Day 1 Agenda

- SBIR/STTR Introduction
- Selecting the Right Agency
- NSF and DoD SBIR/STTR Overview
- NIH Proposal Preparation
- Grantsmanship

Why SBIR/STTR?

Are You Walking Away from Free Money?
Where does SBIR/STTR Fit?

Component of a Funding Strategy

- Debt
- Equity
- Non-Dilutive

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
Goal of SBIR/STTR Programs

a.k.a. “Come Back When”
Capital converts ideas into innovation
Federally funded research creates new ideas
No Capital
Innovation into commercial products


What is SBIR/STTR....

- Mandated by legislation (NDAA FY2017)
  - Current authorization through 2022
  - 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
Some details

- Mandatory set aside % of Extramural R&D budget
  - SBIR 3.2% of outside R&D if over $100M
  - STTR 0.45% of outside R&D if over $1B
- Allows applicant to switch from SBIR to STTR or vice versa between Phase I and II
  - At agency discretion
- Allows overlapping proposals to be submitted, but must accept only one
- Funding “guidelines” vs funding “caps”**
  - Guidelines $150k Phase I; $1 million Phase II
  - Caps up to 150% of guidelines, or
    - $225k Phase I
    - $1.5 million Phase II

** Refer to individual agency solicitations for specific funding guidelines and limits

11 Participating Federal Agencies

<table>
<thead>
<tr>
<th>SBIR/STTR</th>
<th>SBIR Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>DoD - $1.4 B</td>
<td>USDA - $20 M</td>
</tr>
<tr>
<td>HHS - $797 M</td>
<td>DHS - $18 M</td>
</tr>
<tr>
<td>DOE - $206 M</td>
<td>DOT - $8 M</td>
</tr>
<tr>
<td>NSF - $180 M</td>
<td>DOC - $8 M</td>
</tr>
<tr>
<td>NASA - $176 M</td>
<td>ED - $8 M</td>
</tr>
<tr>
<td></td>
<td>EPA - $4 M</td>
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</tbody>
</table>
The Basics of SBIR: 3 Phases

3 Years, ~$1,150,000+

Phase I: 6-12 Months*, $150K*

Phase II: 2 Years*, ~$1,000 K+*

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

* Specifics agency dependent

SBIR/STTR: Planning 3 Phases

Goals

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

- Phase II Goal = Further R&D
  - How far? You decide based on...

- ULTIMATE GOAL= COMMERCIALIZATION!
Introduction to SBIR/STTR

Assumptions

- There is, or will be, a small business
- The small business is developing products
- The products are based on technological innovation
- The small business has, or will have, research facilities
- The small business has, or will have, research personnel employed

*to be defined...

Key Questions...

- **The Project**
  - What do you need the money for?
- **The Company** (there has to be one…)
  - 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?
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?

Commercialization

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

SBIR/STTR Programs

Learn the Rules!
The Company – QUESTIONS:

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

Eligibility for Funding

**ASSESSED AT TIME OF AWARD**

**Small business:**

- For-profit
- U. S. owned and controlled
- < 500 employees
- 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

  """""""""""""""""""""""""""

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

SBIR & STTR Size Regulations

Size and Affiliation

- Under 500 employees for SBIR applicant and its affiliates including:

  - 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
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: 3.2% in 2018
  - STTR: 0.45% 2018

Primary difference is in the 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

However – in either case:
The Applicant Organization is always the Small Business!
**SBIR vs. SBIR**

<table>
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<tr>
<th>SBIR</th>
<th>STTR</th>
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<tr>
<td>Applicant is ALWAYS the Small Business Concern (SBC)</td>
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<tr>
<td>Allows outsourcing*</td>
<td>Requires outsourcing*</td>
</tr>
<tr>
<td>• Requires outsourcing*</td>
<td>• 1° subcontractor must be a non-profit research institution</td>
</tr>
<tr>
<td>Maximum outsourcing limits</td>
<td>Minimum participation requirements</td>
</tr>
<tr>
<td>• ≤ 33% of Phase I</td>
<td>• ≥ 40% by SBC</td>
</tr>
<tr>
<td>• ≤ 50% of Phase II</td>
<td>• ≥ 30% by SBC 1° subcontractor</td>
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<tr>
<td><strong>Company MUST have</strong></td>
<td><strong>“company controlled R&amp;D facilities suitable to do work proposed”</strong></td>
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<tr>
<td>PI must be employed by SBC</td>
<td>PI may be employed by SBC or 1° Subcontractor</td>
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<tr>
<td>• &gt; 50% of full time equivalent</td>
<td>• &gt; 50% of full time equivalent</td>
</tr>
<tr>
<td></td>
<td>• ≥ 10% effort on project</td>
</tr>
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</table>

*outsourcing includes work done by subcontractors and consultants

**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

**OFFICE SPACE FOR RENT**
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)*

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
If you’re coming from a University consider…

