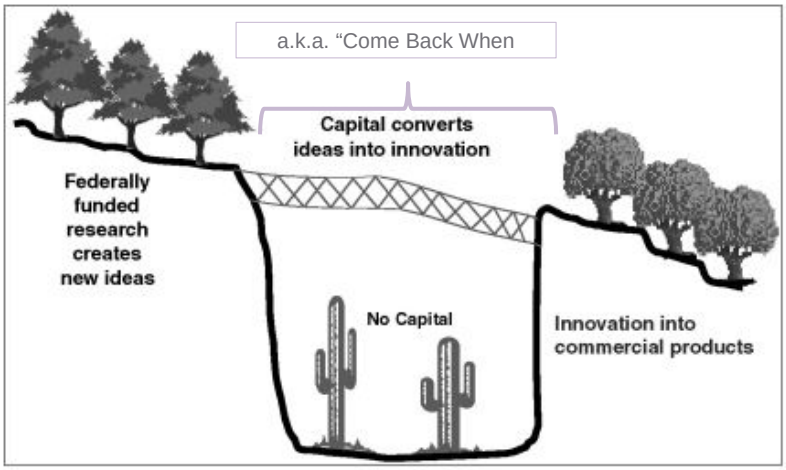
Goal of SBIR/STTR Programs



Source: SBIR and the Phase III Challenge of Commercialization: Report of a Symposium. NAS, 2007.

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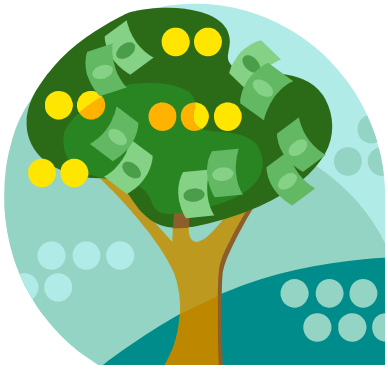
Funding for Commercialization

- Debt
- Equity
- **Non-Dilutive**



SBIR IMPACT

What are SBIR* and STTR**?

$2.5 billion of federal funding to:

- Support **small business** to:
  - Stimulate **technological innovation** to
    - Develop **products** with **commercial merit**

* – Small Business Innovation Research
** – Small Business Technology Transfer

SBIR IMPACT

Purpose of SBIR/STTR Programs

- Stimulate **technological innovation** in the private sector
- Strengthen the role of small business in meeting Federal R&D needs
- Increase **commercial application** of Federally-supported research
- Improve the return on investment from Federally-funded research for economic and social benefits to the Nation.
- ***[Not** an alternative source of funding basic research]*

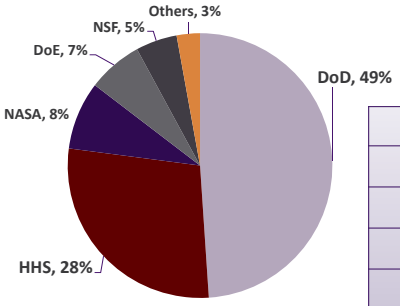
SBIR IMPACT

What is SBIR/STTR….

- Mandated by legislation (NDAA FY2012)
  - Current authorization for 6 years through 2017
  - Separate legislation for SBIR and STTR
- Applies to agencies with extramural research budgets that exceed certain thresholds
  - SBIR applicable to 11 Agencies
  - STTR applicable to 5 of the 11 SBIR agencies
  - Participation mandatory
- SBA "oversees" program implementation and compliance
  - SBIR/STTR Policy Directive
  - Small Business Size Regulations

SBIR IMPACT

Participating Federal Agencies



TOTAL: ~$2.3 B FY 2015

SBIR and STTR	SBIR Only
DOD - $1,200 m	USDA - $19 m
HHS - $690 m	DOT - $4 m
NASA - $204 m	EPA - $7 m
DOE - $164 m	DOC - $9 m
NSF - $124 m	DoED - $8 m
	DHS - $23 m

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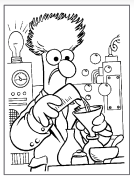
Key Questions…

- The Project:
  - What do you need the money for?
- The Company:
  - Who owns it?
  - What resources does it have?
    - Facilities
    - People
  - Where will it get what it needs?

The Project: What Does SBIR/STTR Fund?

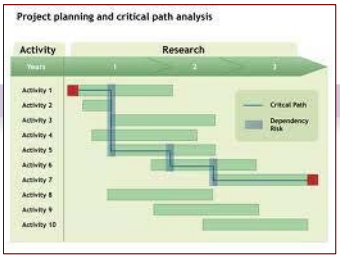
- PRODUCT Development



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

- Credible Commercialization Strategy

The Project



Questions:

- $ for Product Development
  - What is the intended product?
  - What applications will it be used for?
  - What has been done to date?
  - How much is left to do?

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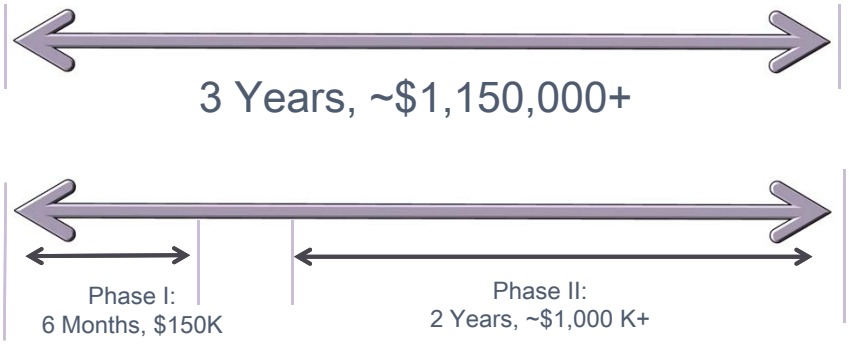
BIO AND HEALTH TECH NYC

The Basics of SBIR: 3 Phases



Phase III: Commercialization (no federal SBIR/STTR $$)

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Three Phases of SBIR/STTR

- Details Agency Dependent
- Phase I – Feasibility*
  - 6 months – 1 year
  - $80k – 225k
- Phase II - Expand results, pursue further development*
  - 2 years
  - $750k - $1.5m
- Phase III – Commercialization
  - Your own $$ (ie - no government $!)
- *Phase I and II supplements available at some agencies

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The Project

Questions:

- Based on “technological innovation”
  - What is the technological innovation that will enable the product to achieve the desired performance?
  - How certain are you that it will work?
  - Is there risk of failure?
  - Will the product be revolutionary or evolutionary?

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The Project

What is Commercialization?

- Ability to provide a solution to a problem in exchange for money
  - Important Problem?
  - Viable Business Model?

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Commercialization

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

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The Project – QUESTIONS:

- Credible Commercialization Strategy
  - Is there a market identified?
  - Has a competitive analysis been done?
  - How will the company generate revenue?
  - What additional resources will be required to achieve commercialization?
  - Have sources of those resources been identified?
    - Strategic Partners
    - Sources of capital

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SBIR/STTR Programs

Learn the Rules!

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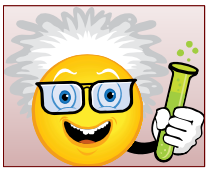
The Company

Questions:

- A for-profit entity?
- Who owns the company?
- Who controls the company?
- Does the company have its own research facilities?
- Is there a qualified PI with primary employment at the company?



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2012 Reauthorization SBA Documents

Small Business Size Regulations

- Final Rule
- Published 12/27/2012
  https://www.federalregister.gov/articles/2012/12/27/2012-30809/small-business-size-regulations-small-business-innovation-research-sbir-program-and-small-business
- Effective Jan 28, 2013

FEDERAL REGISTER

SBIR IMPACT

Eligibility for Funding

- Small business
  - US owned and controlled
  - < 500 employees
  - For-profit
  - Located in the U.S.
  - R&D must be performed in the U.S.

SBIR & STTR Size Regulations

Ownership and Control

- >50% owned and controlled by:
  - i. **US citizens**, **permanent resident aliens** and/or one or more **domestic business concerns** which themselves are >50% owned and controlled by US Citizens or permanent resident aliens

  or

  - i. **Multiple** domestic VCOCs, HFs, or PEFs, provided that no single such investor owns more than 50% **(SBIR ONLY)**

SBIR & STTR Size Regulations

Ownership …

- All ownership, control and affiliation determinations will be made using fully diluted shares on a converted basis
- SBIR applicants must have a place of business in the US
- SBIR applicants must be organized as for-profit businesses under US law
- VCOCs, PEFs, HFs, investing in the SBIR applicant must be organized under US law and have a place of business in the US

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SBIR & STTR Size Regulations

Size and Affiliation

- Under 500 employees for SBIR applicant and its affiliates including:
  - Full-time, part-time or other basis
  - Employees obtained from a temporary employee agency, PEO or leasing concern
- Based on average of number of employees for each pay period in the preceding 12 months

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SBIR & STTR Size Regulations

Size and Affiliation

- Affiliation exists when one business controls or has the power to control another or when a third party controls or has the power to control both businesses

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SBIR & STTR Size Regulations

Timing of Size Certifications

- Size and eligibility certified at the time of award
- If awardee grows to > 500 employees during the time of the award it may continue to perform activities covered by the award
- If awardee merges or is acquired it may only continue for the current funding period and then will have to recertify

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Facilities Requirement

- The research work to be performed by the awardee is to be conducted in:
  - **Company** controlled
  - **Research** space
  - Suitable to do the work proposed

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SBIR vs. STTR

SBIR and STTR are two separate programs

- Not all agencies with both SBIR and STTR programs give you the choice of mechanism
- Separate set-asides
  - SBIR: 2.6% (3.2% in 2017)
  - STTR: 0.35% (0.45% in 2017)

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SBIR vs. STTR

Relationship with a non-profit research institution:

- SBIR allows but does not require the involvement of a non-profit research institution
- STTR requires the involvement of a non-profit research institution

The Applicant Organization is always the Small Business!

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SBIR vs. STTR: Who does the work?

**** APPLICANT IS ALWAYS THE SMALL BUSINESS****

- **Subcontract percentages**
  - **SBIR**: no more than 33% in a Phase I and 50% in a Phase II
  - **STTR**: at least 40% at small business and at least 30% at partner non-profit research institution

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SBIR vs. STTR Facilities Requirement

Therefore the company must do:

- ≥67% of the SBIR Phase I work and
- ≥ 50% of the Phase II work

or

- ≥ 40% of the STTR Phase I and II work in**

***Company controlled research space suitable to do the work proposed!*

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SBIR vs. STTR: Where is the PI?

APPLICANT IS ALWAYS THE SMALL BUSINESS

- **Principal Investigator rules**
  - **SBIR**: PI at least 51% **employed** at small business
  - **STTR**: At small business or non-profit research partner. Must have an 'official relationship' with the small business and at least 10% effort on the project (except for NSF)

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STTR Applications - Extra Requirements

- Company & its University partner must sign intellectual property (IP) agreement (JIT)
- "Budget and Certification of Research Institution" form required
- Virtual companies do not qualify
- Be conscious of conflict of interest issues
  - (Both of the above apply equally to SBIRs that include a subcontract to a non-profit research institution)

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How do you choose ?

- Does the agency offer STTR?
- Is the relevant technology area/specific topic offered under both mechanisms?
- If yes to both above:
  - Do a resource inventory – people and facilities
    - What do I have?
    - What do I need?
    - Where will I fill the gaps?
  - Talk to the Agency

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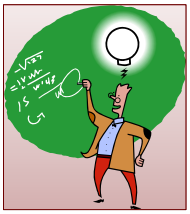
How Can Academics Participate?

- Faculty member can own small company & identify someone else (well-qualified) as PI
- Faculty member can be PI (i.e., with appropriate leave of absence)
- Subcontracts to academic institution
  - Faculty member can be PI's of subcontracts
  - Faculty member can provide analytical and other support services
- Faculty member can be a consultant



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Common Misconceptions

- Universities can apply for STTRs
- If a University is involved you have to do an STTR
- If the IP comes from a University you have to do an STTR
- If the inventor and/or key scientist is faculty you have to do an STTR
- If the PI of an STTR is at the University it is the University's grant/contract
- All of the work of an STTR can be done at the University

SBIR IMPACT

Critical “watch-outs”

Make sure that:

- The company has company-controlled research facilities
- If the PI of an SBIR has a faculty appointment, that they reduce their effort appropriately
- You accurately represent the company’s resources on your application

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DO YOUR HOMEWORK!

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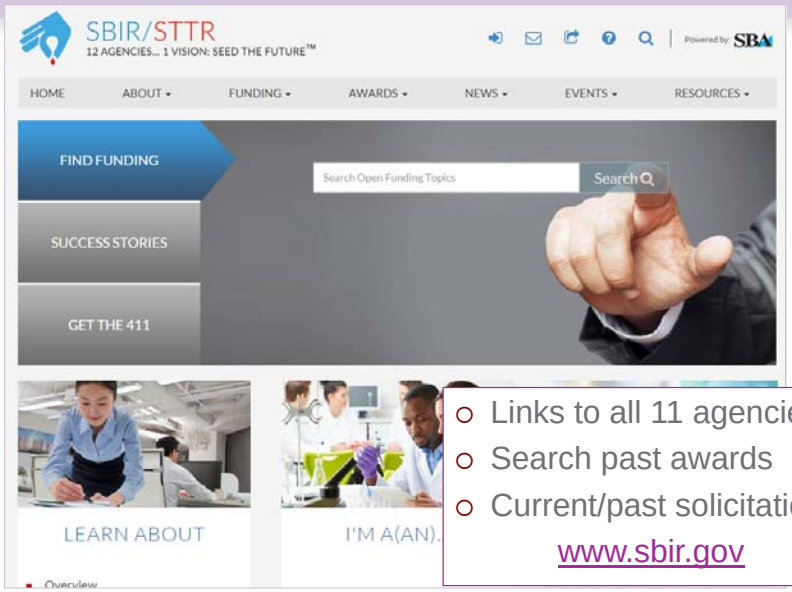
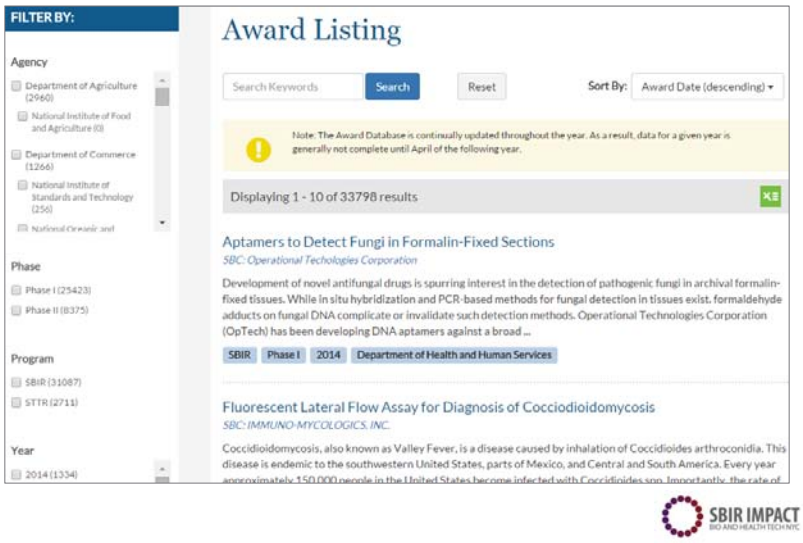
SBIR Information: SBIR.gov

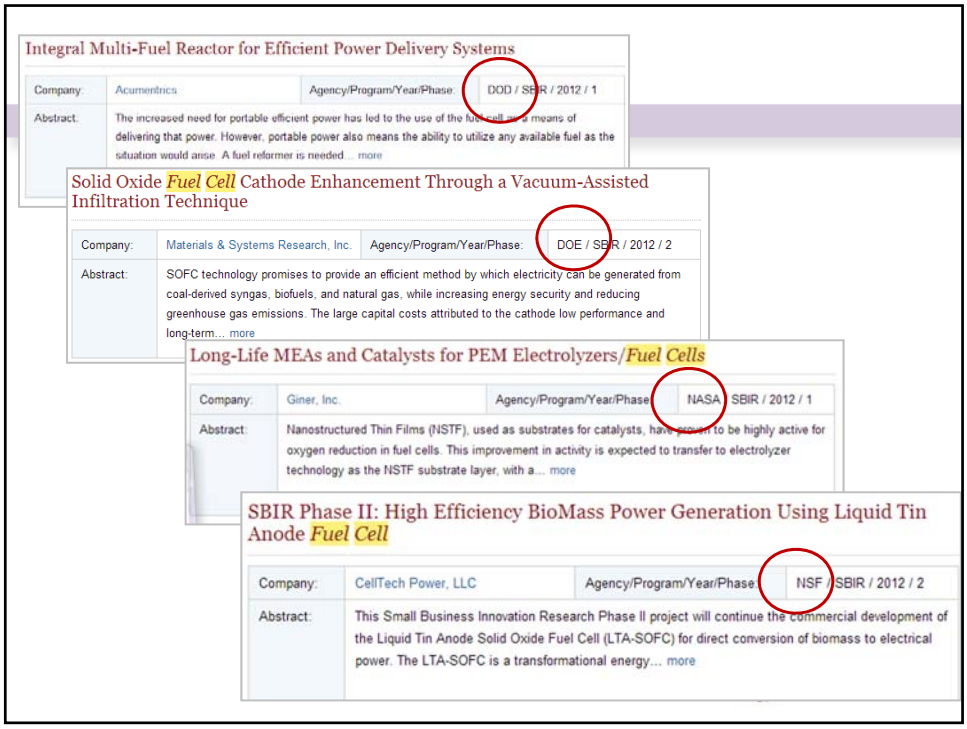


- Links to all 11 agencies
- Search past awards
- Current/past solicitations

www.sbir.gov

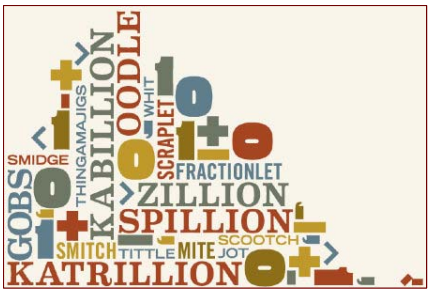
Search Past Awards





SBIR/STTR Terminology

- **"Solicitation"**
  - Funding Opportunity Announcement (FOA)
  - Request for Proposal (RFP); Request for Application (RFA)
- **"Submission"**
  - Proposal
  - Application
- **"Award"**
  - Grant
  - Contract
  - Award mechanism



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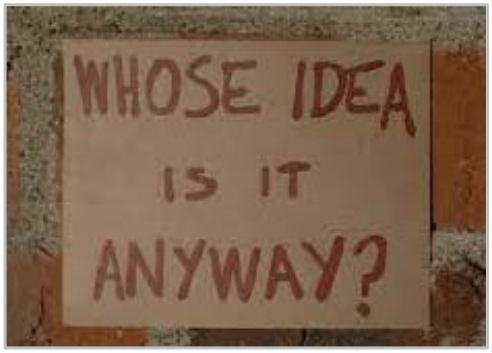
Agency Differences

- Receipt dates, number & timing of solicitations
- Type of award (grant or contract)
- Proposal review process
- R&D topic areas
- $ of award (both Phase I and II's)
- Proposal success rates
- Profit or fee allowed
- Gap funding provided (competing continuation grants)
- Payment types & schedules

SBIR IMPACT

Grants vs. Contracts….



SBIR IMPACT

Agency Differences – Grants vs. Contracts

Contracts

- Procurement
- Well-defined, legally binding statement of work, obligations, responsibilities
- Specific deliverables defined
- Topic Specific Response
- Agency contact limited
- Phase III opportunities

Grants

- Assistance
- Project/proposal is well-defined, but no formal agreement
- Progress/final reports
- Broad topics funded
- Agency contact unlimited
- No Phase III opportunities

SBIR IMPACT

Agency Differences – Grants vs. Contracts

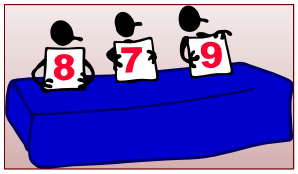
- **Grants – Investigated Initiated Topics**
  - HHS (95% $$), NSF, USDA, DOE
  - Some agencies might have topic areas (aka “buckets”)
  - Open communications
  - External peer review

- **Contracts – Agency-specified topics**
  - DoD, NASA, DHS, EPA, DOT, DOC, ED, HHS (5% $$)
  - Must respond to a topic
  - Limited time to prepare (8-12 weeks)
  - Limited communications during open solicitation
  - Internal review

SBIR IMPACT

Agency Differences – Review Process

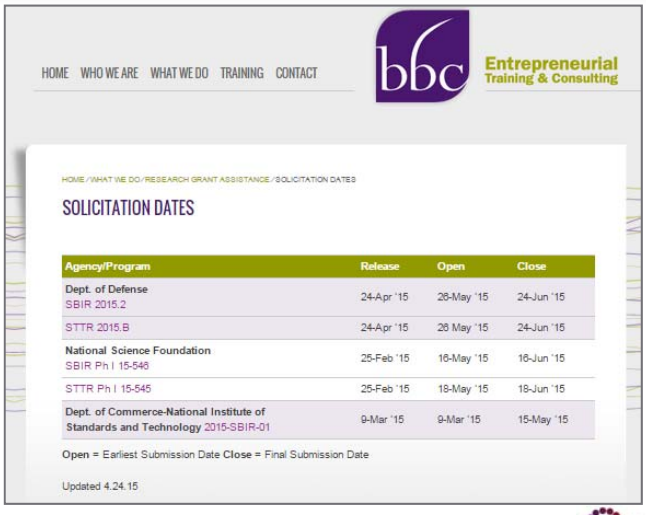
- **Internal Review**
  - DoD, DHS
  - Review panels composed of Agency personnel



- **External Review**
  - NIH, NSF
  - Review panels composed of leading experts in the field
  - Agency personnel do not score/rank applications, but manage the process

SBIR IMPACT

SBIR/STTR Deadlines



HOME WHO WE ARE WHAT WE DO TRAINING CONTACT

bbc Entrepreneurial Training & Consulting

HOME / WHAT WE DO / RESEARCH GRANT ASSISTANCE / SOLICITATION DATES

SOLICITATION DATES

Agency/Program	Release	Open	Close
Dept. of Defense SBIR 2015.2	24-Apr '15	26-May '15	24-Jun '15
STTR 2015.B	24-Apr '15	26 May '15	24-Jun '15
National Science Foundation SBIR Ph I 15-546	25-Feb '15	16-May '15	16-Jun '15
STTR Ph I 15-545	25-Feb '15	18-May '15	18-Jun '15
Dept. of Commerce-National Institute of Standards and Technology 2015-SBIR-01	9-Mar '15	9-Mar '15	15-May '15

Open = Earliest Submission Date Close = Final Submission Date

Updated 4.24.15

SBIR IMPACT

For More Agency Information

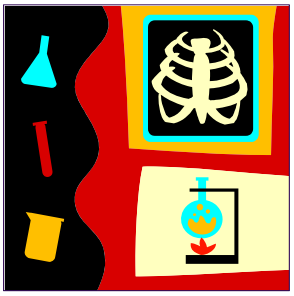
- **2015 National SBIR/STTR Conferences**
  - Washington, DC, June 14 – 17
    Co-located with TechConnect World & National Innovation Summit
- **NIH SBIR/STTR Conference**
  - Seattle, WA, October (tba) 2015

How to be Competitive in SBIR/STTR

- Understand the philosophy of the Agency
- Understand the review process
- Understand the psychology of the reviewers
- Develop and follow a strategic plan
- Follow the rules

Federal SBIR/STTR Agencies Funding Life Sciences

- National Science Foundation
- Department of Defense
  - Army
  - Navy
  - Air Force
  - SOCOM
  - OSD
- National Institutes of Health



SBIR IMPACT

NIH SBIR/STTR Program

NIH National Institutes of Health
Turning Discovery Into Health

SBIR IMPACT

Strategic Planning

BEFORE you start to write your proposal:

- Understand NIH Structure
- Find a Solicitation
- Understand the Review Process
- Define your project
- Understand how to work with NIH

National Institutes of Health

- The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services
- Composed of 27 Institutes and Centers.
- NIH's mission *is 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 the burdens of illness and disability.*

HHS Program Funding 2014

2014 Budget	SBIR	STTR
NIH	$663M	$95M
CDC	$8.97 M	N/A
FDA	$1.29M	N/A
ACF	$81K	N/A

NIH Institutes Differ in Funding

- 20 institutes & 7 centers at NIH
- 23 of 27 make SBIR awards
  - Separate budgets (extramural funding)
  - Do some intelligence work first

NIH is organized into:

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

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

Where does SBIR/STTR Fit at NIH?

Award Mechanisms – Research Grants

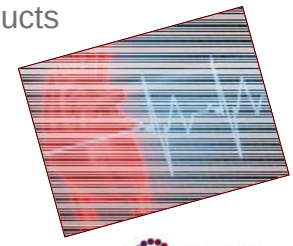
- Traditional – R01
- Small – R03
- Exploratory/Development – R21
- Program Project – P01
- Research Center – P41, P30, P50
- Large Project/Program Planning – P20
- Clinical Trial Planning – R34
- **Small Business – R41, R42, R43, R44**
- Academic Research Enhancement Award (AREA) – R15

http://grants.nih.gov/grants/funding/funding_program.htm

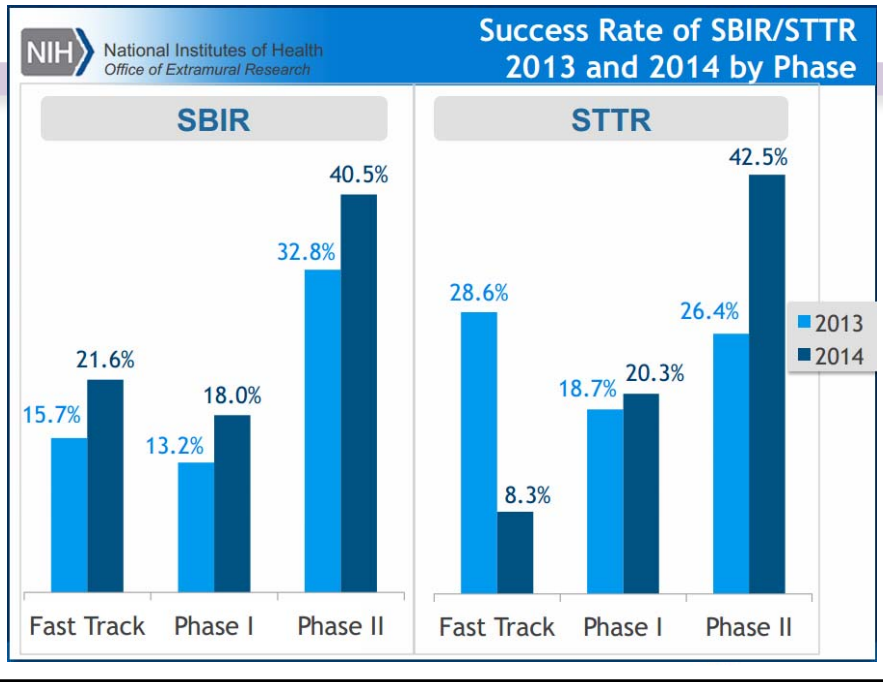
SBIR IMPACT

Purpose of NIH SBIR/STTR Program

- Stimulate technological innovation
  - New technologies
  - Refinement of existing technologies
  - New applications for existing technologies
- Increase the commercial application of NIH supported research
  - New medical or biological products
    - Improved value
    - Improved efficiency
    - Improved costs

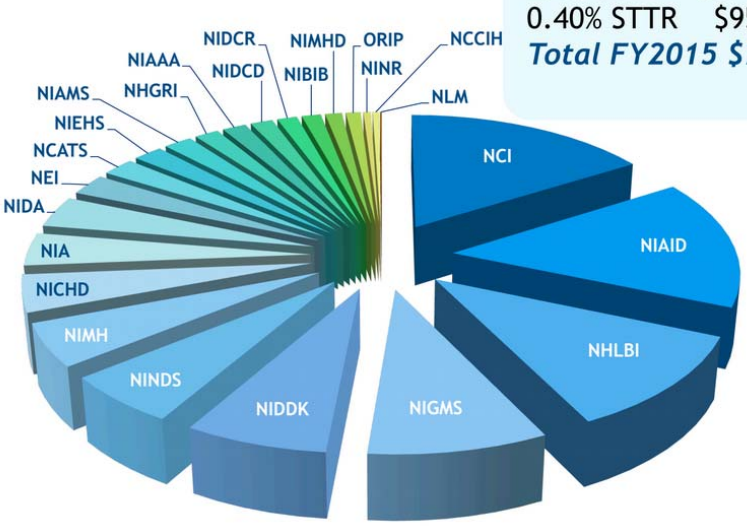


SBIR IMPACT



NIH SBIR/STTR Budget Allocations FY2015

2.9% SBIR $691M
0.40% STTR $95M
Total FY2015 $786M



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www.nih.gov

SBIR IMPACT

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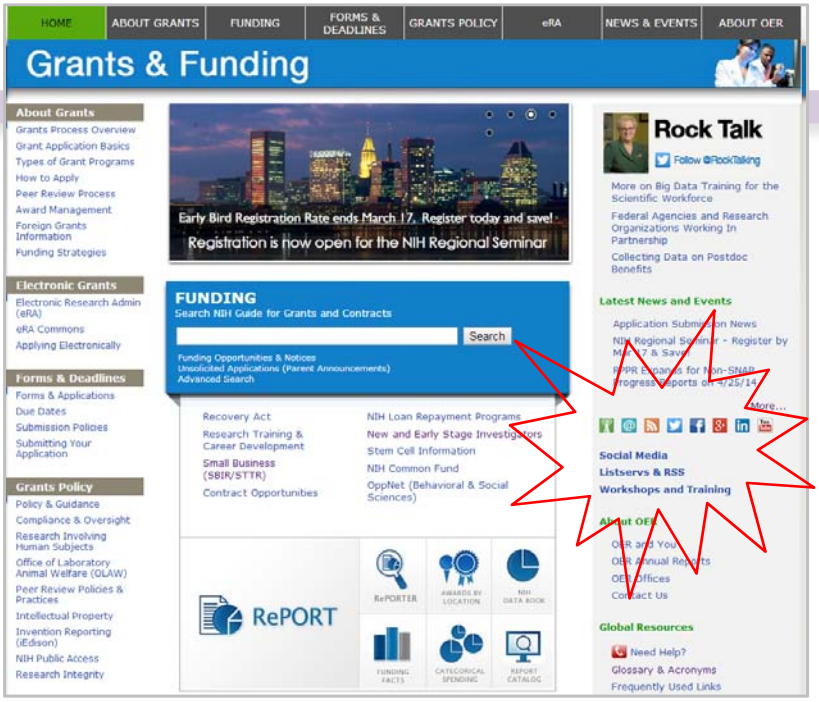

NIH -- Get Connected

https://sbir.nih.gov/engage

SBIR IMPACT

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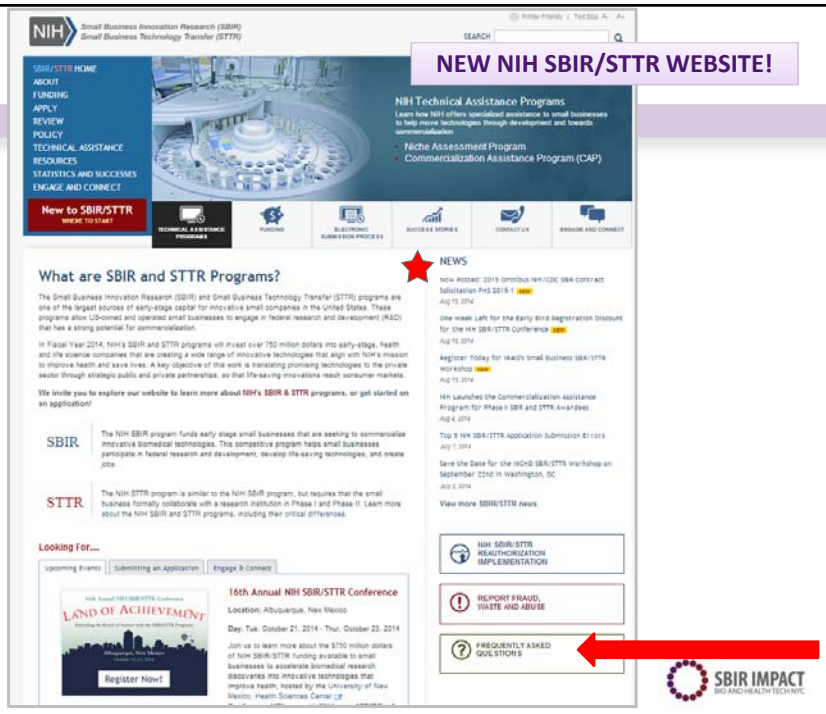
How Does NIH Solicit Applications ?

- Federal Opportunity Announcements (FOA) published:
  - The NIH Guide
  - At grants.gov
- Parent Announcements – cover basic mechanisms
  - Investigator-initiated applications
- Special Opportunities to "fill gaps"
  - Requests for Applications (RFAs) – a one time call with set aside funds
  - Program Announcements (PA) – highlights areas of focus
  - Program Announcement with Special Review (PAR) – for special consideration and "protected" review
  - Program Announcement with Set Aside (PAS) – essentially an RFA with multiple receipt dates

SBIR IMPACT
BIO AND HEALTH TECH NYC



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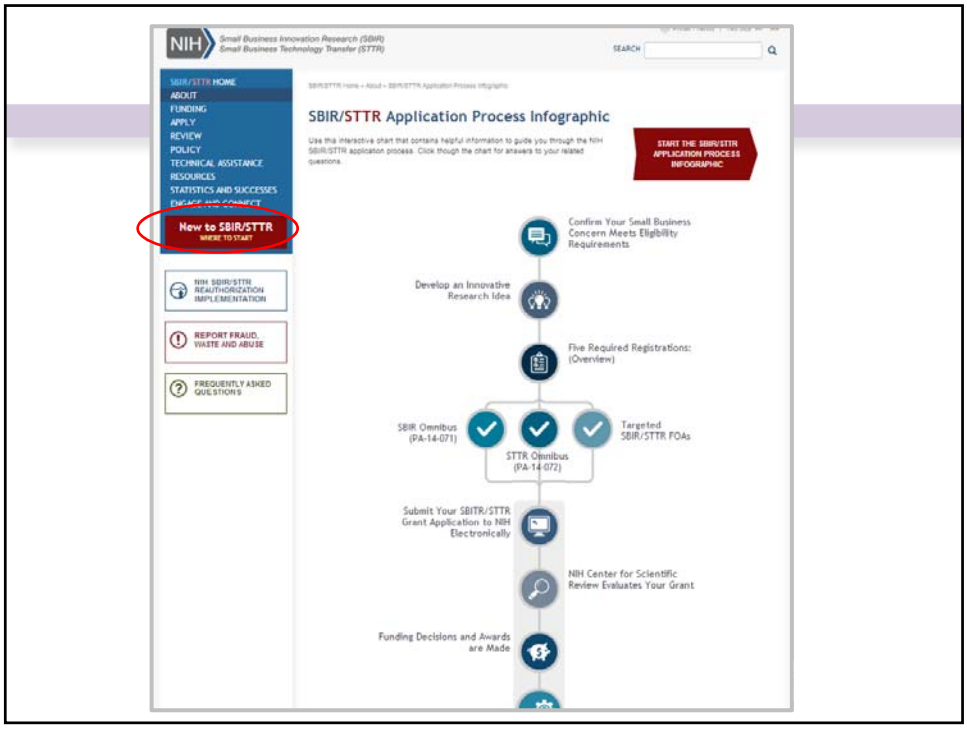
BIO AND HEALTH TECH NYC


NIH
Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)
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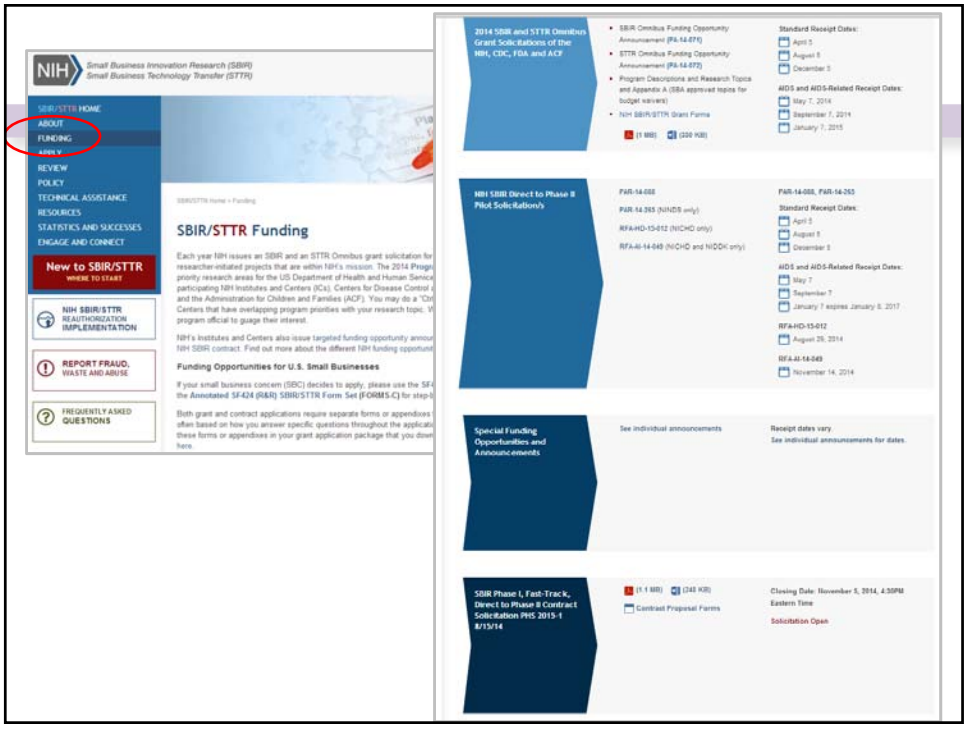
TECHNICAL ASSISTANCE
RESOURCES
STATISTICS AND SUCCESSES
New to SBIR/STTR
WHERE TO START
NIH SBIR/STTR REAUTHORIZATION IMPLEMENTATION
REPORT FRAUD, WASTE AND ABUSE
FREQUENTLY ASKED QUESTIONS
SBIR/STTR Application Process Infographic
START THE SBIR/STTR APPLICATION PROCESS INFOGRAPHIC
Confirm Your Small Business Concern Meets Eligibility Requirements
Develop an Innovative Research Idea
Five Required Registrations: (Overview)
SBIR Omnibus (PA-14-071)
STTR Omnibus (PA-14-072)
Targeted SBIR/STTR FOAs
Submit Your SBIR/STTR Grant Application to NIH Electronically
NIH Center for Scientific Review Evaluates Your Grant
Funding Decisions and Awards are Made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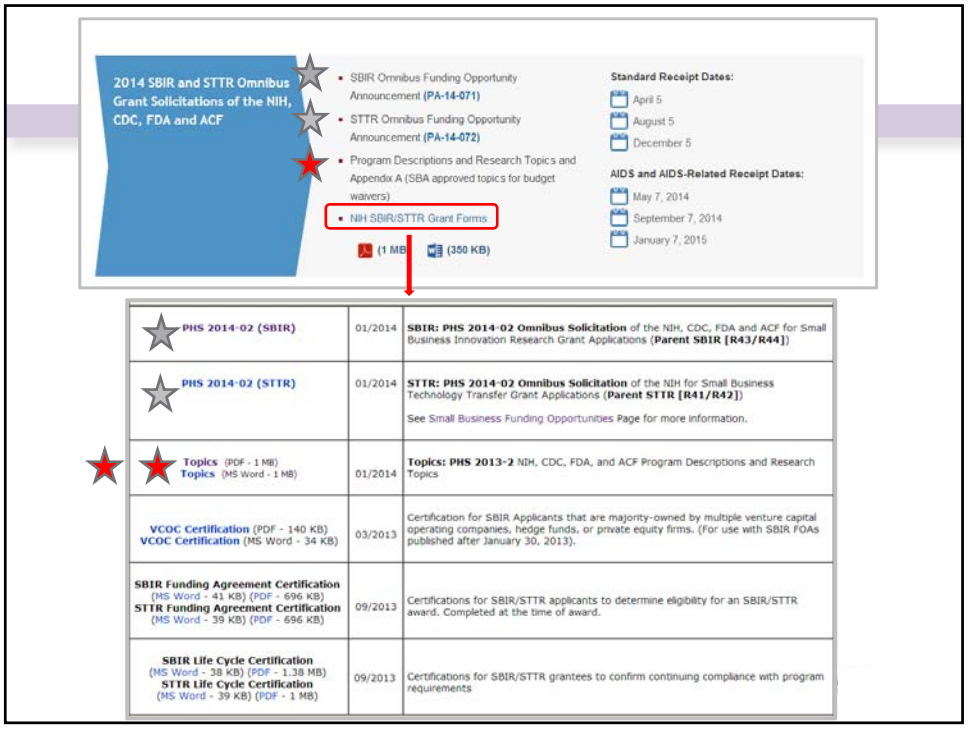
Funding Opportunities for U.S. Small Businesses
2014 SBIR and STTR Omnibus Grant Solicitations of the NIH, CDC, FDA and ACF
NIH SBIR Direct to Phase II Pilot Solicitation/s
Special Funding Opportunities and Announcements
SBIR Phase I, Fast-Track, Direct to Phase II Contract Solicitation PHS 2015-1 8/15/14



SBIR Omnibus Solicitation FOA

Funding Opportunity Title	PHS 2014-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])
Activity Code	R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track
Announcement Type	Reissue of PA-13-234
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PA-14-071
Companion Funding Opportunity	PA-14-072 STTR R41/R42 - Phase I, Phase II, and Fast Track
Number of Applications	See Section III. 3. Additional Information on Eligibility
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.061, 93.084, 93.103, 93.113, 93.121, 93.135, 93.136, 93.172, 93.173, 93.213, 93.233, 93.242, 93.262, 93.273, 93.279, 93.283, 93.286, 93.307, 93.350, 93.351, 93.361, 93.393, 93.394, 93.395, 93.396, 93.399, 93.595, 93.647, 93.837, 93.838, 93.839, 93.841, 93.846, 93.847, 93.853, 93.855, 93.856, 93.859, 93.865, 93.866, 93.867, 93.879, 93.977
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) issued by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Administration for Children and Families (ACF) invites eligible United States small business concerns (SBCs) to submit Small Business Innovation Research (SBIR) grant applications. United States SBCs that have the research capabilities and technological expertise to contribute to the R&D mission(s) of the NIH, CDC, FDA or ACF awarding components identified in this FOA are encouraged to submit SBIR grant applications in response to identified topics (see PHS 2014-2 SBIR/STTR Program Descriptions and Research Topics for NIH, CDC, FDA and ACF

Key Dates

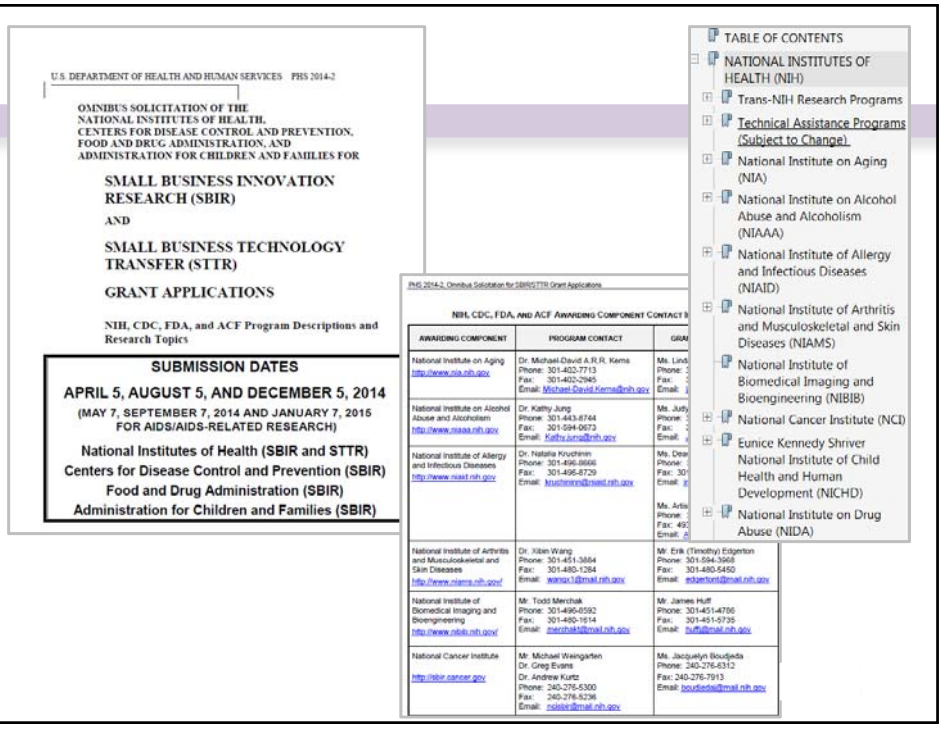
Posted Date	January 17, 2014
Open Date (Earliest Submission Date)	March 5, 2014
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Standard AIDS 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.

SBIR Omnibus Solicitation FOA

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) Administration for Children and Families (ACF)
Components of Participating Organizations	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) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) National Institute of Biomedical Imaging and Bioengineering (NIBIB) *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute on Deafness and Other Communication Disorders (NIDCD) National Institute of Dental and Craniofacial Research (NIDCR) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) 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 Neurological Disorders and Stroke (NINDS) National Institute of Nursing Research (NINR) National Institute on Minority Health and Health Disparities (NIMHD) National Library of Medicine (NLM) National Center for Complementary and Alternative Medicine (NCCAM) National Center for Advancing Translational Sciences (NCATS) Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP) CENTER FOR GLOBAL HEALTH (CGH/CDC) National Center on Birth Defects and Developmental Disabilities (NCBDDD/CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID/CDC) National Center for Injury Prevention and Control (NCIPC/CDC) National Institute for Occupational Safety and Health (NIOSH/CDC) 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, (CPI/FDA) Office of Orphan Products Development (OPD/FDA) Office of Planning, Research and Evaluation, Administration for Children and Families (OPRE/ACF)

You must find a fit!