- Intellectual Property Policy
  - Invention disclosure
  - Ownership
  - Rights to use
- Consulting opportunities
- Conflict-of-interest policy
- Communicate with Tech Transfer

Possible Academic Roles

- Advisor
- Consultant
- Collaborator/Subcontractor
  - Faculty member can be PI’s of subcontracts
  - Faculty member can provide analytical and other support services
- PI
  - of STTR project (except for NSF)
  - of SBIR project (with appropriate leave of absence)
- Inventor
- Founder
  - Faculty member can own small company & identify someone else (well-qualified) as PI

*subject to institution-specific policies
DO YOUR HOMEWORK

Strategic Approach to Project Planning

1. Define/position your product development project
2. Understand “state of the market” & “state of the science”
3. Develop a credible commercialization plan
4. Identify candidate agencies
5. Understand agency mission & research priorities
6. Prepare agency-appropriate exec summary
7. Communicate with agency program staff
Know Your Customer (Agency)

- Which agencies have previously funded projects in your technology area?
  - Do they continue to fund such projects?
- What strategic agency need would your project idea address?
- Does the Program Manager/TPOC* consider your proposed project responsive to an agency priority?
- How and by whom are funding proposals evaluated?

*Technical Point of Contact

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SBIR Information: SBIR.gov

- Links to all 11 agencies
- Search past awards
- Current/past solicitations
  
  www.sbir.gov
Microneedle Delivery of Zanamivir for Treatment of Influenza Infections

Abstract: Yearly influenza epidemics strike millions of people causing up to deaths. Fatally caused by seasonal influenza viruses and but with significant mortality in the young and the elderly populations. When a new pathogenic influenza strain enters the population a pandemic could kill tens of millions of people with a negative economic impact estimated to be over.

Development and Demonstration of Virus-Inspired DNA Origami (VIDEO) Vaccines

Paragon Biosciences (PBS) has designed and demonstrated the feasibility of a new hybrid vaccine nanotechnology that is based upon a DNA origami that can include protein antigens or epitopes, immune stimulators, cell targeting ligands and a transfection payload. This approach offers the opportunity for crafting molecule-defining vaccine nanostructures that stimulate a specific immune response that...

Aerolized Vaccine Dose Analysis (AVIDA) System

To address the need for an instrument to detect aerolized-droplet dose delivery of vaccines, Physical Optics Corporation (POC) proposes to develop a new Aerolized Vaccine Dose Analysis (AVIDA) system based on the combination of planar laser-induced fluorescence, laser diffraction, microscope optics, and an advanced image processing algorithm. This system, using temporal video output, p...
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/STTR Deadlines

OPEN SOLICITATIONS

<table>
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<th>Release</th>
<th>Open</th>
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<td>7-Sep '18</td>
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<td>PA-18-576 PHS 2018-02 STTR-NIH</td>
<td>5-Apr '19</td>
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| Dept. of Defense |         |      |       |
| SBIR 2018.2 and STTR 2018 B | 20-Apr '18 | 22-May '18 | 20-Jun '18 |

| U.S. Dept. of Transportation (DOT) |         |      |       |
| FY 2018 SBIR | 2-Jan '18 | 17-Jan '18 | 20-Mar '18 |

| Dept. of Commerce – Nat'l. Institute of Standards and Technology |         |      |       |
| SBIR FY 2018 Phase I | 18-Jan '18 | 18-Jan '18 | 4-Apr '18 |

| Nat'l Science Foundation |         |      |       |
| SBIR 18-550 STTR 18-551 | 14-Mar '18 | 14-Mar '18 | 14-Jun '18 |

Open = Earliest Submission Date Close = Final Submission Date Updated 3.15.17

TYPICAL PHASE 1 RELEASE AND CLOSE DATES

<table>
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<th>Agency/Program</th>
<th>Release</th>
<th>Close</th>
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<tbody>
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<td>Dept. of Commerce (DOC)</td>
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<tr>
<td>NIST</td>
<td>January</td>
<td>March</td>
</tr>
<tr>
<td>NOAA</td>
<td>November</td>
<td>February</td>
</tr>
</tbody>
</table>

| Dept. of Defense (DOD) |         |       |
| Release 1/A | December | February |
| Release 2/B | April | June |
| Release 3/C | August | October |

| Dept. of Education (DOE) |         |       |
|                         | December | February |

| Dept. of Energy (DOE) |         |       |
| Release 1 | August | October |
| Release 2 | November | February |

| Dept. of Health/Human Services (HHS, CDC, FDA) |         |       |
| Omnibus Stand Date 1 | June | 5-Sep |
| Omnibus Stand Date 2 | June | 5-Jan |
| Omnibus Stand Date 3 | June | 5-Apr |
| Special Topics | Various | Various |
| Contracts | August | October |
| NIDDK | May | June |

| Dept. of Homeland Security (DHS) |         |       |
| S&T and DNDG joint | November | January |

| Dept. of Transportation (DOT) |         |       |
| Environmental Protection Agency (EPA) |         |       |
| Nat'l. Aeronautics and Space Admin. (NASA) |         |       |
| Nat'l. Science Foundation (NSF) |         |       |
| Release 1 | October | December |
| Release 2 | April | June |
| U.S. Dept. of Agriculture (USDA) |         |       |

*Estimated based on past schedules. All dates subject to change without notice.*
Grants vs. Contracts….