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PHS 2014-2

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

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

NIH, CDC, FDA, and ACF Program Descriptions and Research Topics

SUBMISSION DATES

APRIL 5, AUGUST 5, AND DECEMBER 5, 2014

(MAY 7, SEPTEMBER 7, 2014 AND JANUARY 7, 2015 FOR AIDS/AIDS-RELATED RESEARCH)

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

TABLE OF CONTENTS

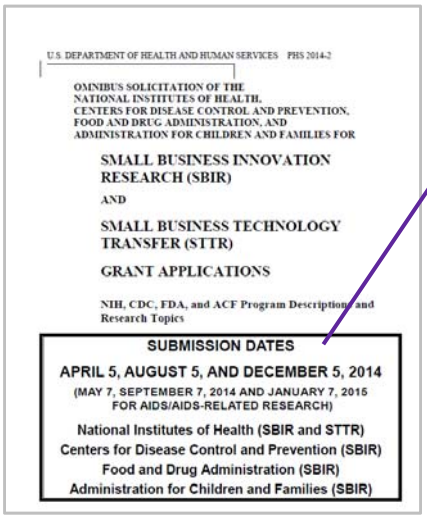
- NATIONAL INSTITUTES OF HEALTH (NIH)
  - Trans-NIH Research Programs
  - Technical Assistance Programs (Subject to Change)
  - National Institute on Aging (NIA)
  - National Institute on Alcohol Abuse and Alcoholism (NIAAA)
  - National Institute of Allergy and Infectious Diseases (NIAID)
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
  - National Institute of Biomedical Imaging and Bioengineering (NIBIB)
  - National Cancer Institute (NCI)
  - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
  - National Institute on Drug Abuse (NIDA)

PHS 2014-2, Omnibus Solicitation for SBIR/STTR Grant Applications

NIH, CDC, FDA, AND ACF AWARDING COMPONENT CONTACT I

AWARDING COMPONENT	PROGRAM CONTACT	GRA
National Institute on Aging http://www.nia.nih.gov	Dr. Michael-David A.R.R. Kerns Phone: 301-402-7713 Fax: 301-402-2945 Email: Michael-David.Kerns@nih.gov	Ms. Linda Phone: Fax: Email:
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Dr. Kathy Jung Phone: 301-443-8744 Fax: 301-594-0673 Email: Kathy.Jung@nih.gov	Ms. Judy Phone: Fax: Email:
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Dr. Natalia Kruchmin Phone: 301-496-8666 Fax: 301-496-8729 Email: kruchmin@niaid.nih.gov	Ms. Dea Phone: Fax: 30 Email: Ms. Arla Phone: Fax: 49 Email:
National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.niams.nih.gov/	Dr. Xibin Wang Phone: 301-451-3864 Fax: 301-480-1284 Email: wangx1@mail.nih.gov	Mr. Erik (Timothy) Edgerton Phone: 301-594-3968 Fax: 301-480-5450 Email: edgertont@mail.nih.gov
National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov/	Mr. Todd Merchak Phone: 301-496-8592 Fax: 301-480-1614 Email: merchakt@mail.nih.gov	Mr. James Huff Phone: 301-451-4706 Fax: 301-451-5735 Email: huffj@mail.nih.gov
National Cancer Institute http://sbir.cancer.gov	Mr. Michael Weingarten Dr. Greg Evans Dr. Andrew Kurtz Phone: 240-276-5300 Fax: 240-276-5236 Email: nciSBIR@mail.nih.gov	Ms. Jacquelyn Boudjeda Phone: 240-276-6312 Fax: 240-276-7913 Email: boudjedaj@mail.nih.gov

SBIR/STTR Standard Due Dates



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(MAY 7, SEPTEMBER 7, 2014 AND JANUARY 7, 2015 FOR AIDS/AIDS-RELATED RESEARCH)

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

- Current Omnibus Solicitation extended:
  - April 5, 2015 (last cycle for current Omnibus)
- Upcoming Omnibus: to be released June 2015
  - September 5, 2015 – *NEW Omnibus Cycle 1*
  - January 5, 2016- *NEW Omnibus Cycle 2*
  - April 5, 2016- *NEW Omnibus Cycle 3*

SBIR IMPACT

NIH SBIR/STTR Special Solicitations

- RFA – Request for Applications
  - Specific program purpose
  - Funds set aside for the competition
  - Generally identify a single application receipt date
  - Unique receipt dates
- PA – Program Announcement
  - Requesting applications in the stated scientific areas
  - Money is not set aside
  - Standard receipt dates

SBIR IMPACT

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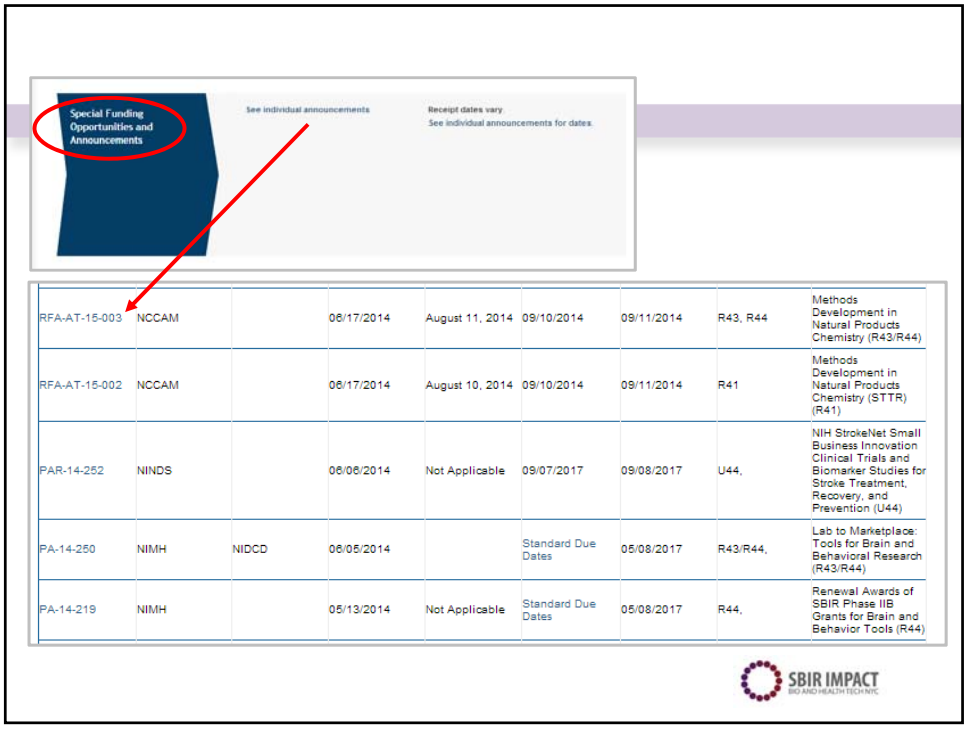
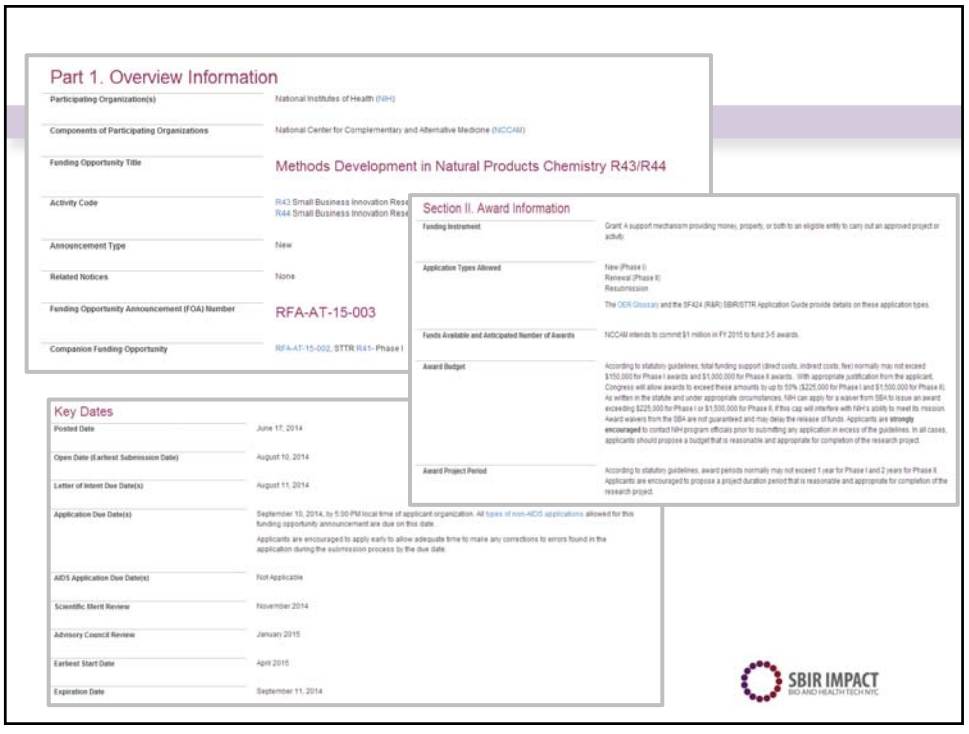

Special Funding Opportunities and Announcements
See individual announcements
Receipt dates vary.
See individual announcements for dates.
RFA-AT-15-003 NCCAM 06/17/2014 August 11, 2014 09/10/2014 09/11/2014 R43, R44 Methods Development in Natural Products Chemistry (R43/R44)
RFA-AT-15-002 NCCAM 06/17/2014 August 10, 2014 09/10/2014 09/11/2014 R41 Methods Development in Natural Products Chemistry (STTR) (R41)
PAR-14-252 NINDS 06/06/2014 Not Applicable 09/07/2017 09/08/2017 U44, NIH StrokeNet Small Business Innovation Clinical Trials and Biomarker Studies for Stroke Treatment, Recovery, and Prevention (U44)
PA-14-250 NIMH NIDCD 06/05/2014 Standard Due Dates 05/08/2017 R43/R44, Lab to Marketplace: Tools for Brain and Behavioral Research (R43/R44)
PA-14-219 NIMH 05/13/2014 Not Applicable Standard Due Dates 05/08/2017 R44, Renewal Awards of SBIR Phase IIB Grants for Brain and Behavior Tools (R44)
SBIR IMPACT


Part 1. Overview Information
Participating Organization(s) National Institutes of Health (NIH)
Components of Participating Organizations National Center for Complementary and Alternative Medicine (NCCAM)
Funding Opportunity Title Methods Development in Natural Products Chemistry R43/R44
Activity Code
Announcement Type New
Related Notices None
Funding Opportunity Announcement (FOA) Number RFA-AT-15-003
Companion Funding Opportunity
Section II. Award Information
Funding Instrument
Application Types Allowed
Funds Available and Anticipated Number of Awards
Award Budget
Award Project Period
Key Dates
Posted Date June 17, 2014
Open Date (Earliest Submission Date) August 10, 2014
Letter of Intent Due Date(s) August 11, 2014
Application Due Date(s)
AIDS Application Due Date(s) Not Applicable
Scientific Merit Review November 2014
Advisory Council Review January 2015
Earliest Start Date April 2015
Expiration Date September 11, 2014
SBIR IMPACT

Other Special Solicitations

- Fast Track
  - Not all Institutes will fund a Fast Track
  - Phase I and II submitted in one application
  - Project attributes should include:
    - Robust preliminary data
    - Extremely measurable Phase I Aims
    - Strong commercialization plan AND resources
- Direct to Phase II (special solicitation)
  - New in April 2014
  - Not all I/Cs are participating
  - NOT the same as a Fast Track
  - You must have done the equivalent of a Phase I but with non-SBIR funds
- Phase II Competing Renewals (aka Phase II B)
  - Not offered by all Institutes/Centers
  - Some I/Cs participate via the Omnibus
  - Some I/Cs release a separate solicitation (e.g. NCI Phase II Bridge Award)

SBIR IMPACT BIO AND HEALTH TECH NYC

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Other Special Solicitations

If you are considering one of the following:

- Fast Track
- Direct to Phase II (special solicitation)
- Phase II Competing Renewals (aka Phase II B)

TALK TO PROGRAM STAFF AT THE APPROPRIATE INSTITUTE WELL IN ADVANCE OF THE DEADLINE

SBIR IMPACT BIO AND HEALTH TECH NYC

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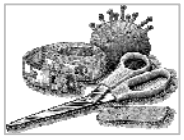
Do your homework @ NIH

- Which Institute?
- Which Mechanism?
- Scope?
- Timing?

SBIR IMPACT

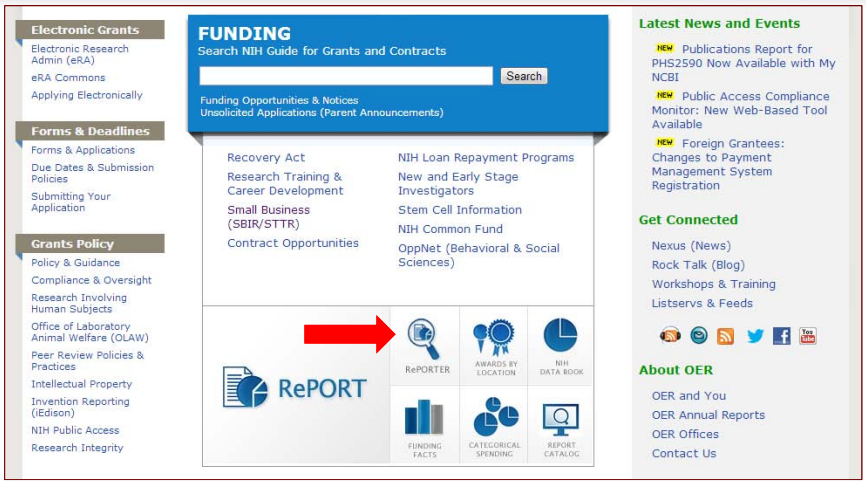
NIH Strategic Planning

- DIRECT YOUR PROPOSAL!
  - Find a home
    - Search Reporter
    - Talk to Program Staff
  - Ensure appropriate review
    - Review CSR Study Sections
  - Tailor your project



SBIR IMPACT

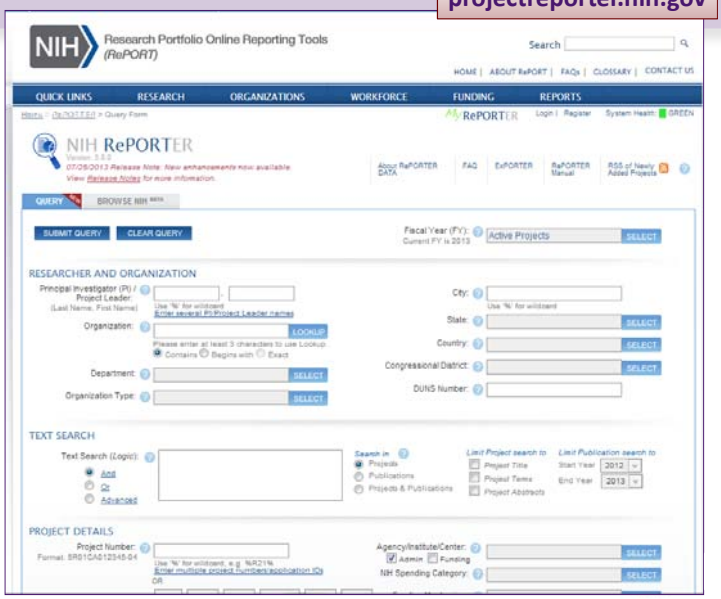
NIH Reporter



SBIR IMPACT

NIH Reporter

projectreporter.nih.gov



Decoding Your NIH Grant Number

Application Type	Activity Code	Institute Code	Serial Number	Support Year	Extension
1	R41	EB	12345	01	A1
1 = new 2 = renewal 3 = supplement 5 = non-competing continuation 7 = Change of Grantee Institution 9 = Change of NIH awarding institute or division	R = Research project P = Program project or Center T = Training (institutional) F = Fellowship (individual) K = Career Development U = Cooperative agreement	AA = NIAAA AG = NIA AI = NIAID AR = NIAMS AT = NCCAM CA = NCI DA = NIDA DC = NIDCD DE = NIDCR DK = NIDDK EB = NIBIB ES = NIEHS EY = NEI GM = NIGMS HD = NICHD	Unique, up to six digits HG = NHGRI HL = NHLBI LM = NLM MD = NCMHD MH = NIMH NR = NINR NS = NINDS RR = NCRR TW = FIC	Years of Continuous Funding	A1 = resubmission S1 = supplement

NIH SBIR & STTR Grant Codes

R41	Small Business Technology Transfer (STTR) Grants - Phase I
R42	Small Business Technology Transfer (STTR) Grants - Phase II
R43	Small Business Innovation Research Grants (SBIR) - Phase I
R44	Small Business Innovation Research Grants (SBIR) - Phase II

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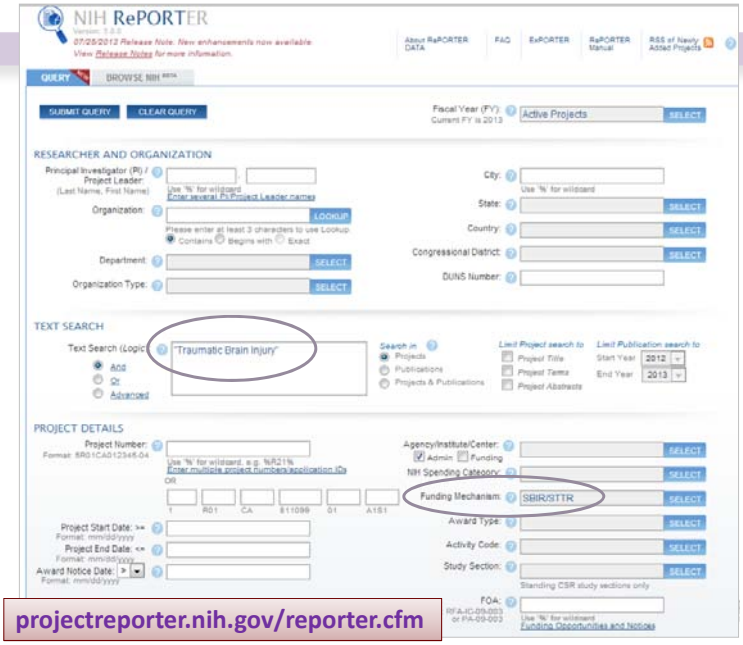
Do your homework @NIH (Reporter)



projectreporter.nih.gov/reporter.cfm

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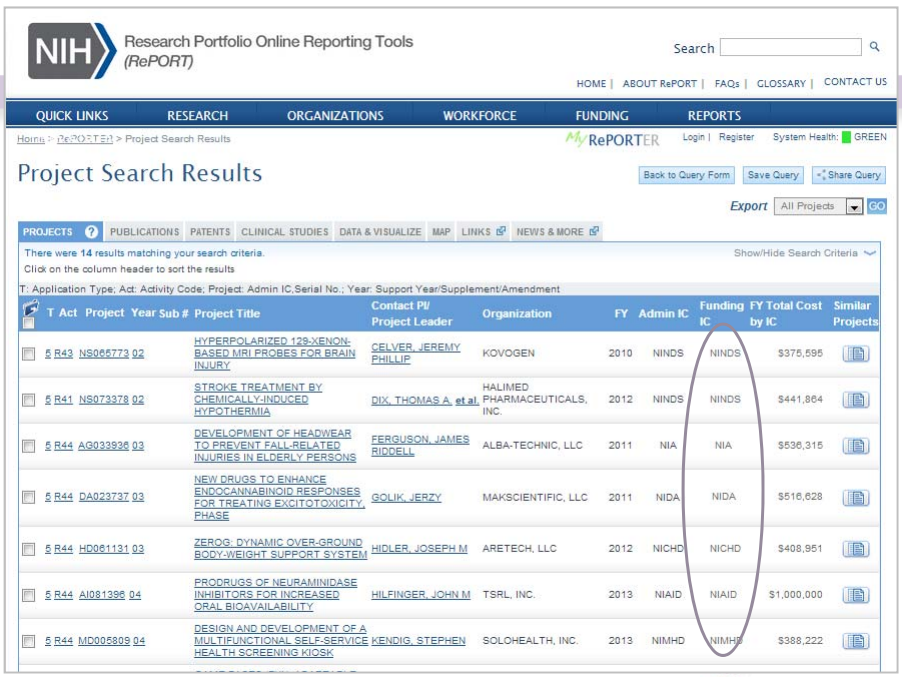

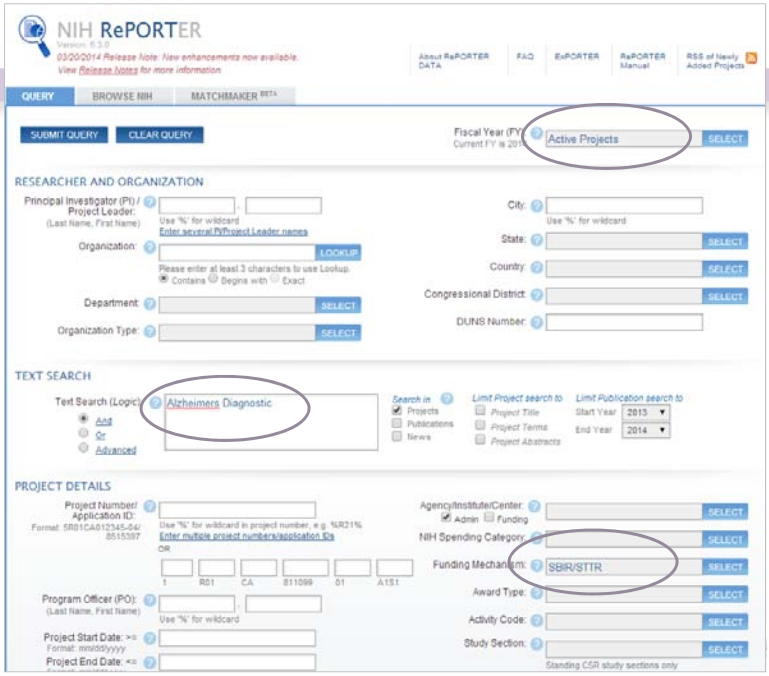
NIH RePORTER
QUERY
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CLEAR QUERY
Active Projects
SELECT
RESEARCHER AND ORGANIZATION
Principal Investigator (PI) / Project Leader:
Organization:
Department:
Organization Type:
City:
State:
Country:
Congressional District:
DUNS Number:
TEXT SEARCH
Text Search (Logic):
Alzheimers Diagnostic
And
Or
Advanced
Search in
Projects
Publications
News
Limit Project search to
Project Title
Project Terms
Project Abstracts
Limit Publication search to
Start Year
End Year
PROJECT DETAILS
Project Number/ Application ID:
Program Officer (PO):
Project Start Date:
Project End Date:
Agency/Institute/Center:
NIH Spending Category:
Funding Mechanism:
SBIR/STTR
Award Type:
Activity Code:
Study Section:

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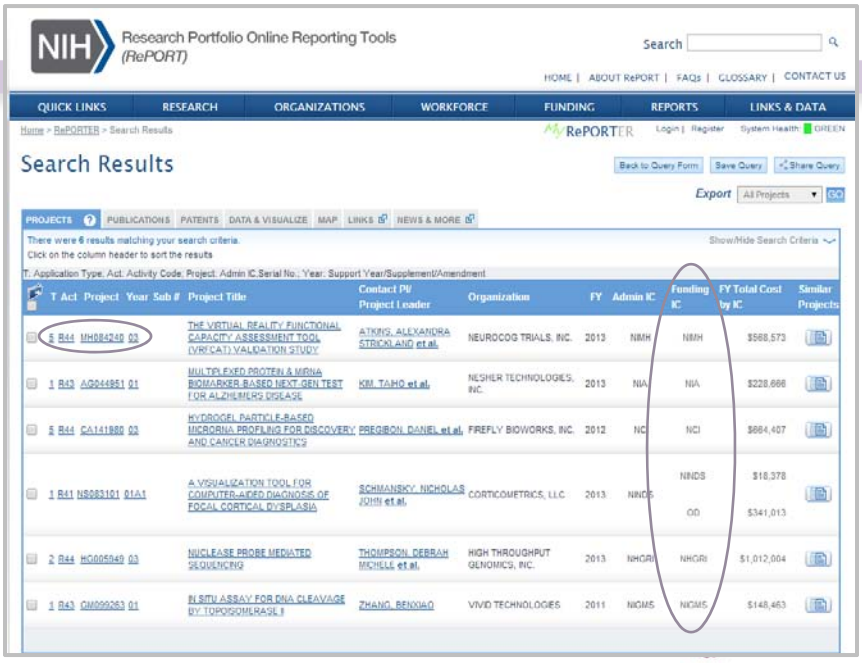
NIH
Research Portfolio Online Reporting Tools
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Share Query
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All Projects
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PUBLICATIONS
PATENTS
DATA & VISUALIZE
MAP
LINKS
NEWS & MORE
There were 6 results matching your search criteria.
Click on the column header to sort the results
T Act Project Year Sub # Project Title
Contact PI/ Project Leader
Organization
FY
Admin IC
Funding IC
FY Total Cost by IC
Similar Projects
5 R44 MH084240 03
THE VIRTUAL REALITY FUNCTIONAL CAPACITY ASSESSMENT TOOL (VRFCAT) VALIDATION STUDY
ATKINS, ALEXANDRA STRICKLAND et al.
NEUROCOG TRIALS, INC.
2013
NIMH
NIMH
$568,573
1 R43 AG044861 01
MULTIPLEXED PROTEIN & MIRNA BIOMARKER BASED NEXT GEN TEST FOR ALZHEIMER'S DISEASE
KIM, TAHO et al.
NESHER TECHNOLOGIES, INC.
2013
NIA
NIA
$228,666
5 R44 CA141880 03
HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS
PREGIBON, DANIEL et al.
FIREFLY BIOWORKS, INC.
2012
NCI
NCI
$664,407
1 R41 NS083101 01A1
A VISUALIZATION TOOL FOR COMPUTER-AIDED DIAGNOSIS OF FOCAL CORTICAL DYSPLASIA
SCHMANSKY, NICHOLAS JOHN et al.
CORTICOMETRICS, LLC
2013
NINDS
NINDS
OD
$18,378
$341,013
2 R44 HG005940 03
NUCLEASE PROBE MEDIATED SEQUENCING
THOMPSON, DEBRAH MICHELLE et al.
HIGH THROUGHPUT GENOMICS, INC.
2013
NHGRI
NHGRI
$1,012,004
1 R43 GM099263 01
IN SITU ASSAY FOR DNA CLEAVAGE BY TOPOISOMERASE I
ZHANG, BENXIAO
VIVID TECHNOLOGIES
2011
NIGMS
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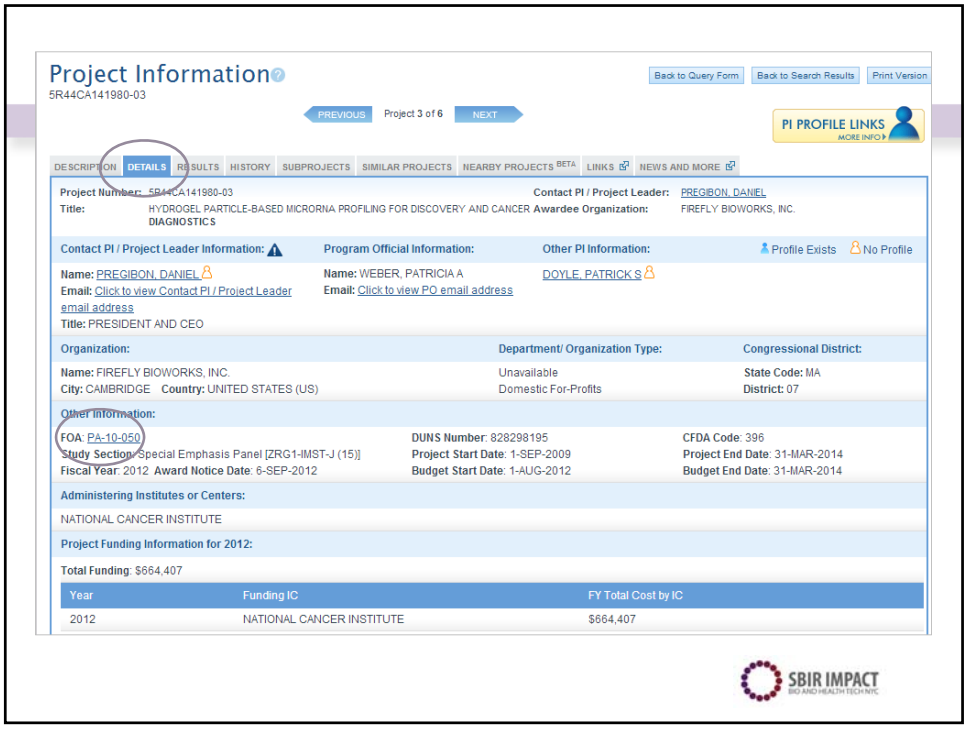
$148,463



Project Information
5R44CA141980-03

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PREVIOUS Project 3 of 6 NEXT

PI PROFILE LINKS MORE INFO

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

Project Number: 5R44CA141980-03
Title: HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS
Contact PI / Project Leader: PREGIBON, DANIEL
Awardee Organization: FIREFLY BIOWORKS, INC.

Contact PI / Project Leader Information:
Name: PREGIBON, DANIEL
Email: Click to view Contact PI / Project Leader email address
Title: PRESIDENT AND CEO

Program Official Information:
Name: WEBER, PATRICIA A
Email: Click to view PO email address

Other PI Information:
DOYLE, PATRICK S

Profile Exists | No Profile

Organization:
Name: FIREFLY BIOWORKS, INC.
City: CAMBRIDGE **Country:** UNITED STATES (US)

Department/ Organization Type:
Unavailable
Domestic For-Profits

Congressional District:
State Code: MA
District: 07

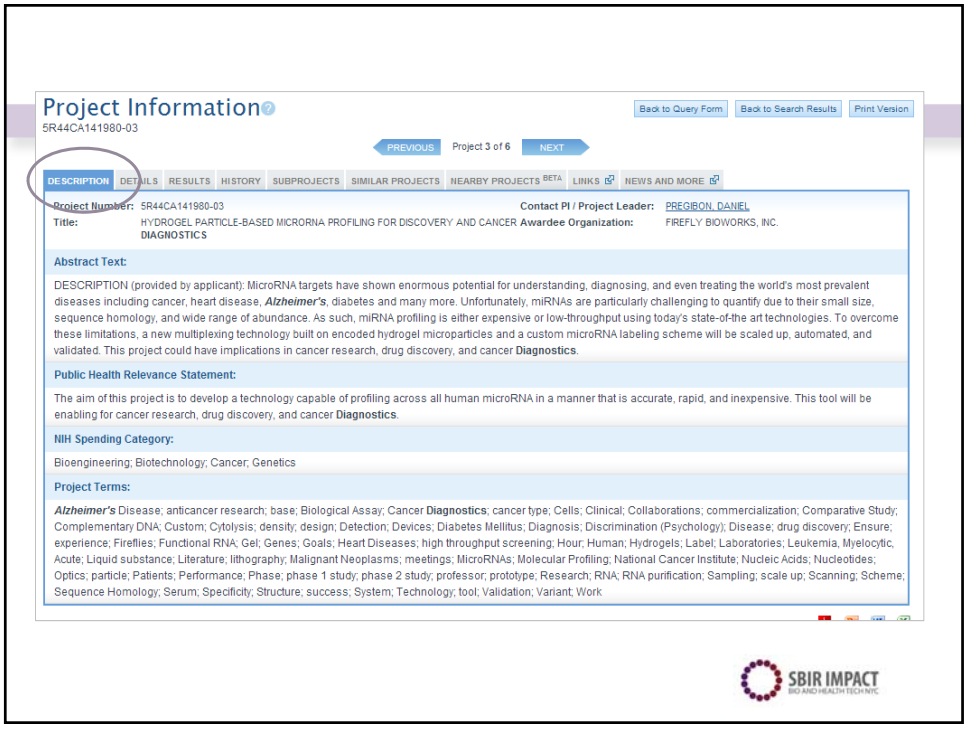
Other Information:
FOA: PA-10-050
Study Section: Special Emphasis Panel [ZRG1-IMST-J (15)]
Fiscal Year: 2012 **Award Notice Date:** 6-SEP-2012
DUNS Number: 828298195
Project Start Date: 1-SEP-2009
Budget Start Date: 1-AUG-2012
CFDA Code: 396
Project End Date: 31-MAR-2014
Budget End Date: 31-MAR-2014

Administering Institutes or Centers:
NATIONAL CANCER INSTITUTE

Project Funding Information for 2012:
Total Funding: $664,407

Year	Funding IC	FY Total Cost by IC
2012	NATIONAL CANCER INSTITUTE	$664,407

SBIR IMPACT BIO AND HEALTH TECH NYC



Project Information
5R44CA141980-03

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

Project Number: 5R44CA141980-03
Title: HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS
Contact PI / Project Leader: PREGIBON, DANIEL
Awardee Organization: FIREFLY BIOWORKS, INC.

Abstract Text:

DESCRIPTION (provided by applicant): MicroRNA targets have shown enormous potential for understanding, diagnosing, and even treating the world's most prevalent diseases including cancer, heart disease, ***Alzheimer's***, diabetes and many more. Unfortunately, miRNAs are particularly challenging to quantify due to their small size, sequence homology, and wide range of abundance. As such, miRNA profiling is either expensive or low-throughput using today's state-of-the art technologies. To overcome these limitations, a new multiplexing technology built on encoded hydrogel microparticles and a custom microRNA labeling scheme will be scaled up, automated, and validated. This project could have implications in cancer research, drug discovery, and cancer **Diagnostics**.

Public Health Relevance Statement:

The aim of this project is to develop a technology capable of profiling across all human microRNA in a manner that is accurate, rapid, and inexpensive. This tool will be enabling for cancer research, drug discovery, and cancer **Diagnostics**.

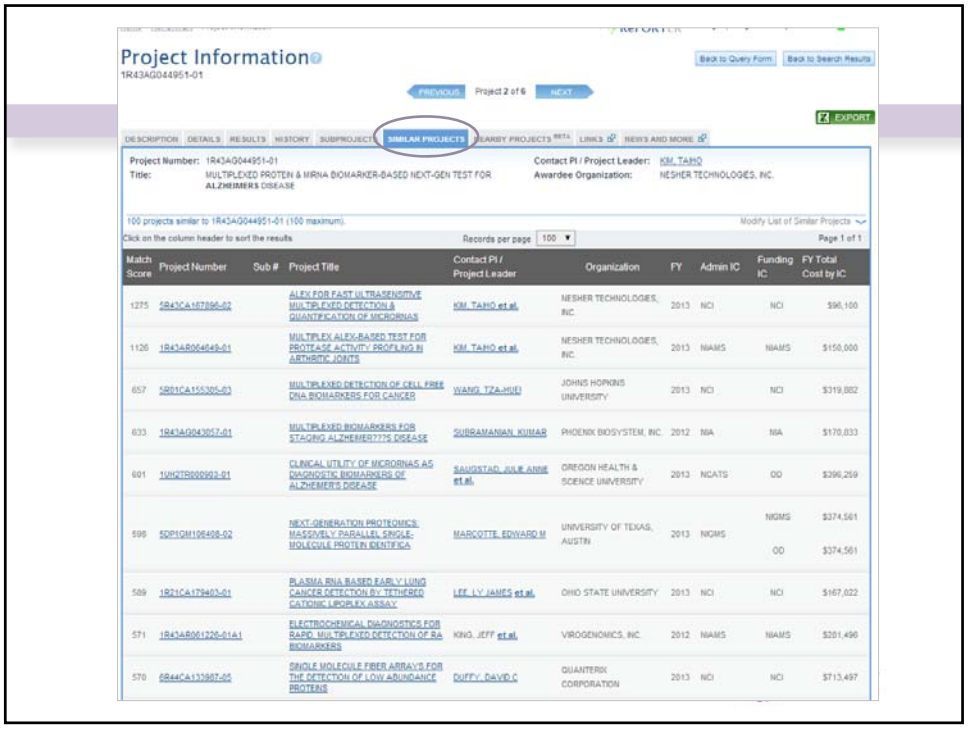
NIH Spending Category:

Bioengineering; Biotechnology; Cancer; Genetics

Project Terms:

Alzheimer's Disease; anticancer research; base; Biological Assay; Cancer **Diagnostics**; cancer type; Cells; Clinical; Collaborations; commercialization; Comparative Study; Complementary DNA; Custom; Cytolysis; density; design; Detection; Devices; Diabetes Mellitus; Diagnosis; Discrimination (Psychology); Disease; drug discovery; Ensure; experience; Fireflies; Functional RNA; Gel; Genes; Goals; Heart Diseases; high throughput screening; Hour; Human; Hydrogels; Label; Laboratories; Leukemia, Myelocytic, Acute; Liquid substance; Literature; lithography; Malignant Neoplasms; meetings; MicroRNAs; Molecular Profiling; National Cancer Institute; Nucleic Acids; Nucleotides; Optics; particle; Patients; Performance; Phase; phase 1 study; phase 2 study; professor; prototype; Research; RNA; RNA purification; Sampling; scale up; Scanning; Scheme; Sequence Homology; Serum; Specificity; Structure; success; System; Technology; tool; Validation; Variant; Work

SBIR IMPACT BIO AND HEALTH TECH NYC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Project 2 of 6
NEXT
EXPORT
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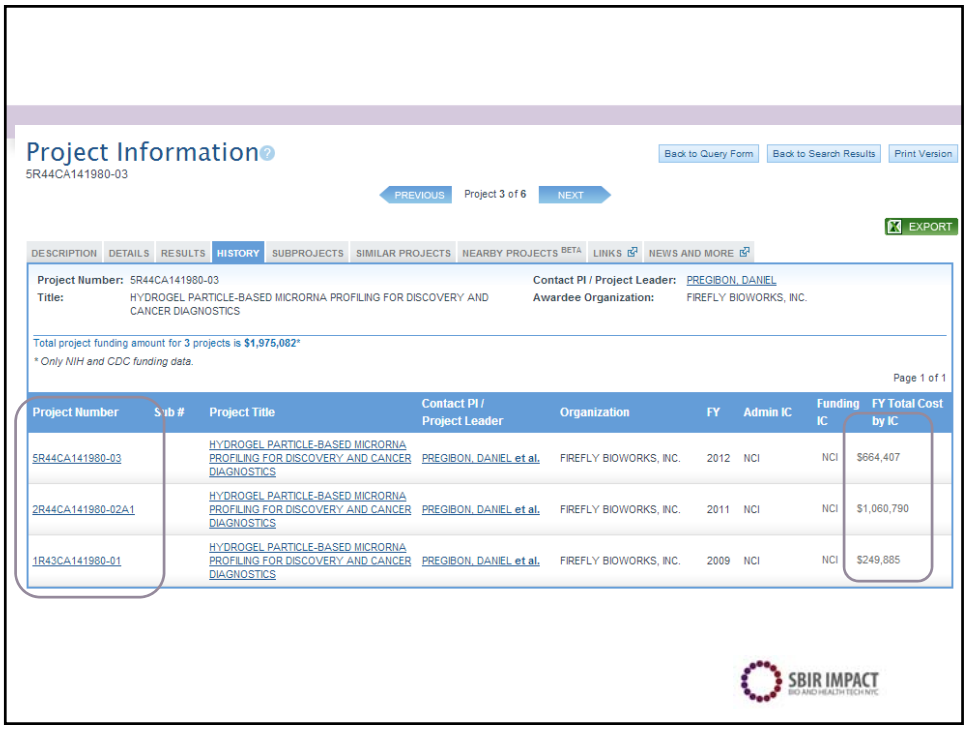
DETAILS
RESULTS
HISTORY
SUBPROJECTS
SIMILAR PROJECTS
NEARBY PROJECTS BETA
LINKS
NEWS AND MORE
Project Number: 1R43AG044951-01
Title: MULTIPLEXED PROTEIN & MRNA BIOMARKER-BASED NEXT-GEN TEST FOR ALZHEIMERS DISEASE
Contact PI / Project Leader: KIM, TAHO
Awardee Organization: NESHER TECHNOLOGIES, INC.
100 projects similar to 1R43AG044951-01 (100 maximum).
Modify List of Similar Projects
Click on the column header to sort the results
Records per page 100
Page 1 of 1
Match Score
Project Number
Sub #
Project Title
Contact PI / Project Leader
Organization
FY
Admin IC
Funding IC
FY Total Cost by IC
1275 5R43CA167896-02 ALEX FOR FAST ULTRASENSITIVE MULTIPLEXED DETECTION & QUANTIFICATION OF MICRORNAS KIM, TAHO et al. NESHER TECHNOLOGIES, INC. 2013 NCI NCI $96,100
1126 1R43AR064649-01 MULTIPLEX ALEX-BASED TEST FOR PROTEASE ACTIVITY PROFILING IN ARTHRITIC JOINTS KIM, TAHO et al. NESHER TECHNOLOGIES, INC. 2013 NIAMS NIAMS $150,000
657 5R01CA155305-03 MULTIPLEXED DETECTION OF CELL FREE DNA BIOMARKERS FOR CANCER WANG, TZA-HUEI JOHNS HOPKINS UNIVERSITY 2013 NCI NCI $319,882
633 1R43AG043057-01 MULTIPLEXED BIOMARKERS FOR STAGING ALZHEIMER???S DISEASE SUBRAMANIAN, KUMAR PHOENIX BIOSYSTEM, INC. 2012 NIA NIA $170,833
601 1UH2TR000903-01 CLINICAL UTILITY OF MICRORNAS AS DIAGNOSTIC BIOMARKERS OF ALZHEIMER'S DISEASE SAUGSTAD, JULIE ANNE et al. OREGON HEALTH & SCIENCE UNIVERSITY 2013 NCATS OD $296,259
598 5DP1GM106408-02 NEXT-GENERATION PROTEOMICS: MASSIVELY PARALLEL SINGLE-MOLECULE PROTEIN IDENTIFICA MARCOTTE, EDWARD M UNIVERSITY OF TEXAS, AUSTIN 2013 NIGMS NIGMS $374,561 OD $374,561
589 1R21CA179403-01 PLASMA RNA BASED EARLY LUNG CANCER DETECTION BY TETHERED CATIONIC LIPOPLEX ASSAY LEE, LY JAMES et al. OHIO STATE UNIVERSITY 2013 NCI NCI $167,022
571 1R43AR061228-01A1 ELECTROCHEMICAL DIAGNOSTICS FOR RAPID, MULTIPLEXED DETECTION OF RA BIOMARKERS KING, JEFF et al. VIROGENOMICS, INC. 2012 NIAMS NIAMS $251,496
570 5R44CA133687-05 SINGLE MOLECULE FIBER ARRAYS FOR THE DETECTION OF LOW ABUNDANCE PROTEINS DUFFY, DAVID C QUANTERIX CORPORATION 2013 NCI NCI $713,497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EXPORT
DESCRIPTION
DETAILS
RESULTS
HISTORY
SUBPROJECTS
SIMILAR PROJECTS
NEARBY PROJECTS BETA
LINKS
NEWS AND MORE
Project Number: 5R44CA141980-03
Title: HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS
Contact PI / Project Leader: PREGIBON, DANIEL
Awardee Organization: FIREFLY BIOWORKS, INC.
Total project funding amount for 3 projects is $1,975,082*
* Only NIH and CDC funding data.
Page 1 of 1
Project Number
Sub #
Project Title
Contact PI / Project Leader
Organization
FY
Admin IC
Funding IC
FY Total Cost by IC
5R44CA141980-03 HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS PREGIBON, DANIEL et al. FIREFLY BIOWORKS, INC. 2012 NCI NCI $664,407
2R44CA141980-02A1 HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS PREGIBON, DANIEL et al. FIREFLY BIOWORKS, INC. 2011 NCI NCI $1,060,790
1R43CA141980-01 HYDROGEL PARTICLE-BASED MICRORNA PROFILING FOR DISCOVERY AND CANCER DIAGNOSTICS PREGIBON, DANIEL et al. FIREFLY BIOWORKS, INC. 2009 NCI NCI $249,885
SBIR IMPACT

1.4 Interactions with PHS Staff

The PHS agencies encourage applicants to communicate with staff throughout the entire application, review and award process. Web site addresses and staff phone numbers of relevant NIH awarding components and other PHS agencies are listed in the table below.

Table 1.4-1. Awarding Component Contact Information Table

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Institute on Aging http://www.nia.nih.gov	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 http://www.niaaa.nih.gov	Dr. Gary Murray Phone: 301-443-9940 Fax: 301-594-0673 Email: Gary.Murray@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 http://www.niaid.nih.gov	Dr. Paula Strickland Phone: 301-435-8563 Fax: 301-480-1993 Email: pstrickland@nih.gov	Mr. Michael Wright Phone: 301-451-2688 Fax: 301-493-0597 Email: mawright@mail.nih.gov
National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.niams.nih.gov/	Dr. Xibin Wang Phone: 301-451-3884 Fax: 301-480-1284 Email: wangx1@mail.nih.gov	Ms. Sheila Simmons Phone: 301-594-9812 Fax: 301-480-5450 Email: simmonss@mail.nih.gov Mr. Erik (Timothy) Edgerton Phone: 301-594-3968

Grant Writing 101:

Understand the Review Process

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

SBIR IMPACT

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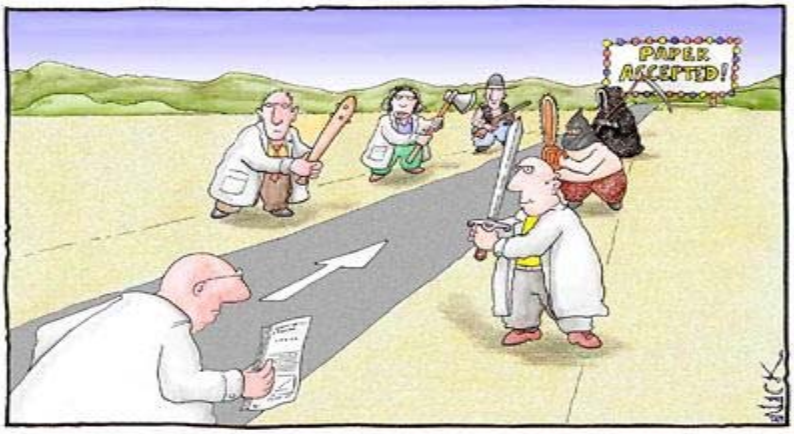
The Peer Review Process



Most scientists regarded the new streamlined peer-review process as 'quite an improvement.'

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SBIR IMPACT

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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

center for scientific review

SBIR IMPACT

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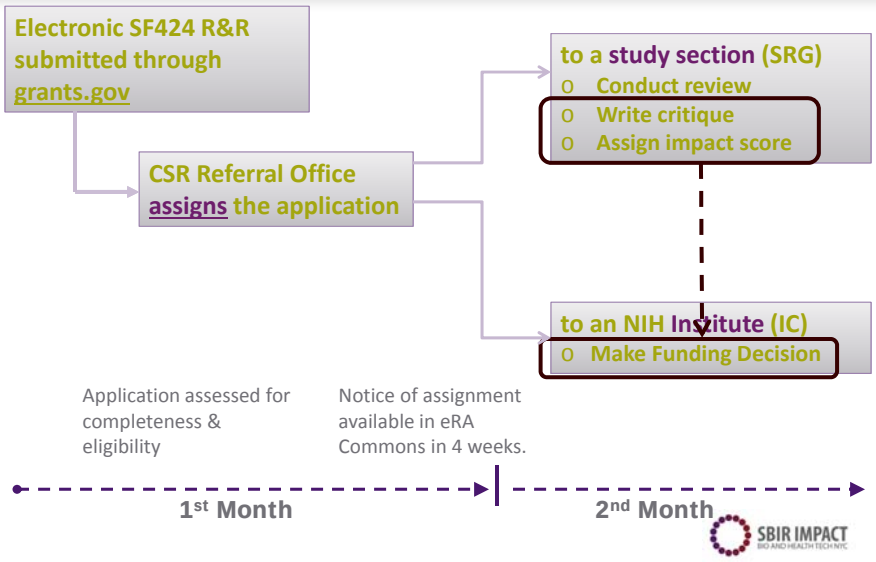
CSR – Division of Receipt and Referral



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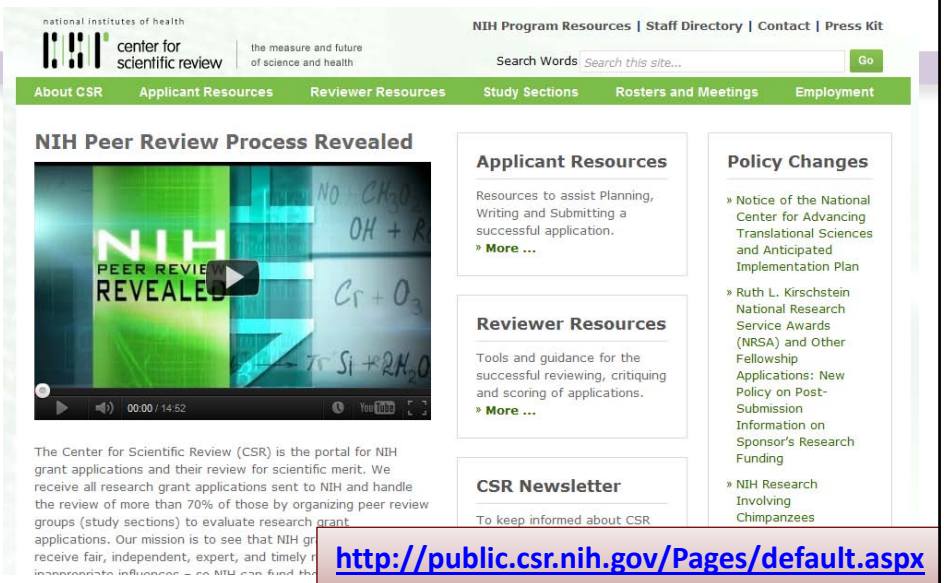

http://public.csr.nih.gov/Pages/default.aspx

SBIR IMPACT

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Who Are the NIH Reviewers?

Review panels are assembled on an ad hoc basis for each meeting; therefore designations and scientific emphasis may change with each review cycle.

SBIR IMPACT

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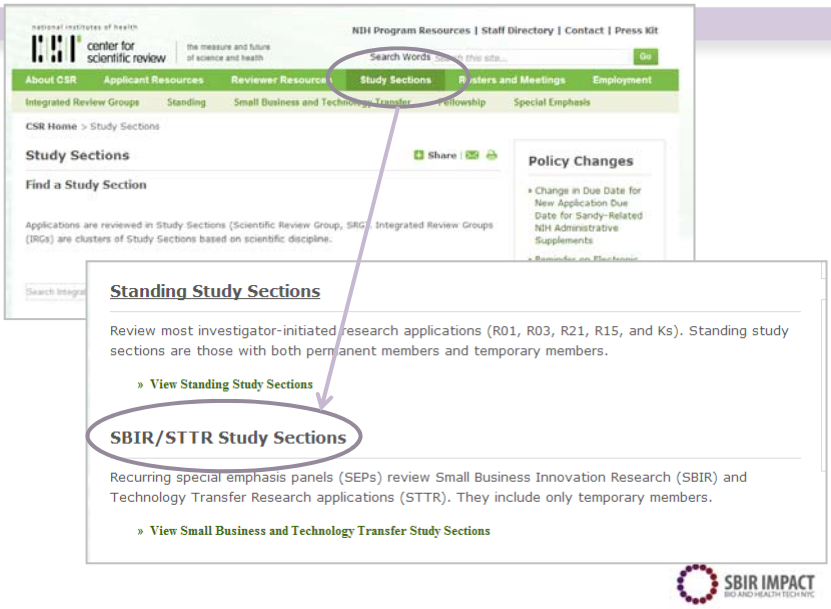
CSR – SBIR /STTR Study Sections



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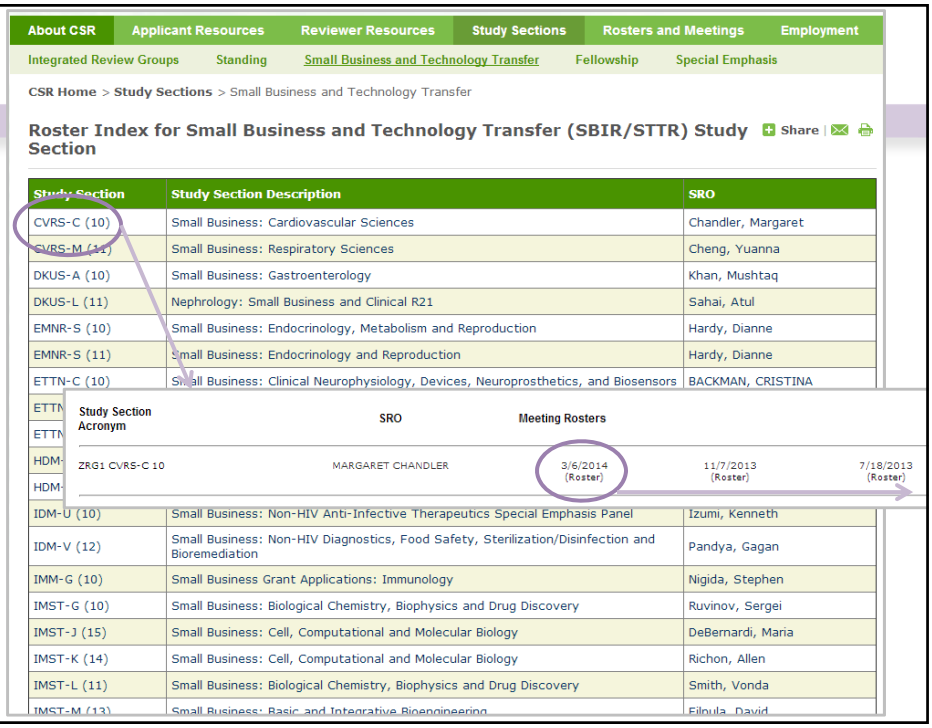

Meeting Roster - ZRG1 CVRS-C 10 (3/6/2014 - 3/7/2014)

CENTER FOR SCIENTIFIC REVIEW
SPECIAL EMPHASIS PANEL
ZRG1 CVRSC 10
3/6/2014-3/7/2014
MEETING ROSTER

CHAIRPERSON

KELLER, BRADLEY BARTH , MD
PROFESSOR
KOSAIR CHARITIES CHAIR AND CHIEF
DIVISION OF PEDIATRIC HEART RESEARCH
CARDIOVASCULAR INNOVATION INSTITUTE
UNIVERSITY OF LOUISVILLE
LOUISVILLE, KY 40202

MEMBERS

BOND, BRIAN ROBERT , PHD
PRESIDENT AND CEO
GATEWAY PHARMACOLOGY LABORATORIES
ST. LOUIS , MO 63005

CHRISTENSON, ROBERT H , PHD
PROFESSOR
DEPARTMENT OF CLINICAL PATHOLOGY
SCHOOL OF MEDICINE
UNIVERSITY OF MARYLAND
BALTIMORE, MD 21201

DONAHUE, J KEVIN , MD
PROFESSOR OF MEDICINE
DIRECTOR OF ELECTROPHYSIOLOGY RESEARCH
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
WORCESTER, MA 01605

EDMUNDS, JEREMY , PHD
DIRECTOR IMMUNOLOGY CHEMISTY
ABBVIE LABORATORIES
WORCESTER, MA 01605

EFIMOV, IGOR R , PHD
PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
WASHINGTON UNIVERSITY AT SAINT LOUIS
SAINT LOUIS, MO 63130

GANZ, PETER , MD
PROFESSOR
CHIEF, DIVISION OF CARDIOLOGY
DIRECTOR, CENTER OF EXCELLENCE IN
VASCULAR RESEARCH
SAN FRANCISCO GENERAL HOSPITAL
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA 94110

GIORDANO, FRANK J , MD
ASSOCIATE PROFESSOR
SECTION OF CARDIOVASCULAR MEDICINE
YALE UNIVERSITY SCHOOL OF MEDICINE
NEW HAVEN, CT 06510

GIROUARD, STEVEN D , PHD
PRESIDENT AND CEO
SECURUS MEDICAL GROUP, INC.
CLEVELAND, OH 44106

HODGSON-ZINGMAN, DENICE , MD
ASSOCIATE PROFESSOR
DEPARTMENT OF INTERNAL MEDICINE
CARDIOVASCULAR MEDICINE DIVISION
UNIVERSITY OF IOWA HOSPITALS AND CLINICS
IOWA CITY, IA 52242

KOCH, WALTER J , PHD
PROFESSOR AND DIRECTOR
CENTER FOR TRANSLATIONAL MEDICINE
SCHOOL OF MEDICINE
TEMPLE UNIVERSITY
PHILADELPHIA, PA 19140

SUBRAMANIAM, DANISE ROGERS , PHD
ADVISOR-PROJECT MANAGEMENT
ELI LILLY AND COMPANY
INDIANAPOLIS, IN 46285

VALDES, ROLAND , PHD
PROFESSOR
DEPARTMENT PATHOLOGY AND LAB MEDICINE
SCHOOL OF MEDICINE
UNIVERSITY OF LOUISVILLE
LOUISVILLE, KY 40202

VELAZQUEZ, ERIC J , MD
PROFESSOR
DIVISION OF CARDIOVASCULAR MEDICINE
DIRECTOR, CARDIAC DIAGNOSTIC UNIT
AND ECHOCARDIOGRAPHY LABOATORIES
DUKE CLINICAL RESEARCH INSTITUTE, DUKE
DURHAM, NC 27705

WEBB, CHARLES K , PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOENGINEERING
CLEMSON UNIVERSITY
CLEMSON, SC 29634

SCIENTIFIC REVIEW OFFICER

CHANDLER, MARGARET, PHD
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

GRANTS TECHNICAL ASSISTANT

KHANDAGLE, MEGHANA
CENTER FOR SCIENTIFIC REVIEW
6701 ROCKLEDGE DRIVE,
BETHESDA, MD 20892

The Review Process at CSR

- Assignment
  - The Division of Receipt and Referral (DRR) assigns each application to a **review group** and to one or more **Institutes/Centers** for funding consideration.
    - Referral staff have access to the entire application, not just the title and Abstract. In many cases, they concentrate on the Abstract and Specific Aims.
    - Requests made by investigators and the assignment of previous applications are also considered.
    - An Institute or Center (IC) is identified for primary assignment for funding.
    - Applications may also receive dual IC assignments.
    - The grant application is assigned for review to the CSR or to one of the other IC Review groups.

SBIR IMPACT
BIO AND HEALTH TECH NYC

The Review Process at CSR

- Review
  - Prior to the meeting reviewers are assigned to your application
    - Your Scientific Review Officer (SRO) will analyze the content of your application, check for completeness and compliance with policies, and decide which reviewers can best evaluate it.
    - Reviewers have access to your application approximately 6 weeks before the Study Section meeting.
    - Each application is assigned to three or more reviewers, and at least two of them provide full written critiques. These assigned reviewers lead the discussions at the meeting.
    - Before the Study Section meets, reviewers confidentially submit preliminary critiques. Reviewers also assign preliminary scores for each review criterion and for the overall impact of the application.

SBIR IMPACT

The Review Process at CSR

- Review
  - The SRO uses the preliminary overall impact scores to order the reviews. Applications in the lower half are not typically discussed.
  - Study sections convene for 1 to 2 days.
  - Assigned reviewers present their evaluations and mail reviews are read.
  - After a general discussion, reviewers privately submit overall impact scores to CSR.
  - Relevant NIH program staff are encouraged to attend, but do not participate.
  - The Advisory Council of the funding institute will then consider the study section's recommendations.

SBIR IMPACT

NIH Review Criteria

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

IMPACT

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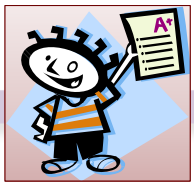
NIH Review Process



- Preliminary Impact Score of 1 - 9 (best to worst)
  - Each criterion also scored; unrelated to impact score
- Preliminary scores used to determine which are discussed
  - Rank order discussion process
- Final impact score by each panel member for those discussed
  - Overall impact score = mean x 10 (range from 10-90)
- All applications receive written summary statement
  - Streamlined applications receive scores on each criterion in addition to critiques

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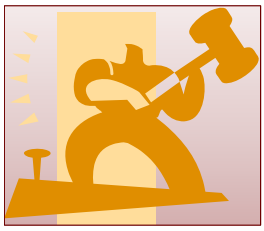
Significance / Impact

- **Overall <u>Impact</u> Score:** assessment of the *likelihood* for the project to exert a *sustained, powerful influence* on the research field(s) involved.



SBIR IMPACT

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NIH Funding Decisions

- Ratings from scientific/technical evaluation
  - Overall Impact scores of 1 to 9 (best to worst)
  - Rank Priority Discussion
  - All applications receive written summary statement
- Areas of high program relevance
- Program balance among areas of research
- Available funds
- Extent of commercialization status
  - >15 Phase II awards in prior 5 fiscal years

SBIR IMPACT

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NIH Review Process

NIH National Institutes of Health *Office of Extramural Research*

Timeline: New Applications

Due Date	Scientific Review	Council Review	Award Date *(earliest)*
Sept 5	Oct/Nov	Jan/Feb	March
Jan 5	Feb/Mar	May/June	July
April 5	June/July	Aug	Sept or Dec

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NIH Review Process

Small Business Concern

Submits SBIR/STTR Grant Application to NIH

center for scientific review

Assign to IC and IRG

Scientific Review Groups Evaluate Scientific Merit

Score of > ??? Resubmission?

Score of 10 - ??

Advisory Council or Board Recommend approval

IC Staff Prepare funding Plan for IC Director

Assurances are met

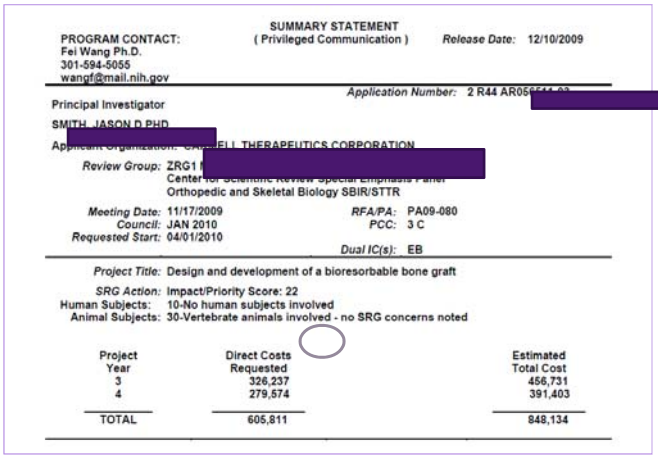
IC Allocates Funds

Grantee Conducts Research

Applicant Initiates Research Idea

SBIR IMPACT

Summary Statements



SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
Fei Wang Ph.D.
301-594-5055
wangf@mail.nih.gov

Release Date: 12/10/2009

Application Number: 2 R44 AR056644-02 [redacted]

Principal Investigator
SMITH, JASON D PHD [redacted]

Applicant Organization: CAMPBELL THERAPEUTICS CORPORATION

Review Group: ZRG1 [redacted]
Center for Scientific Review Special Emphasis Panel
Orthopedic and Skeletal Biology SBIR/STTR

Meeting Date: 11/17/2009
Council: JAN 2010
Requested Start: 04/01/2010

RFA/PA: PA09-080
PCC: 3 C

Dual IC(s): EB

Project Title: Design and development of a bioresorbable bone graft

SRG Action: Impact/Priority Score: 22
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Project Year	Direct Costs Requested	Estimated Total Cost
3	326,237	456,731
4	279,574	391,403
TOTAL	605,811	848,134

SBIR IMPACT
BIO AND HEALTH TECH NYC

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Summary Statements

CRITIQUE 1:

Significance: 3
Investigator(s): 2
Innovation: 2
Approach: 3
Environment: 3

1. Significance:

Strengths

- A total of 800 million bone grafting procedures are performed in the US with a market size of about $1.6B. Currently, demineralized bone matrix (DBM) and BMP2 are utilized. The proposed technology offers certain advantages over existing products. For example, PRP can be collected hypothetically from an individual autologously and processed as the proposed Plasmix Bone Putty.

Weaknesses

- As opposed to DBM and BMP2, Plasmix Bone Putty will likely require a two-stage procedure.

2. Investigator(s):

Strengths

- Strong team of engineers (Lee Weiss), biologists (Phil Campbell) and personnel in the small business concern. Three individuals were hired in Phase I. Consultants in place to work on various aspects as proposed.

Weaknesses

- Somewhat unclear who will perform animal surgery although animal work was done in Phase I.

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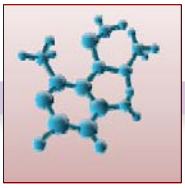
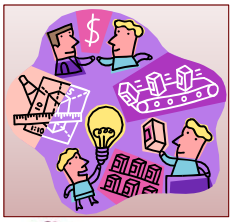
Review Criteria



- Significance
  - Technical merit
  - Commercial value
- Investigators
- Innovation
- Approach
- Environment



SBIR IMPACT

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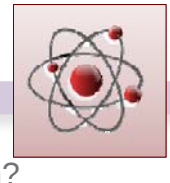
Significance: Merit of Project



- Does this study address an important problem?
- Will the Specific Aims be reached when experiments are completed?
  - If so, how will scientific knowledge or clinical practice be advanced?
- What will be the effect of these studies on concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

SBIR IMPACT

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Significance: Commercial Value

- How strong is the commercial potential of the project in terms of leading to a marketable product or process?
- What may the product or process be worth?
- Will the technology have a competitive advantage over existing or alternative technologies in meeting the market needs?

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Investigators

- Knowledgeable
  - Investigators appropriately trained and well suited to carry out this work?
- Skilled
  - Is the work proposed appropriate to the experience level of the principal investigator and other researchers?
- Are the investigators 'productive'?
  - Persistent, Passionate, Focused
- Does the investigative team bring complementary and integrated expertise to the project?

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Innovation

- Is the project original and innovative?
- Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

SBIR IMPACT

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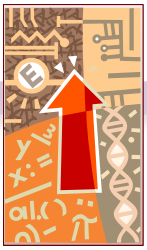
Quality of Approach



- Is there a solid **hypothesis** to be tested?
- Sound experimental design & methods
  - Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?

SBIR IMPACT

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Environment

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements?
- Is there evidence of institutional support?

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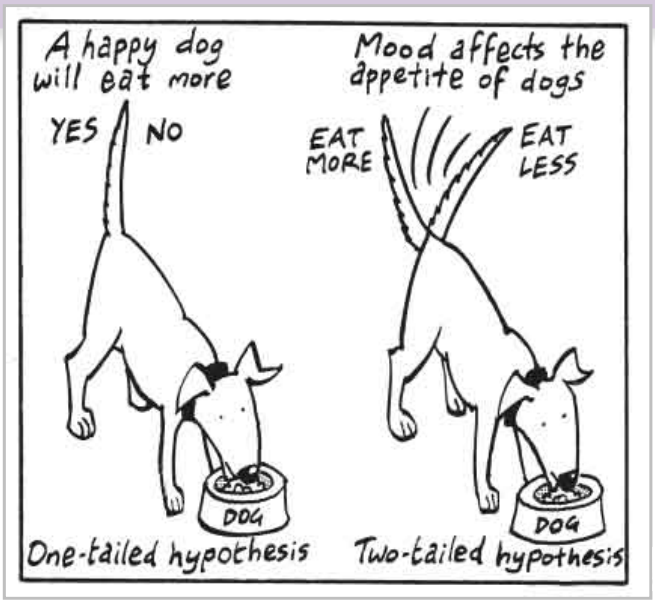
Hypothesis-Driven Research



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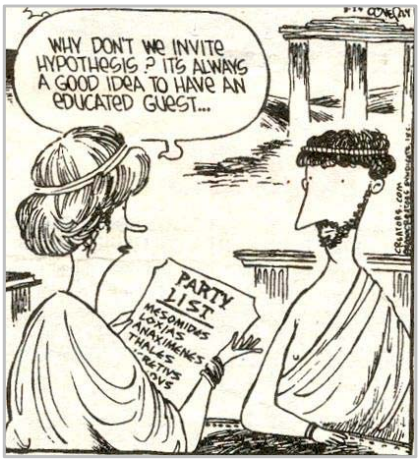

SBIR IMPACT

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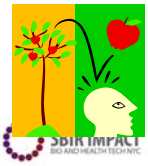
Develop Research Project 1/2

1. Make knowledgable observations

2. Search for background facts

3. Identify a problem caused by gap in knowledge or technology



4. Develop theories on causation & solution for the problem

SBIR IMPACT

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Develop Research Project 2/2

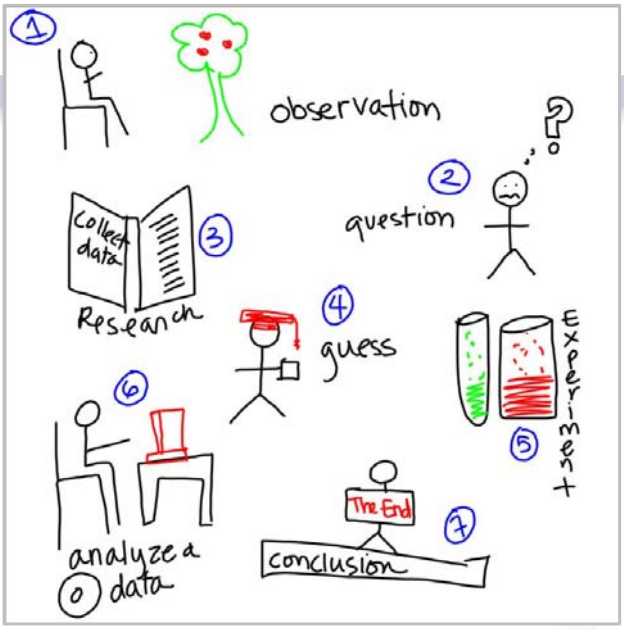
5. Seek clues on feasibility of a solution -> Preliminary results

6. Formulate an hypothesis to test

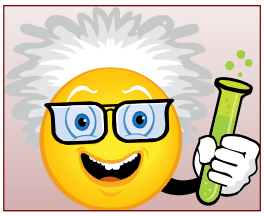
7. Define specific research aims

8. Define the research process

9. Secure resources



Essential Features of a Hypothesis



- Must be **testable**:
  - Availability of means and tools
  - Competence of investigator
- Must be **reasonable**:
  - Compatible with existing knowledge
- Must be **significant**:
  - Promises to result in valuable new knowledge or technology

SBIR IMPACT

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Strategic Planning

BEFORE you start to write your proposal:

- Understand NIH Structure
- Find a Solicitation
- Understand the Review Process
- Define your project
- Understand how to work with NIH

- Proposal Preparation…

SBIR IMPACT

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NIH SBIR/STTR Proposal Preparation

Key Planning Steps

- Acquire preliminary data
- Conduct scientific literature search and market research
- Plan experiments/R&D activities
- Develop commercialization strategy
- Convene the technical team
- Secure facilities and other resources

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Writing the Proposal

Primary Questions to be Answered

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

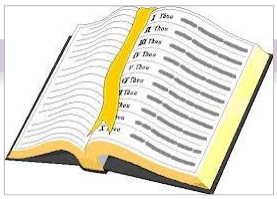
SBIR IMPACT

Components of an NIH SBIR/STTR

- 1. Introduction to Application (1pg)
- 2. Specific Aims (1 pg)
- 3. Research Strategy (6 or 12 pg)
  - Significance
  - Innovation
  - Approach
- 4. Inclusion Enrollment Report
- 5. Progress report/Publication List (Phase II proposals only)
- 6. Protection of Human Subjects
- 7. Inclusion of Women and Minorities
- 8. Targeted/Planned Enrollment Table
- 9. Inclusion of Children
- 10. Vertebrate Animals
- 11. Select Agents
- 12. Multiple PD/PI Plan
- 13. Consortium/Contractual Arrangements
- 14. Letters of Support
- 15. Resource Sharing Plans
- 16. Appendix
- Bibliography and Refs Cited
- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Senior/Key Person Profiles
- Biographical Sketches (4 pg ea.)
- Facilities & Other Resources
- Equipment
- Project Budget
- Subaward Budget
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- Forms

SBIR IMPACT

Which sections?



What you are going to do?

Why is it worth doing?

- Specific Aims Section
- Research Strategy
- Commercialization Plan (Phase II and FastTrack)

SBIR IMPACT

Components of an NIH SBIR/STTR

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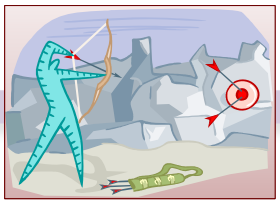
SBIR IMPACT

Specific Aims



- Single and most important page of application
- Sets out what you intend to do
- An Executive Summary of the Proposal

SBIR IMPACT

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Specific Aims

- Introductory paragraph should
  - Capture the vision with a broad goal justifying the research question
  - Summarize relevance and feasibility of the approach
  - Engage the reader with
    - strong, solid, testable hypotheses, or
    - discrete, finite technology development goal
- Succinctly state each research aim in one sentence
  - Experiments (as described in the research strategy section) support aims, aims test the hypothesis
- Be focused
  - aims independent yet related to overall goal
  - avoid dense text and acronym overload

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Importance of Specific Aims

- Criteria by which success of Phase I will be judged
  - Q: Did you demonstrate feasibility?
  - A: Did you accomplish the specific aims?

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Specific Aims – Outline **Phase I**

- 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

SBIR IMPACT

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Specific Aims – Outline **Phase II**

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

PAGE LIMIT: One PAGE

SBIR IMPACT

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Tips on Specific Aims

- Don't state a hypothesis that you cannot test with the experiments you are proposing
- Avoid descriptive phrases like: To correlate… To describe… To develop…
- Avoid wishy-washy, passive tense, or flowery language
- Write aims in active form with strong meaningful verbs
- No "fishing expeditions" – microarray experiments, expression cloning, etc.

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Aims vs. Activities

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

Components of an NIH SBIR/STTR

- 1. Introduction to Application (1pg)
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  - **Innovation**
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- Forms

SBIR IMPACT

Research Strategy

- Significance
- Innovation
- Approach

SBIR IMPACT

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Significance

- Explain the **importance** of the problem or critical barrier to progress in the field.
- How will the proposed project improve scientific knowledge, technical capability, and/or clinical practice.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the aims are achieved.
- Describe the **commercial potential** of the project to lead to a marketable product, process or service.

SBIR IMPACT

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Significance

- Amplify initial paragraphs of the Specific Aims.
- Does the study address an important health related problem? How do you know?
- Define existing knowledge base via evaluating relevant literature. What are the knowledge gaps?
- Will my solution matter? Quantify, qualify the impact on:
  - Scientific knowledge
  - Technical capacity
  - Clinical practice

SBIR IMPACT

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Significance

- Demonstrate:
  - Significant product
  - Significant science
  - Significant need in the market
  - Significant commercial opportunity

Use references!

SBIR IMPACT

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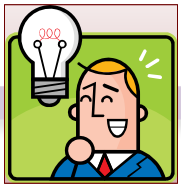
Innovation



- Clearly state the technological innovation.
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

SBIR IMPACT

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Innovation

- How will this effort shift current research or clinical practice paradigms?
- Is the proposed work new? Creative? Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions(s) to be developed.
- How will the results direct/inform future research/product development?
- Will success improve the "State-of-the-art", establish new research directions, change clinical practice?

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Approach

- Describe the overall strategy, methodology, and analyses to be used. Include how data will be collected, analyzed, and interpreted.
- Discuss **potential problems**, **alternative strategies**, and **benchmarks** for success.
- Describe the strategy to establish **feasibility**, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, or materials that may be hazardous to personnel and precautions to be exercised.
- Include information on Preliminary Studies.
- Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application.

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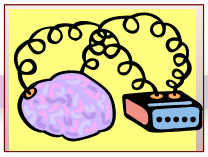
Approach – Phase I



- **Preliminary Data/Prior Work**
  - are not *required* for Phase I applications (but if you don't have any, get some)
  - should support the proposed Phase I aims
  - Demonstrates that the investigator has:
    - mastery of (and/or access to) the required techniques
    - ability to manage and work with collaborators/partners
    - sufficient attention to important details (i.e. accurate, carefully assembled figures, tables, graphs)
- Reviewers will **not** look anything up! Provide sufficient, relevant details for an informed judgment

SBIR IMPACT

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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

** for Direct to Phase II write as if you had a Phase I

SBIR IMPACT

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Approach

- Do experiments relate to the Specific Aims?
  - Provide an overview and conceptual framework
- Are the experiments logical and well-integrated?
  - Why are the proposed methods the best way to go? Be sure this study is not "a technology looking for a problem"!
  - Less detail needed for established techniques
  - Alternatives for high risk elements add to the feasibility
- Are the end-points/milestones clearly defined?
- Is the appropriate statistical analysis included?
- Is there a sensible timeline?

SBIR IMPACT

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Research Strategy – BBC Outline

Significance

- 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

SBIR IMPACT

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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?

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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)
- Specific Aim (separate section for each aim)
  - Rationale
  - Experimental Design & Methods
  - Data Analysis & Interpretation
  - Potential Pitfalls / Alternative Approaches
  - Expected Outcomes

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Research Strategy – BBC 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
- Specific Aim (separate section for each aim)
  - Rationale
  - Experimental Design & Methods
  - Data Analysis & Interpretation
  - Potential Pitfalls / Alternative Approaches
  - Expected Outcomes

SBIR IMPACT

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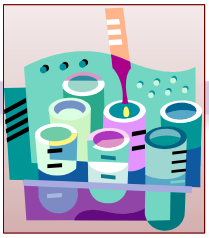
Approach - Outline

For Each Specific Aim:

- [Restate the 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?

SBIR IMPACT

Summary



- Tell the reviewers:
  - What (Specific Aims)
  - Why (Significance, Innovation, Prior Work)
  - How (Research Strategy)
- Summarize who, when and where:
  - Gantt Chart
    - Detailed timeline for project
    - Details who will be responsible for completion of each aims
    - Where the work will be done (company, subcontractor etc.)

SBIR IMPACT

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Gantt Chart (who, when, where?)

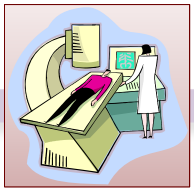
Specific Aims	Month					
	1	2	3	4	5	6
Specific Aim 1	↔	↔				
Experiment 1 A. Scientist, Ph.D. NewCo. Labs	↔					
Experiment 2 A.N. Scientist, Ph.D. NewCo. Labs		↔				
Specific Aim 2			↔			
Experiment 1 A. Engineer, M.S. MidWest University			↔	↔		
Specific Aim 3				↔	↔	↔
Experiment 1 A.N. Scientist, Ph.D. Research Co. 2				↔	↔	↔

Components of an NIH SBIR/STTR

- 1. Introduction to Application (1pg)
- 2. Specific Aims (1 pg)
- 3. Research Strategy (6 or 12 pg)
  - Significance
  - Innovation
  - Approach
- **4. Inclusion Enrollment Report**
- **5. Progress report/Publication List (Phase II proposals only)**
- **6. Protection of Human Subjects**
- **7. Inclusion of Women and Minorities**
- **8. Targeted/Planned Enrollment Table**
- **9. Inclusion of Children**
- **10. Vertebrate Animals**
- 11. Select Agents
- 12. Multiple PD/PI Plan
- 13. Consortium/Contractual Arrangements
- 14. Letters of Support
- 15. Resource Sharing Plans
- 16. Appendix
- Bibliography and Refs Cited
- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Senior/Key Person Profiles
- Biographical Sketches (4 pg ea.)
- Facilities & Other Resources
- Equipment
- Project Budget
- Subaward Budget
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- Forms

SBIR IMPACT

Human Subjects



If you have human subjects

- You must upload 5 pdf attachments:
  - Inclusion Enrollment Report
  - Protection of Human Subjects (includes Data & Safety Monitoring Plan)
  - Inclusion of Women and Minorities
  - Targeted/Planned Enrollment Table
  - Inclusion of Children

SBIR IMPACT

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IRB Training

- If human subjects are to be used, training and certification is mandatory
- All research must be under guidance of an Institutional Review Board (IRB)
- Academic Institutions may act on behalf of small business
- NIH Office of Human Subjects Research
  - http://ohsr.od.nih.gov
- Various online certification options

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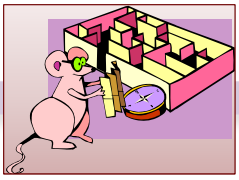
Where to get help on Human Subjects

- The NIH SBIR/STTR Application Guide (Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan)
- The National Institutes of Health (NIH) Human Research Protections Program (HRPP)
  - http://ohsr.od.nih.gov
- Research Involving human subjects
  - http://grants.nih.gov/grants/policy/hs/

Vertebrate Animals



- Address the following five key points
  - Describe the proposed use of the animals in the work outlined e.g. species, strains, ages, sex, numbers
  - Justify the use of animals, the choice of species, and the numbers to be used.
  - Information on veterinary care.
  - Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited.
  - Describe any method of euthanasia to be used and the reasons for its selection.

SBIR IMPACT

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Components of an NIH SBIR/STTR

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- Forms

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Bibliography & References Cited

- Include the names of all authors the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations.
- Follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.
- Should include any references cited in the Research Plan Component.
- Should be limited to relevant and current literature.
- Don't forget important conversations, correspondence.
- No page limitation, but be concise and select only those literature references pertinent to the proposed research.

SBIR IMPACT

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Components of an NIH SBIR/STTR

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SBIR IMPACT

Project Summary/Abstract (30 lines)

- A summary of the proposed activity suitable for dissemination to the public.
  - A succinct/accurate description of the proposed work when separated from the application.
  - State the application's long-term objectives and specific aims, refer to the health relatedness of the project.
  - Describe concisely the research design and methods for achieving the stated goals.
  - Understandable to a scientifically literate lay reader.
  - No proprietary/confidential information.
  - < 30 lines of text.

SBIR IMPACT

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Phase I Abstract - outline

- Introduction
- Problem to be addressed
- Product
- Technological Innovation
- Long-Term Goal
- Phase I Summary
  - Phase I Hypothesis
  - Specific Aims for Phase I
- Phase II Objectives
- Commercial Opportunity

SBIR IMPACT

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Phase II Abstract - outline

- Introduction
- Problem to be addressed
- Product
- Technological Innovation
- Long-Term Goal
- Phase I Outcomes (e.g., feasibility)
- Phase II Summary
  - Phase II Hypothesis
  - Specific Aims for Phase II
- Commercial Opportunity

SBIR IMPACT

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Public Health Relevance

- For NIH and other PHS agencies applications, this attachment will reflect the second component of the Project Summary – relevance.
- Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

SBIR IMPACT

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Appendices

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- Subaward Budget
- Cover Letter
- **Commercialization Plan (12 pg):**
  - **Phase II & Fast Track only**
- Forms

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Important Reminder

A good idea is necessary but not sufficient

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What is Commercialization?

- Ability to provide a solution to a problem **in exchange for money**

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NIH Commercialization Plan

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

No more than 12 pages

SBIR IMPACT

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Which sections?

Who is going to do the work?

Where will the work be done?

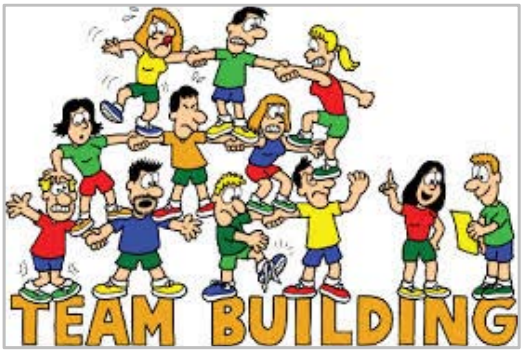
How much will it cost?

- Biographical Sketches
- Facilities and Resources
- Letters of Support
- Budget and Budget Justification

SBIR IMPACT

The Team

Key Persons vs. Non-Key Persons



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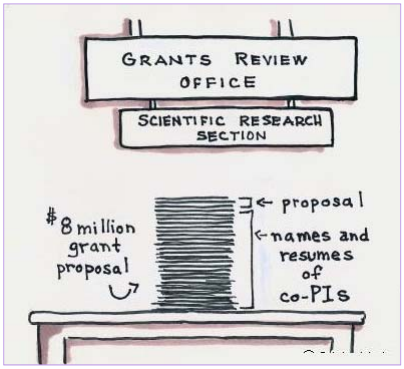
Key Personnel



- Your (the SBC's) employees
- Subcontractor's employees
- Consultants
- Other Significant Contributors

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Components of an NIH SBIR/STTR – THE TEAM

- 1. Introduction to Application (1pg)
- 2. Specific Aims (1 pg)
- 3. Research Strategy (6 or 12 pg)
  - Significance
  - Innovation
  - Approach
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SBIR IMPACT BIO AND HEALTH TECH NYC

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- 12. Multiple PD/PI Plan

(BBC's opinion….)

SBIR IMPACT BIO AND HEALTH TECH NYC

Multiple PD/PI Plan

- For applications designating multiple PDs/PIs, a leadership plan must be included.
- A rationale for choosing a multiple PD/PI approach should be described.
- The governance and organizational structure of the leadership team and the research project should be described, including
  - communication plans,
  - process for making decisions
  - procedures for resolving conflicts.
- The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated.

SBIR IMPACT

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Biosketches

- **Each** member of key personnel needs to tailor the personal statement
- Publications now limited to 15
  - 5 most recent
  - 5 best
  - 5 most relevant to the application
- Still max. 4 pages

SBIR IMPACT

Biographical Sketches

- Extends the page limit from 4 to 5 pages
- Allows researchers to describe up to 5 of their most significant contributions to science, along with the historical background that framed their research.
- Investigators can outline the central findings of prior work and the influence of those findings on the investigator's field.
- Investigators involved in Team Science are provided the opportunity to describe their specific role(s) in the work.
- Each description can be accompanied by a listing of up to 4 relevant peer-reviewed publications or other non-publication research products, including patents; databases; educational aids or curricula; instruments or equipment; models; protocols; and software.
- Researchers are allowed to include a link to a full list of their published work as found in e.g. MyBibliography or SciENcv .

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Biosketch – Personal Statement

- Personal Statement – why experience and qualifications make the applicant particularly well-suited for role in the project
  - how you are qualified for your assigned role on study
  - how your formal education, training & experience contribute to feasibility of work
  - your access to resources/collaborations

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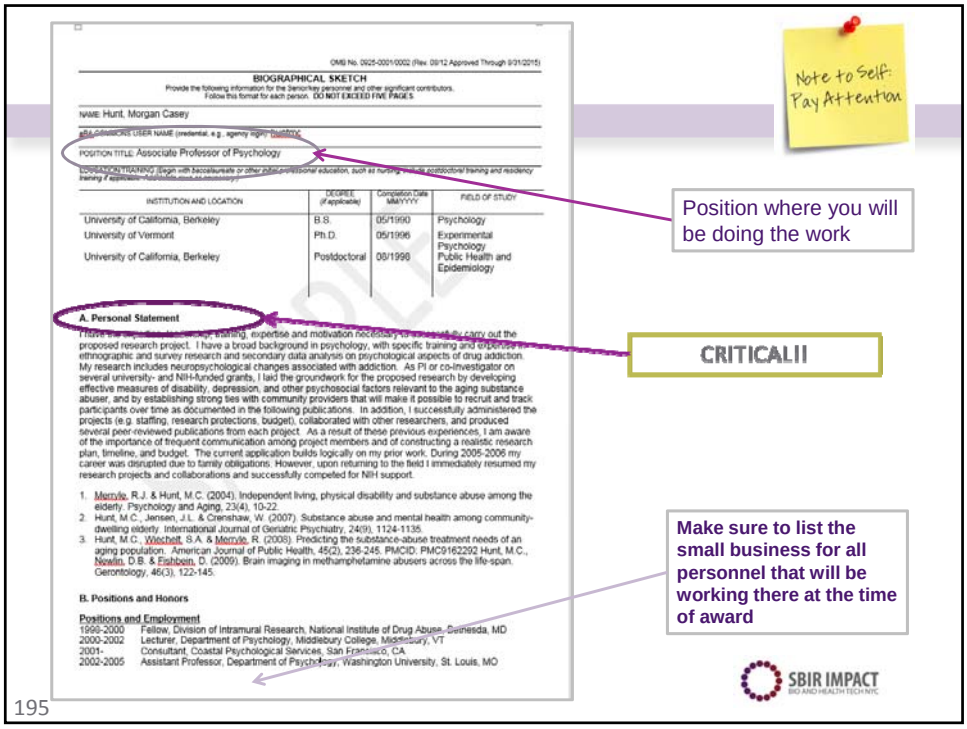
OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)
BIOGRAPHICAL SKETCH
Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.
NAME: Hunt, Morgan Casey
POSITION TITLE: Associate Professor of Psychology
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
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
proposed research project. I have a broad background in psychology, with specific training and experience in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological 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. Merrylo, 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., Wiechelt, S.A. & Merrylo, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292 Hunt, M.C., Nowlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.
B. Positions and Honors
Positions and Employment
1999-2000 Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001- Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
Note to Self: Pay Attention
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
SBIR IMPACT
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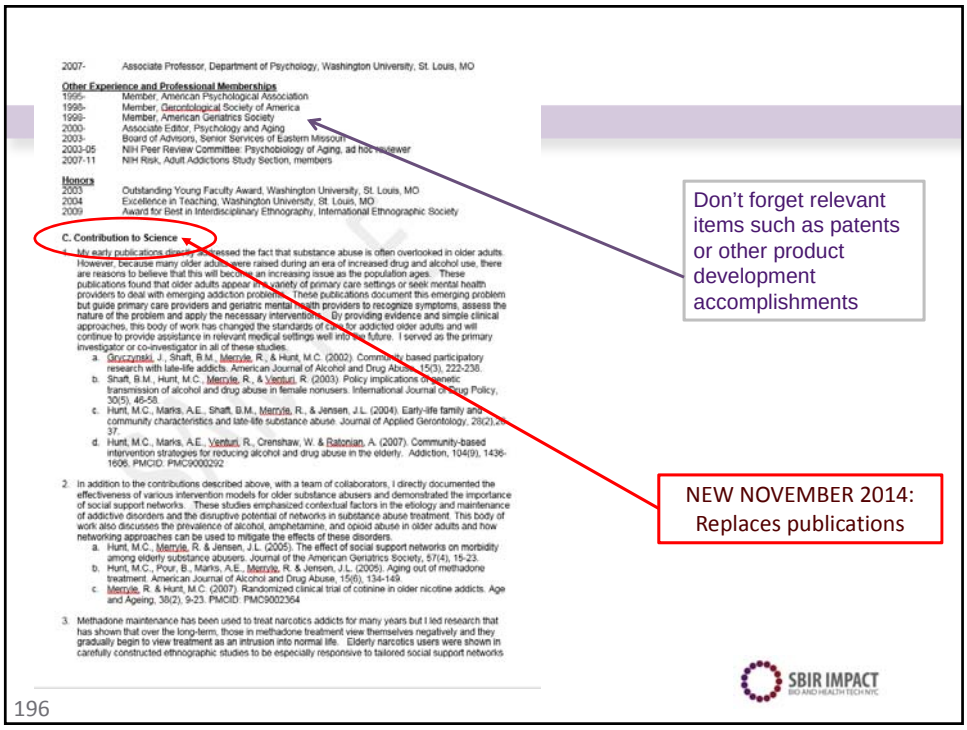
2007- Associate Professor, Department of Psychology, Washington University, St. Louis, MO
Other Experience and Professional Memberships
1995- Member, American Psychological Association
1998- Member, Gerontological Society of America
1998- Member, American Geriatrics Society
2000- Associate Editor, Psychology and Aging
2003- Board of Advisors, Senior Services of Eastern Missouri
2003-05 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11 NIH Risk, Adult Addictions Study Section, members
Honors
2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004 Excellence in Teaching, Washington University, St. Louis, MO
2009 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society
C. Contribution to Science
1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
a. Gryczynski, J., Shaft, B.M., Merrylo, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
b. Shaft, B.M., Hunt, M.C., Merrylo, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.
c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merrylo, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),
37.
d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292
2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.
a. Hunt, M.C., Merrylo, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.
b. Hunt, M.C., Pour, B., Marks, A.E., Merrylo, R. & Jensen, J.L. (2006). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
c. Merrylo, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364
3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks
Don't forget relevant items such as patents or other product development accomplishments
NEW NOVEMBER 2014: Replaces publications
SBIR IMPACT
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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), 45-61.
b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
c. Merryle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304
d. Hunt, M.C., Jensen, J.L. & Merryle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PqT7IEFIAJBtGMRDdWFmjWAO/?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 Merryle (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

R21 AA998075 Hunt (PI) 01/01/11-12/31/13
Community-based intervention for alcohol abuse
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
Role: PI

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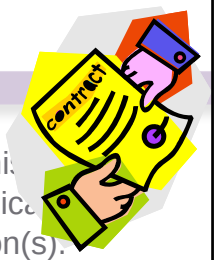
Consortium/Contractual Arrangements



- Explain the programmatic, fiscal, and administ arrangements to be made between the applic organization and the consortium organization(s).
- Explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. List any subcontracts or enter “Not applicable”
- Write a paragraph on what the deliverables will result from the arrangement.

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Consortium/Contractual Arrangements (STTR)

- Certification showing the cooperative R&D arrangement between the small business concern and the research institution requested prior to an award.
- The single partnering research institution must certify that > 30% of the work of the STTR project will be performed by the research institution.
- The signature of the authorized representative of the research institution affirming certifications made by the research institution must be included in a letter:…

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Consortium/Contractual Arrangements (STTR)

- The small business concern and the research institution certify jointly that:
  - the project will be conducted jointly by the small business concern and the research institution in which > 40 % of the work will be performed by the small business concern and > than 30 % of the work will be performed by the research institution
  - the small business concern will be the primary party that will exercise management direction and control of the performance of the project."

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Letters of Support

- Consultants (required)
- Subcontractors (include in contractual arrangements section)
- Contingent Resources, e.g.:
  - Company research pace
  - Leaves of absence
- R&D Resources
- Commercialization Resources, e.g.:
  - Funding
  - Strategic Partners
  - Key Customers

SBIR IMPACT

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Letters of Support -- Consultants

- Required from each consultant
  - Prepared on the letterhead of the consultant and addressed to the Small Business Concern (SBC). Letter should:
  - Refer to the specific project by name
  - Verify the consultant's commitment to the project
  - Confirm his/her role in the project.
  - Acknowledge the PD/PI as the lead on the project
  - Specify what assets or services the consultant will contribute (e.g. expertise, number of hours/ percent of effort)
  - Quantify the consultant's remuneration
- Biographical sketch

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Components of an NIH SBIR/STTR – The Environment

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- Subaward Budget
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- Forms

SBIR IMPACT

Facilities and Other Resources

- Not just a cut-and-paste list!
- Address how the (scientific) environment will contribute to probability of success, unique features of environment, etc.
- Other aspects of the environment can include:
  - Scientific Advisory Board
  - Management Team
  - Community Support

SBIR IMPACT

Facilities and Other Resources

- To assess the capability of the resources available to perform the effort proposed.
  - Identify the facilities to be used (Lab, Animal, Computer, Office, Clinical and Other).
  - Indicate capacities, capabilities, relative proximity, extent of availability to the project.
  - Describe only resources directly applicable to the work
  - Provide any information describing the Other Resources available to the project.
- All research by the small business and its collaborators must be in U.S. facilities available to and under the control of each party.

SBIR IMPACT

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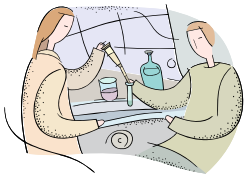
Facilities and Resources – include:

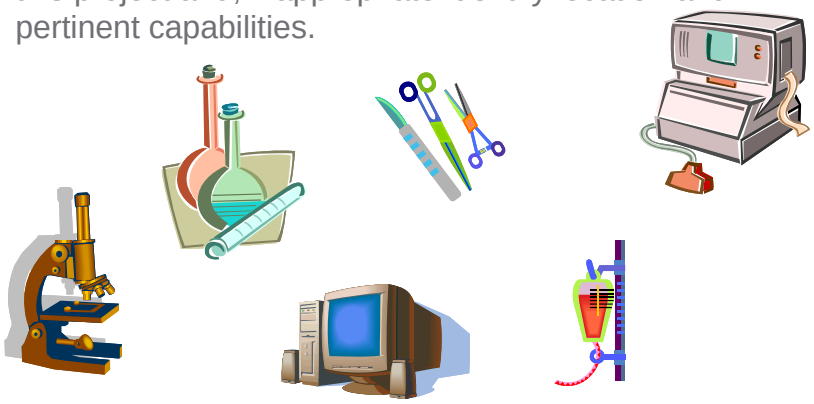
- Company's Research Facility(s)
- Subcontractors' Research Facilities
- Other R&D Resources
  - Other Significant Contributors (e.g., Scientific Advisory Board)
- Commercialization Resources
  - Management
  - Strategic Partners
  - Funding
  - Regulatory/Reimbursement



SBIR IMPACT

Equipment

- List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.



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Components of an NIH SBIR/STTR

- 1. Introduction to Application (1pg)
- 2. Specific Aims (1 pg)
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  - Significance
  - Innovation
  - Approach
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- 14. Letters of Support
- 15. Resource Sharing Plans
- 16. Appendix
- Bibliography and Refs Cited
- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Senior/Key Person Profiles
- Biographical Sketches (4 pg ea.)
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- **Project Budget**
- **Subaward Budget**
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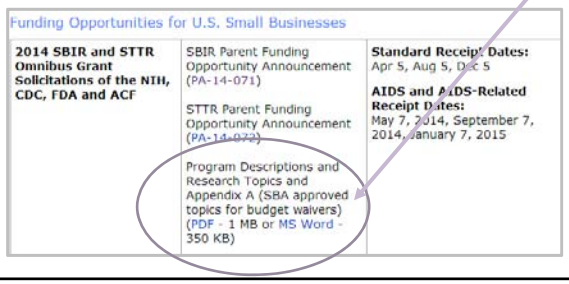
Budget limitations

NEW: Reauthorization Impacts

- Guidelines:
  - $150,000 Phase I, $1,000,000 Phase II
- "Limits" – max 150% of guidelines, therefore:
  - $225,000 Phase I, $1,500,000 Phase II
- New with 2014 Omnibus: Appendix A

Talk to program staff!



SBIR IMPACT

REMINDER: "Outsourcing" Limits

- SBC (applicant organization) must do required minimum (% of direct + indirect)
  - SBIR - Phase I - ≥ 67%
  - SBIR - Phase II - ≥ 50%
  - STTR - Phase I & II - ≥ 40%
- Therefore total of Consultants + Subcontractor Costs must be:
  - SBIR - Phase I - <33.3%
  - SBIR - Phase II - <50%
  - STTR - Phase I & II - ≥ 30% for primary subcontractor; <30% for all other consultants + subcontractors

SBIR IMPACT

Budgets

- Direct Costs
- Indirect Costs (F&A)
  - 40% Phase I, **40% Phase II or be prepared for an IDC rate negotiation**
  - Basis is "total direct costs"
  - *A rate of 40% of total direct costs is requested. This amount is appropriate to cover the company's current projected indirect costs and is consistent with NIH's policy for Phase I SBIR proposals when the company does not already have a previously negotiated indirect cost rate.*
- Fee
  - *A fee of 7% of total costs (direct and indirect) is requested. This fee contributes to the growth of the small business concern by allowing expansion of resources and personnel development. The fee is consistent with a normal profit margin provided for research and development work.*
- Unallowable Costs

SBIR IMPACT

Budget approach

When a cap or restriction is enforced

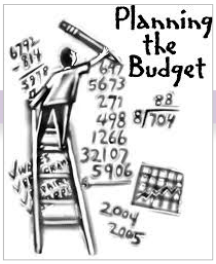
Work backwards to determine the direct dollars

If Budget Cap = $225,000		
Direct Costs =		$150,000
Indirect Costs =	$150,000 x 40%	$60,000
Fee =	($150,000 + $60,000) x **6.99%**	$14,679
TOTAL:	**Direct + Indirect + Fee**	**$224,679**

Therefore – design your project to fit $150k directs

SBIR IMPACT

Budget Figures



Plan For This

	Phase I	Phase II
Direct	$ 150,000	$ 1,000,000
Indirect@40%	$ 60,000	$ 400,000
Fee@7%	$ 14,679	$ 97,860
Total	**$ 224,679**	**$ 1,497,860**

SBIR IMPACT

Commercialization Assistance

Two Options at NIH

- NIH sponsored programs:
  - Niche Assessment program for Phase I awardees
  - Commercialization Assistance Program (CAP) for Phase II awardees

OR

- Request $5000 for technical assistance (e.g., 'commercialization' assistance)
  - In addition to the maximum allowable budget
  - Must specify consultant and provide justification

SBIR IMPACT

$5k Commercialization Assistance

Increase technical assistance (e.g., 'commercialization' assistance)

- $5,000/award/year above the allowable cap
- Identify your own service provider
  - Note: You won't be able to participate in agency sponsored programs
- Include the cost in the budget (follow agency specific instructions)
- Include a detailed description of services your vendor will provide in the budget justification
- Secure a letter of commitment from the vendor

***confirm participation/instructions with specific agency!*

SBIR IMPACT

Budget Justification

A budget justification is required for each budget submitted.

- Written justification for each dollar requested
- Provide detail
- Stand alone document
- Be convincing

SBIR IMPACT

Budget Justification

- Every line item in your budget should have a subheading and corresponding paragraph in the Budget Justification.
- Include all justification information for all years in the same file.
- List the names, employment status, project role, calendar months (% effort), and salary for ALL project personnel.
- If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget.
- Should be a stand-alone document.

SBIR IMPACT BIO AND HEALTH TECH NYC

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Budget Best Practices**

1. Develop your budget early
2. Make sure that your direct costs are consistent with the work proposed
3. Request indirect costs
4. Request fee
5. Understand the difference between direct costs, indirect costs and fee!

**refer to BBC June 2012 Pursuit Newsletter

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SBIR IMPACT

The Cover Letter

- Include a cover letter!
- Application title
- PA or RFA title, if you are responding to an NIH initiative
- Request of an assignment and referral to a particular IC (NIH makes the final determination.)
- List of people (e.g., competitors) who should not review your application and why
- Disciplines involved, if multidisciplinary
- NOT 'OPTIONAL!'

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Cover Letter Example

NewCo. 1 Science St, Michigan

CSR
To Whom it May concern:
Application title. Funding Opportunity (PA or RFA) title of the NIH initiative.
Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI
National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC
Cancer Etiology Study Section – CE

The reasons for this request are [provide a narrative explanation for the request(s)].

Sincerely,
A. N. Entrepreneur
Entrepreneur
ACE SBIR Co

SBIR IMPACT

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SBIR IMPACT

Introduction to Application

- Only if you are submitting a **Resubmission.**
- An introduction that summarizes the substantial additions, deletions, or changes.
- Must include responses to the criticisms and issues raised in the Summary Statement.
- Identify the changes in the Research Design and Methods section clearly by bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text.
- One page.

SBIR IMPACT

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Proposal Format

- Read the solicitation!
- NIH Font and Page limits (PA-13-234)
  - Arial, Helvetica, Palatino Linotype or Georgia
  - 11 point or greater
  - ½ inch or greater margins
  - No headers or footers
- Follow instructions for marking confidential information
- Graphics
- Think of the reviewer!
- Convert all documents to .pdf before submission

SBIR IMPACT

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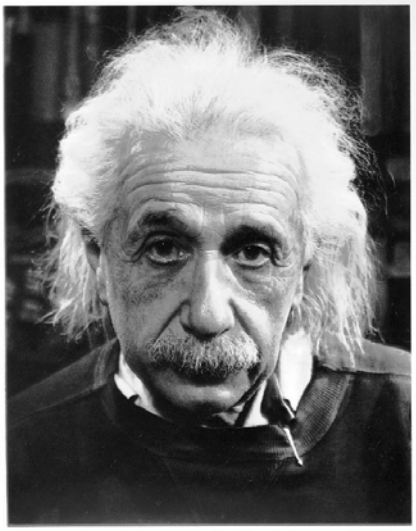


"If you can't explain it simply, you don't understand it well enough"

- Albert Einstein

Think of the reviewer

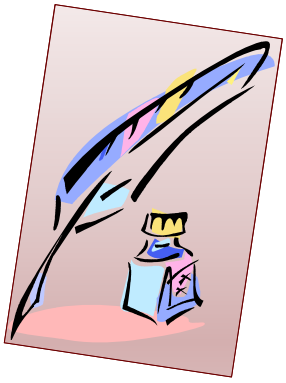
- Headings.
  - Make it easy for reviewers to find information.
- Keep it short and simple.
  - State the key points directly e.g. use Scientific American as a model for the non-technical parts.
- Guide reviewers with helpful graphics.
  - Graphics can help reviewers grasp a lot of information quickly and easily, and they break the monotony.
- Edit adn prooff your propsal.
  - Reviewers assess science, BUT they are influenced by the writing and appearance of your application.


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. 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.

SBIR IMPACT
BIO AND HEALTH TECH NYC

Style tips…

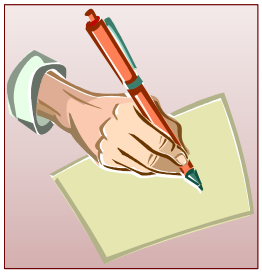
- Be concise & precise
- No emotion or exaggeration
- Use proper technical writing
- Provide necessary detail
- Avoid jargon & abbreviations
- Avoid use of first person (I/we)



SBIR IMPACT
BIO AND HEALTH TECH NYC

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



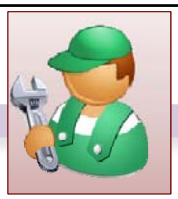
SBIR IMPACT

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."

SBIR IMPACT

Resubmission to NIH



- Acknowledge all criticisms & respond positively
- Have someone review proposal & summary statement
- Listen to external advice
- Resubmit
  - Must have substantive changes
  - Must address issues identified in the summary statement
  - 1 page Introduction

SBIR IMPACT

JIT – Just in Time Information

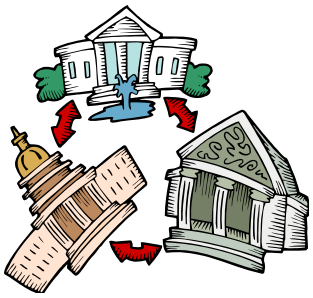
This is NOT a notice of grant award

- 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

SBIR IMPACT

Bayh-Dole Act

- The Bayh-Dole Act requires a grantee institution to disclose an invention to the granting agency



http://grants1.nih.gov/grants/guide/notice-files/not95-003.html

SBIR IMPACT

When do you report inventions?

- Annual Invention Reporting is required
- The Bayh-Dole Act and its Implementing Regulations
  - https://s-edison.info.nih.gov/iEdison/37CFR401.jsp
- Extramural Invention Reporting Compliance Responsibilities
  - https://s-edison.info.nih.gov/iEdison/timeline.jsp

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How do you report inventions?

- iEdison (http:/iEdison.gov)
- iEdison Tutorial
  - http://era.nih.gov/ProjectMgmt/iedison2/index.cfm
- iEdison Registration
  - https://s-edison.info.nih.gov/iEdison/RegistrationRequestForm.jsp

Help Line: (301) 435-1986

Email: Edison@od.nih.gov

SBIR IMPACT

Reporting Requirements

- Federal Financial Report
  - http://www.dpm.psc.gov/
  - Final Progress Report
  - no form; 90 days post expiration
- Final Invention Statement and Certification
  - HHS 568
- Annual Invention Utilization Reports
- Phase II Data Collection Requirement for Government Tech-Net Database
  - http://technet.sba.gov
  - Register prior to applying for Phase II

SBIR IMPACT

When to Contact NIH Program Staff

- Pre-Application
  - Assess the "fit"
  - What's New: FOAs
- Review Issues: Dos/Don'ts
- Post Review
  - Review Summary Statement
  - What the rating means
  - Strengths and weaknesses
  - Likelihood of funding
  - Next steps

SBIR IMPACT

When to Contact NIH Review Staff

- Point of contact during review process
- Concerns about I/C or Study Section Assignment
- Recruitment/Assignment of Reviewers

SBIR IMPACT

When to contact NIH Grants Management

- Pre-Award Steps: Just-in-time (JIT) information
  - Eligibility verification statement
  - Human and Animal subjects training and approvals
  - Documentation of PD/PI's employment
  - Other support for key personnel
  - Verification of access to performance site
  - Consortium/subcontract information
- Post-Award Advice/Guidance
  - Annual Progress Reports
  - Financial Status Reports
  - Invention Reporting
  - Updated approvals
  - Closeout activities

SBIR IMPACT

BBC's Grant Assistance

- Assistance in identifying appropriate solicitations
- Guidance on proposal preparation, including assessments of technical objectives and hypotheses, and drafting supporting documents Detailed technical reviews of proposals with extensive feedback
- Review and edits on draft and final versions
- How-to information on agency registrations and electronic submission
- Post-submission support, from filing assurances and developing in-house grant support systems, to proposal revision and resubmission

SBIR IMPACT

Electronic Submission

GRANTS.GOV℠

SBIR IMPACT

Electronic Submission

- Three rules:
  - You must be REGISTERED
  - You must submit ON TIME
  - You must VERIFY

SBIR IMPACT

Registrations

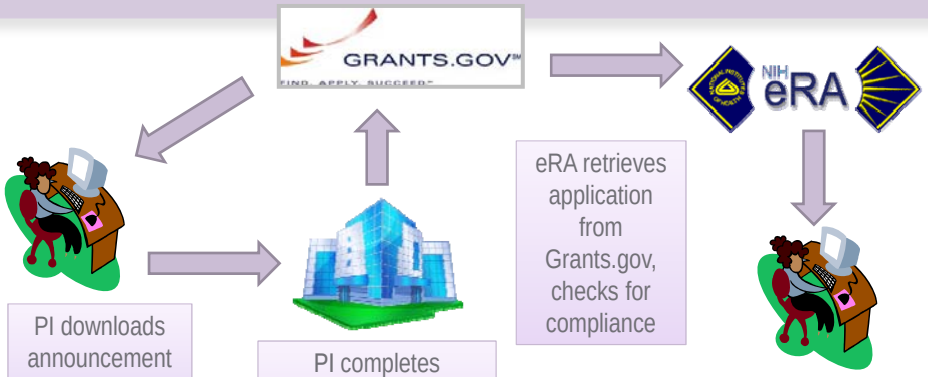
All organizations submitting proposals to NIH must have the following:

- Prerequisites:
  - EIN – Employee Identification Number (IRS)
  - DUNS – Data Universal Number (D&B)
  - SAM – System for Award Management

- THREE REGISTRATIONS
  - Grants.gov
  - NIH Electronic Research Administration (eRA Commons)
  - SBIR.gov – Company registry

SBIR IMPACT

Overview of Electronic Application @ NIH



SBIR IMPACT

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System Capability Issues

1 - Adobe Reader

There are software applications that allow you to successfully navigate the Grants.gov pages and complete your application.

Computer	Operating System	Forms Program	Compatible
Mac	10.6.8	Adobe Reader (10.1.4, 11.0.2)	Yes
Mac	Tiger / Leopard	Adobe Reader (8.1.1,8.1.2,8.1.3,8.1.4,8.1.5,8.1.6,9.0,9.1,9.1.1,9.1.2,9.2,9.3.2, 9.4)	Yes
PC	Windows 8	Adobe Reader (10.1.4, 11.0.0.3)	Yes
PC	Windows 7	Adobe Reader (10.1.4, 11.0.2)	Yes
PC	Windows XP	Adobe Reader (8.1.1,8.1.2,8.1.3,8.1.4,8.1.5,8.1.6,8.1.7,9.0,9.1,9.1.1,9.1.2,9.2,9.3.2,9.4, 10.1.4, 11.0.2)	Yes
PC	Windows Vista	Adobe Reader (8.1.1,8.1.2,8.1.3,8.1.4,8.1.5,8.1.6,8.1.7,9.0,9.1,9.1.1,9.1.2,9.2,9.3.2,9.4, 10.1.4, 11.0.2)	Yes

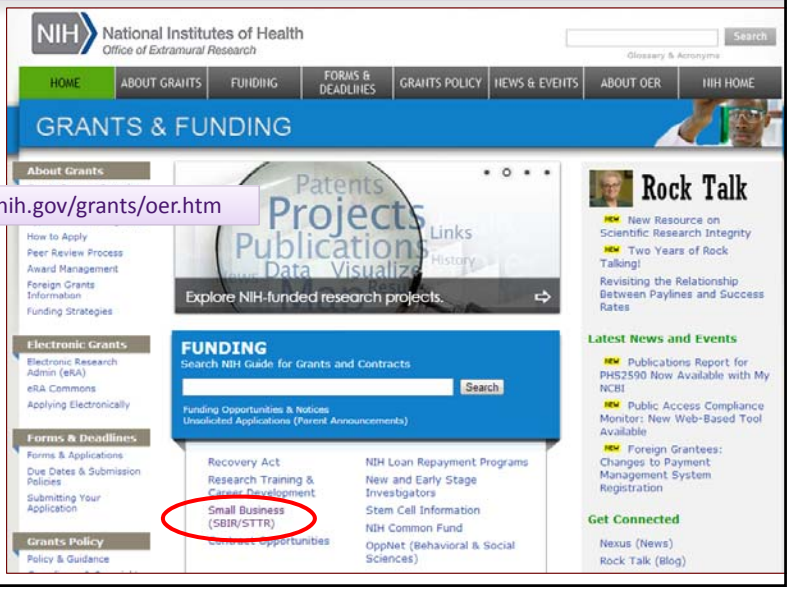
http://www.grants.gov/web/grants/support/technical-support/recommended-software.html

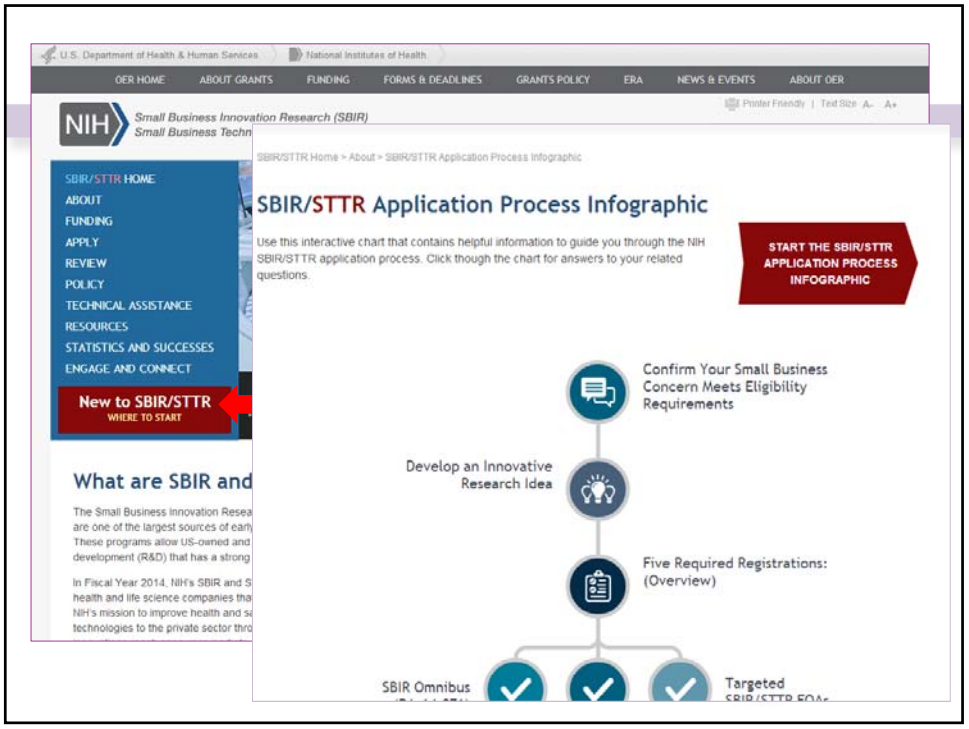
2 – Browser: Use Internet Explorer to be safe!

SBIR IMPACT

Find & Download Opportunity

http://grants.nih.gov/grants/oer.htm

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ABOUT GRANTS
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GRANTS POLICY
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NEWS & EVENTS
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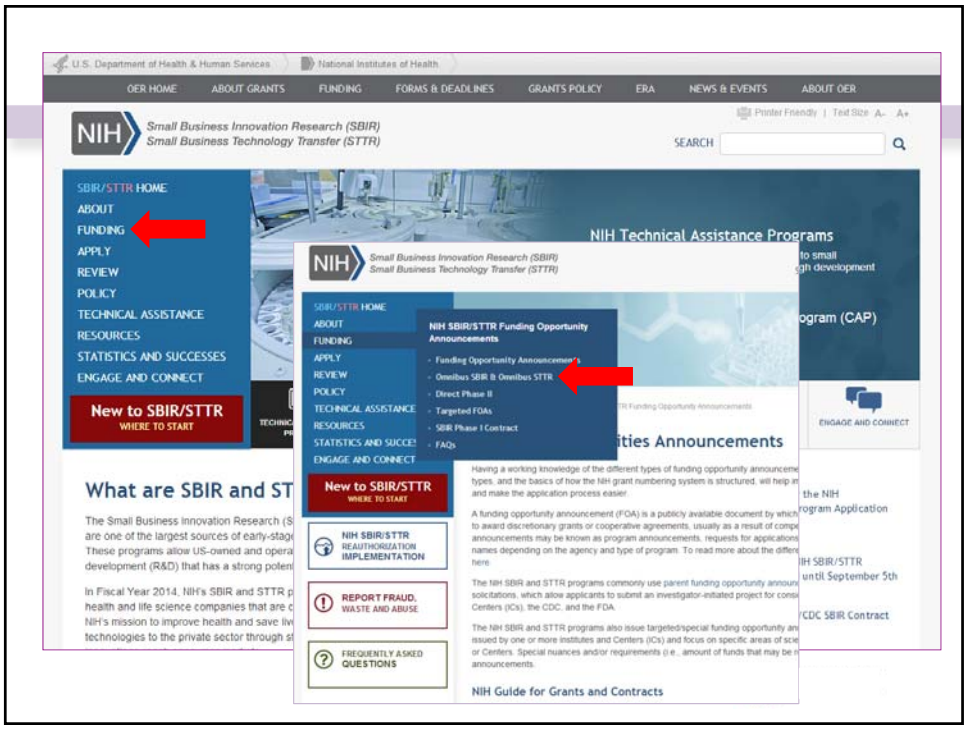
NIH
Small Business Innovation Research (SBIR)
SBIR/STTR HOME
ABOUT
FUNDING
APPLY
REVIEW
POLICY
TECHNICAL ASSISTANCE
RESOURCES
STATISTICS AND SUCCESSES
ENGAGE AND CONNECT
New to SBIR/STTR
WHERE TO START
What are SBIR and
SBIR/STTR Home > About > SBIR/STTR Application Process Infographic
SBIR/STTR Application Process Infographic
Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click though the chart for answers to your related questions.
START THE SBIR/STTR APPLICATION PROCESS INFOGRAPHIC
Confirm Your Small Business Concern Meets Eligibility Requirements
Develop an Innovative Research Idea
Five Required Registrations: (Overview)
SBIR Omnibus
Targeted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Small Business Technology Transfer (STTR)
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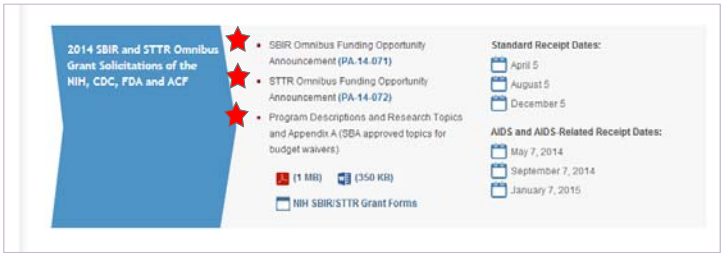
ENGAGE AND CONNECT
New to SBIR/STTR
WHERE TO START
NIH Technical Assistance Programs
NIH SBIR/STTR Funding Opportunity Announcements
Omnibus SBIR & Omnibus STTR
Direct Phase II
Targeted FOAs
SBIR Phase I Contract
FAQs
ities Announcements
NIH SBIR/STTR REAUTHORIZATION IMPLEMENTATION
REPORT FRAUD, WASTE AND ABUSE
FREQUENTLY ASKED QUESTIONS
NIH Guide for Grants and Contracts
ENGAGE AND CONNECT

NIH SBIR/STTR Omnibus Solicitation



SBIR IMPACT
BIO AND HEALTH TECH NYC

PHS 2014-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF (Parent SBIR [R43/R44])

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) Administration for Children and Families (ACF)
Components of Participating Organizations	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) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Funding Opportunity Title	PHS 2014-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])
Activity Code	R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track
Announcement Type	Reissue of PA-13-224
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PA-14-071
Companion Funding Opportunity	PA-14-072 STTR R41/R42- Phase I, Phase II, and Fast-Track
Number of Applications	See Section III. 3. Additional Information on Eligibility
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.081, 93.084, 93.105, 93.113, 93.121, 93.135, 93.156, 93.172, 93.173, 93.213, 93.233, 93.242, 93.262, 93.273, 93.279, 93.283, 93.286, 93.307, 93.350, 93.351, 93.361, 93.393, 93.394, 93.395, 93.396, 93.399, 93.595, 93.647, 93.837, 93.838, 93.839, 93.941, 93.846, 93.847, 93.853, 93.855, 93.856, 93.859, 93.865, 93.866, 93.867, 93.879, 93.977
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) issued by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Administration for Children and Families (ACF) invites eligible United States small business concerns (SBCs) to submit Small Business Innovation Research (SBIR) grant applications. United States SBCs that have the research capabilities and ... NIH, CDC, FDA or ACF awarding components identified in this FOA are encouraged to ... PHS 2014-2 SBIR/STTR Program Descriptions and Research Topics for NIH, CDC,

http://grants.nih.gov/grants/guide/pa-files/PA-14-071.html

Key Dates

Posted Date	January 17, 2014
Open Date (Earliest Submission Date)	March 5, 2014
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.

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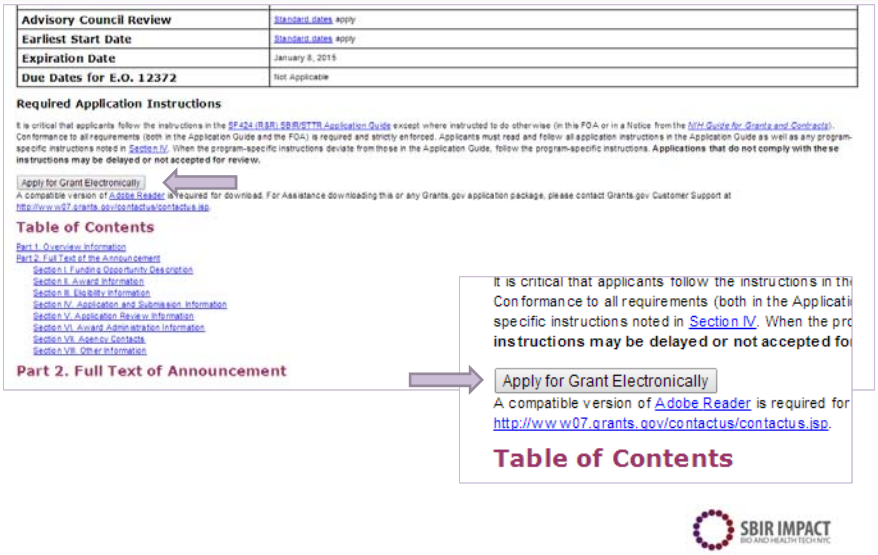
NIH PHS 2014-02 Omnibus Solicitation



Advisory Council Review	Standard dates apply
Earliest Start Date	Standard dates apply
Expiration Date	January 8, 2015
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) SBIR/STTR Application Guide except where instructed to do otherwise (in this FOA or in a Notice from the NIH Guide for Grants and Contracts). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Apply for Grant Electronically

A compatible version of Adobe Reader is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://www07.grants.gov/contactus/contactus.jsp.

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Part 1. Overview Information
Part 2. Full Text of the Announcement
Section I. Funding Opportunity Description
Section II. Award Information
Section III. Eligibility Information
Section IV. Application and Submission Information
Section V. Application Review Information
Section VI. Award Administration Information
Section VII. Agency Contacts
Section VIII. Other Information

Part 2. Full Text of Announcement

It is critical that applicants follow the instructions in th
Conformance to all requirements (both in the Applicati
specific instructions noted in Section IV. When the pro
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Apply for Grant Electronically

A compatible version of Adobe Reader is required for
http://www07.grants.gov/contactus/contactus.jsp.

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Forms Package: B2 or not B2?

Registrations in Multiple Federal Systems are Required to Submit

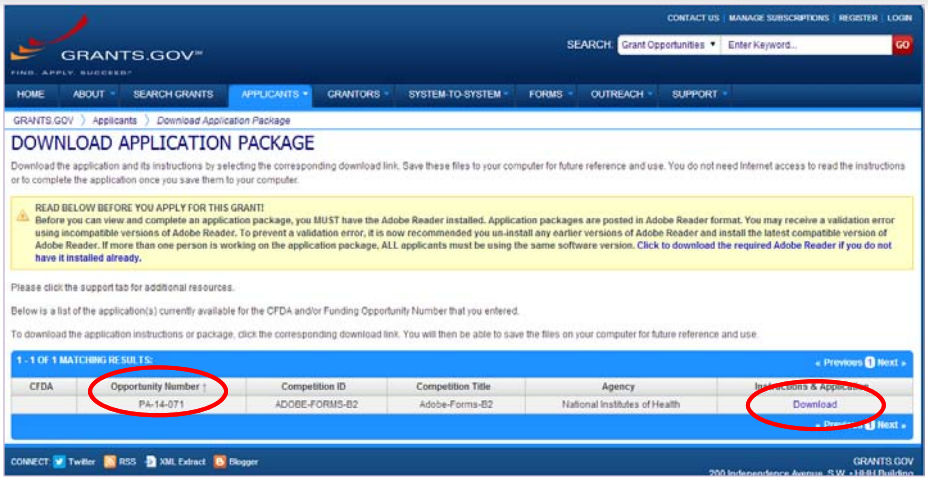
See Registrations for details.

New SBIR/STTR Requirement: SBIR/STTR applicants also must be registered in the SBA Company Registry. See FOA instructions on how to register and how to attach proof of registration to your application package.

All registrations must be completed and active to apply. System for Award Management (SAM) registration must be renewed annually. It may take 6 weeks to complete all registrations. We urge you to complete all registrations and renewals as soon as possible.

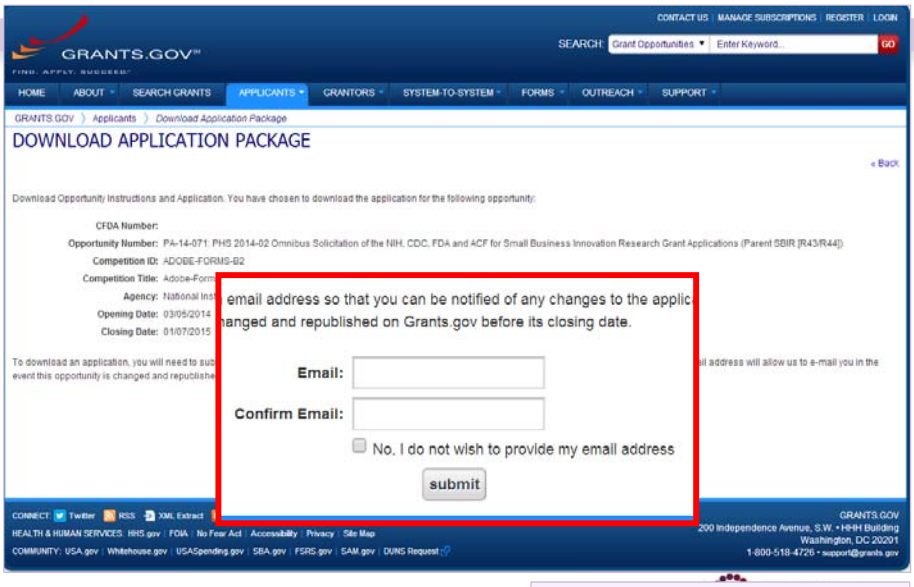
Proceed to Application Download Screen

Download application package

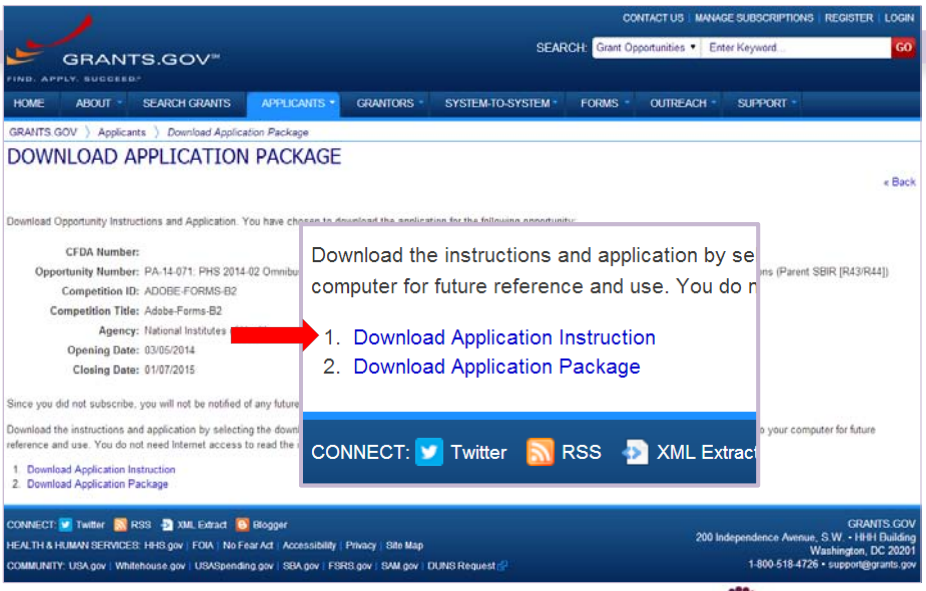


Check Opportunity Number

Click to Download Instructions and Application



Sign-up for Agency updates to FOA



Download Application Guide

SF424 (R&R) SBIR/STTR Application Instruction Links for ADOBE-FORMS-B Application Packages

The application guide and supplemental instructions for this Funding Opportunity Announcement are located at the following links in either MS Word or PDF format. Applicants are encouraged to return to these links for the most current revision of these instructions.

- Part I: Instructions for Preparing and Submitting an Application (MS Word) (PDF)
- Part II: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan & Part III: Policies, Assurances, Definitions, and Other Information (MS Word) (PDF)

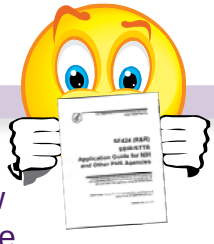
General Information and Help Links

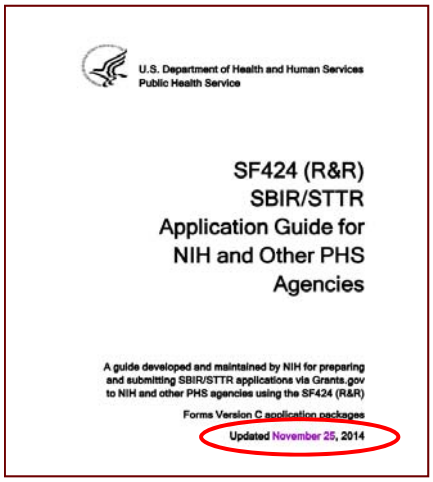
- General information on Applying Electronically
- Finding Help

Free Software Downloads

- Grants.gov Download Software Page

NIH SBIR/STTR Application Guide





U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R)
SBIR/STTR
Application Guide for
NIH and Other PHS
Agencies

A guide developed and maintained by NIH for preparing and submitting SBIR/STTR applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

Forms Version C application packages

Updated November 25, 2014

- Read and follow application guide instructions
- Agency-specific instructions are marked with the HHS logo

SBIR IMPACT

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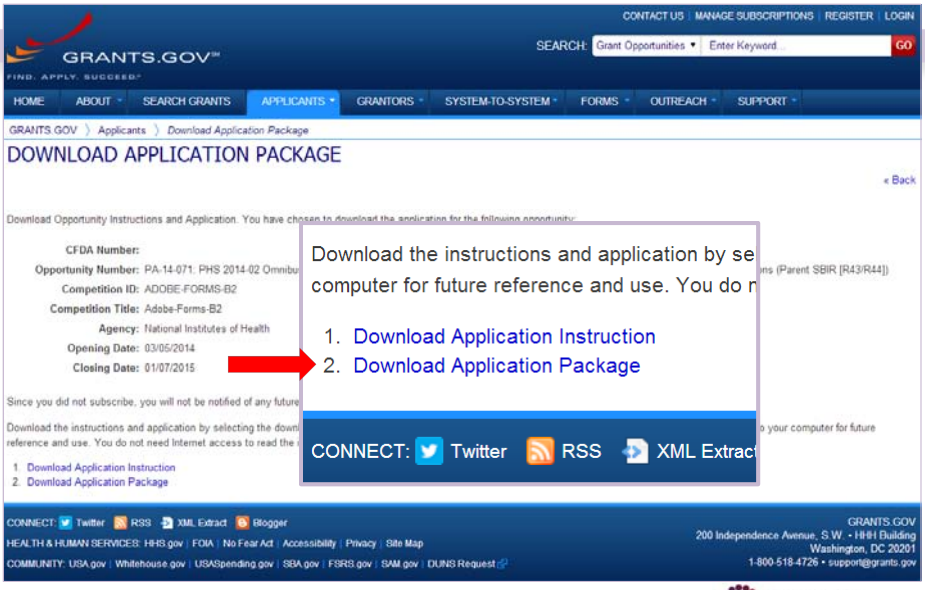
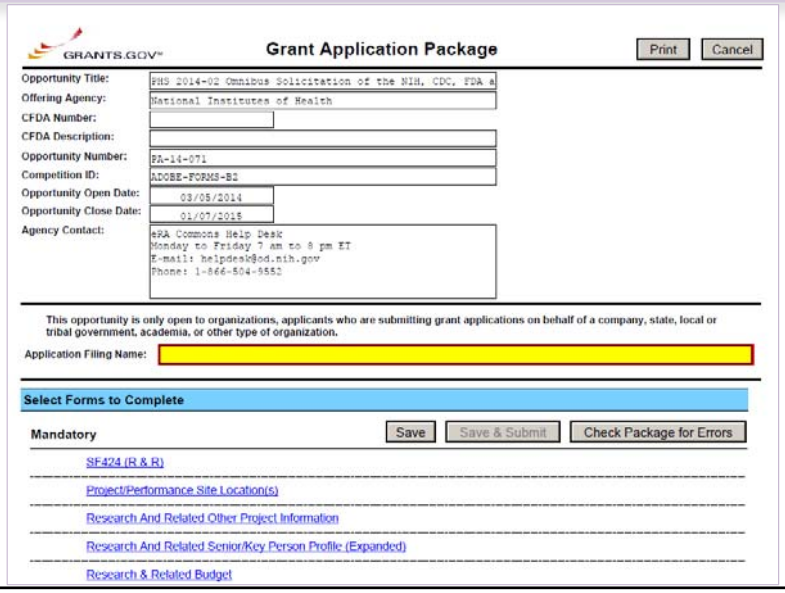


SBIR IMPACT

Grant Application Package



GRANTS.GOV™ **Grant Application Package** Print Cancel

Opportunity Title:	PHS 2014-02 Omnibus Solicitation of the NIH, CDC, FDA a
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PA-14-071
Competition ID:	ADOBE-FORMS-B2
Opportunity Open Date:	03/05/2014
Opportunity Close Date:	01/07/2015
Agency Contact:	eRA Commons Help Desk Monday to Friday 7 am to 8 pm ET E-mail: helpdesk@od.nih.gov Phone: 1-866-504-9552

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name:

Select Forms to Complete

Mandatory — Save | Save & Submit | Check Package for Errors

- SF424 (R & R)
- Project/Performance Site Location(s)
- Research And Related Other Project Information
- Research And Related Senior/Key Person Profile (Expanded)
- Research & Related Budget

NIH SBIR/STTR Components - Attachments

- Introduction to Application
- Specific Aims
- Research Strategy:
  - Significance
  - Innovation
  - Approach
- Inclusion Enrollment Report
- Progress report/Publication List (Phase II proposals only)
- Protection of Human Subjects
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan

- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Appendix
- Bibliography and Refs Cited
- Project Summary/Abstract
- Public Health Relevance Statement/Narrative
- Senior/Key Person Profiles
  - Biographical Sketches
- Facilities and Other Resources
- Equipment
- Project Budget
- Subaward Budget
- Cover Letter
- Commercialization Plan

SBIR IMPACT BIO AND HEALTH TECH NYC

	Company	Subcontractors	Consultants	Others
Introduction (resub)	?			
Project Narrative	√			
Abstract	√			
Specific Aims	√			
Research Strategy	√	◊	◊	?
Human Subjects	√	?		
Vertebrate Animals	√	?		
Bibliography	√	?	?	
Budget	√	√	◊	?
Budget Justification	√	√		
Biographical Sketches	√	√	√	?
Facilities & Resources	√	√		?
Equipment	√	√		?
Select Agents	√	?		
Subcontactor Arrangements	√	√		
Letters of Support		√	√	?
Cover Letter	√			
Commercialization Plan (PH II)	?			
Forms	√			

NIH Proposal Attachments Checklist

PHS 398 Research Plan:

- ❑ 1. Introduction to Application *(Resubmissions only)*
- ❑ 2. Specific Aims *(max 1 page)*
- ❑ 3. Research Strategy *(6 pages Phase I, 12 pages Phase II)*
  - ❑ 4. Inclusion Enrollment Report *(for projects with clinical research only)*
  - ❑ 5. Progress Report Publication List *(Renewal applications only)*
  - ❑ 6. Protection of Human Subjects
  - ❑ 7. Inclusion of Women and Minorities
  - ❑ 8. Targeted/Planned Enrollment Table
  - ❑ 9. Inclusion of Children
  - ❑ 10. Vertebrate Animals (*only if you are using Vertebrate Animals)*

SBIR IMPACT BIO AND HEALTH TECH NYC

NIH Proposal Attachments Checklist

PHS 398 Research Plan:

- 11. Select Agent Research *(if you are using anything hazardous)*
- 12. Multiple PD/PI Leadership Plan *(if you have Multiple PIs)*
- 13. Consortium/Contractual Arrangements *(if you have any subawards)*
- 14. Letters of Support *(from consultants, subcontractors, commercial partners)*
- 15. Resource Sharing Plan(s) *(if you are developing model organisms or receiving > $500k direct costs per year)*
- 16. ~~Appendix~~ *(Typically **no appendices** are allowed for an SBIR/STTR)*

SBIR IMPACT

NIH Proposal Attachments Checklist

SBIR/STTR Information

- 7. Commercialization Plan *(for Phase II and Fast-track proposals only)*
- 8. Commercialization History (*If you have received previous SBIR Phase II awards)*

RESEARCH & RELATED Other Project Information

- 7. Project Summary/Abstract *(must be < 30 lines)*
- 8. Project Narrative (*2-3 sentences on how your project will improve the national health)*
- 9. Bibliography/References
- 10. Facilities & Resources
- 11. Equipment
- 12. Other Attachments *(rarely should you attach anything here)*

SBIR IMPACT

NIH Proposal Attachments Checklist

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

- Biosketch for each Senior/Key person

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1

- K. Budget Justification *(for company)*

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

- *Subaward Budget Justification*

PHS Cover Letter

- PHS Cover Letter *(Request Study Section and Institute Assignment)*

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Timing…

- Applications will be considered "on time" as long as submitted error free to Grants.gov on or before 5pm local time
- Prior to submission date:
  - Make corrections & resubmit through Grants.gov
- After submission date:
  - Application is considered late

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Electronic Submission Advice

- Don't wait until last minute to submit
- Don't rely on email
  - Be proactive in checking verifications
- Do be patient
  - Expect errors and warnings
  - Build in time to fix what is wrong
- Do print and save the application
- Do keep the tracking and accession numbers

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Make Sure To...

Process Overview

- **Register early!** Registration at both Grants.gov and eRA Commons is required, can take 8 weeks or more and MUST be completed before the submission deadline. Learn more.
  - Verify that your organization is registered with the new System for Award Management (SAM). You must maintain an active entity registration. **This registration must be renewed annually through the SAM.gov web site.** Use the SAM.gov "Manage Entity" function to manage your entity registrations. See the Grants Registrations User Guide at https://www.sam.gov for additional information.
- **Carefully follow the requirements** found in the application guide and funding opportunity announcement. Instructions in the FOA supersede those found in the application guide.
- **Check your application** for common errors before you submit (use our Annotated Forms for extra tips).
- **Correct any errors or warnings** before the submission deadline.
- **Verify that your application is viewable in the eRA Commons.** If you cannot view the application in the Commons, NIH can't review it!
- **Submit early.** The best way to reduce stress and ensure successful submission is to submit well ahead of the due date.

NIH Help Resources

Electronic Submission

- Registrations **(IMPORTANT! May take at least 6 weeks, so register early!)**
- SF424 (R&R) Application and Electronic Submission Information - **Instructions for Preparing an SBIR or STTR Application**
- Applying Electronically
- ERA Commons
- SBA Company Registry
  - New requirement - See Section IV. Application and Submission Information, "SF424(R&R) Other Project Information Component" in the SBIR/STTR Application Guide for NIH and other PHS Agencies for instructions on how to register and how to attach proof of registration to your application package. Applicants must have a DUNS number to complete this registration. SBA Company registration is NOT required before SAM, Grants.gov or eRA Commons registration.
- Annotated SF424 Form set for SBIR/STTR applications
- eSubmission Tips for Small Businesses (PDF)
- Checkpoints for Electronic Submission
- Service Providers
- FAQs
- Avoiding Common Errors

http://grants.nih.gov/grants/funding/sbir.htm

SBIR IMPACT

Need help?

- Use the Help Desks
  - Grants.gov
  - eRA Commons
- Ask BBC
  - kris@bbcetc.com
  - andrea@bbcetc.com
  - 734.930.9741

SBIR IMPACT

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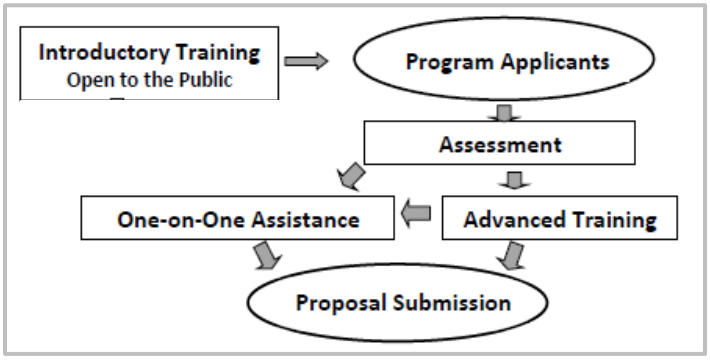
SBIR IMPACT BIO AND HEALTH TECH NYC

An Initiative Of NYCEDC

Managed By bbc Entrepreneurial Training & Consulting

- Program Overview



SBIR IMPACT

SBIR Impact NYC

Training – Open to the public

- On-site SBIR/STTR Introductory Workshops
  - Cycle 1: ABC's of SBIR/STTR Funding, Feb. 2, Columbia University
  - Cycle 2: Full day, May 21, NY Genome Center
  - Cycle 3: ABC's of SBIR/STTR Funding
    NYU Leslie eLab

SBIR IMPACT

SBIR Impact NYC

One-on-one Assistance

- Limited to 20 companies total in 2015
- On-line application
  - 2015: Three cycles

Cycle	1	2	3
Application Deadline	Jan 14	Apr 22	Sep 9
Participants Notified by:	Jan 23	Apr 30	Sep 18

- $500 Fee per Company
  - 1.5 Day Intensive Workshop for multiple company participants (mandatory)
  - Proposal templates and outlines
  - Weekly group webinars
  - 20 hours of one-on-one consulting

SBIR IMPACT BIO AND HEALTH TECH NYC

SBIR Impact NYC

Intensive Training (limited attendance)

- Mandatory participation by SBIR Impact NYC companies (included in program fee)
- Open to deferred applicants ($150 fee to attend)
- 1.5 days
- Detailed instruction on developing competitive SBIR/STTR proposals (Focus on NIH)
  - Cycle 1: February 3-4, Columbia U
  - Cycle 2: May 19-20, NY Genome Center
  - Cycle 3: October 1-2, NYU

SBIR IMPACT BIO AND HEALTH TECH NYC

SBIR Impact NYC

Criteria for acceptance

- Intend to submit an SBIR/STTR application within nine months of being admitted to the program
- Have identified a relevant SBIR/STTR solicitation and/or agency
- Participate in an assessment call
- Meet SBIR program eligibility requirements
- Have secured a qualified Principal Investigator
- Have identified suitable R&D space
- Are working on an appropriate project with scientific and commercial viability
- Meet NYC geographic and technology sector requirements
- Commit to attend one of the advanced training sessions
- Commit to meet the one-on-one consulting proposal development timelines

SBIR IMPACT BIO AND HEALTH TECH NYC

SBIR IMPACT BIO AND HEALTH TECH NYC

Assistance for NYC Bio & Health Tech Ventures

Intro to SBIR/STTR & NIH Proposal Prep Workshop

May 21, 2014

Becky Aistrup

www.sbirnyc.com

734.930.9741

An initiative of

NYCEDC
New York City Economic Development Corporation

Managed by

bbc Entrepreneurial Training & Consulting