WHOSE IDEA IS IT ANYWAY?

Agency Differences -- Grants vs. Contracts

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

**Contracts**
- Procurement
- Well-defined, legally binding statement of work, obligations, responsibilities
- Specific deliverables defined
- Topic Specific Response
- Agency contact limited
- Phase III opportunities
Agency Differences -- Grants vs. Contracts

- **Grants – Investigator Initiated Topics**
  - HHS (95% $$), NSF, USDA, DOE, ED
  - 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

Agency Differences -- Review Process

- **Internal Review**
  - DoD, NASA, 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
For More Agency Information

- **SBIR/STTR Innovation Summit**
  - May 14-16, 2018
  - Anaheim, CA

- **NIH SBIR/STTR Conference**
  - November 30 – December 1, 2018
  - Dallas, TX

How to be Competitive in SBIR/STTR

- Understand the goals of the Agency
- Understand and address the agency’s review criteria
- Convene a strong team
- Identify appropriate facilities and resources
- Develop and follow a strategic plan
- Follow the rules
- Complete your registrations
- Submit Early!
Mission of NSF

The mission of The National Science Foundation is to promote the progress of science; to advance the national health, prosperity, and welfare; and to secure the national defense.
Key Points About NSF

- NSF is a “granting” agency
  - Investigator-initiated projects
  - Peer reviewers evaluate proposals
- Both SBIR and STTR programs
- Two deadlines annually (June & December)
- Strong emphasis on commercialization

What Does NSF SBIR Fund?

- We fund **high-risk, high-payback** innovations
  - With the potential for commercialization
  - That demonstrate strategic partnerships with research collaborators, customers, industry partners, and equity investors
- We do NOT fund
  - Basic research
  - *Evolutionary* optimization of existing products and processes or modifications to broaden the scope of an existing product, process or application
  - Analytical or “market” studies of technologies
What Does NSF SBIR/STTR Fund?

- "High Degree of Technical Risk"
  - Has never before been attempted or successfully done
  - Is still facing technical hurdles
- "Potential for Significant Commercial Impact"
  - A product-market fit… validated by customers
  - Can potentially disrupt target market segment
  - Presents competitive barriers-to-entry
  - Offers potential societal benefits via commercialization

NSF SBIR Program Interests

**Twelve Broad Topics**

- Advanced Manufacturing and Nanotechnology (MN)
- Advanced Materials and Instrumentation (MI)
- Biological Technologies (BT)
- Biomedical Technologies (BM)
- Chemical & Environmental Technologies (CT)
- Educational Technologies & Applications (EA)
- Electronic Hardware, Robotics & Wireless Technologies (EW)
- Information Technologies (IT)
- Internet of Things (I)
- Other Topics (OT)
- Semiconductors (S) & Photonic (PH) Devices & Materials
- Smart Health (SH)

[https://seedfund.nsf.gov/portfolio/](https://seedfund.nsf.gov/portfolio/)
NSF SBIR/STTR Solicitation Schedule

<table>
<thead>
<tr>
<th>Program</th>
<th>Release Date</th>
<th>Accept Proposals</th>
<th>Closing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release 1</td>
<td>March</td>
<td>May</td>
<td>June</td>
</tr>
<tr>
<td>Release 2</td>
<td>September</td>
<td>November</td>
<td>December</td>
</tr>
</tbody>
</table>

- **2018 Deadlines:**
  - June 14, 2018 (NSF SBIR 18-550, STTR 18-551)
  - December 2018

- **Phase II Deadlines**
  - Approximately 8, 14, or 20 months after effective date of the Phase I award
  - Phase I award letter will include exact date

NSF: How to Apply
https://seedfund.nsf.gov/apply/

1 See what we fund

Criteria
Here are the criteria we use to determine which companies to fund:

- **Game-changing**: Your innovation could make a difference to people worldwide or revolutionize an industry.
- **High-risk**: Your product is based on unproven technology that needs further testing (and funding for that testing).
- **Market pull**: You have evidence that your product or service could meet an important, unmet need for your customers.
- **Scale**: If you successfully bring your product or service to market, it could form the foundation for a scalable business and make a large impact in your target market.

Portfolio
Check out our portfolio to see what companies we’ve recently funded.

Technology topic areas
Review this list of technology topic areas (sectors we fund) to see which best aligns with your company’s work. If none of the technology topic areas quite reflects your work, but you feel your company is otherwise a good fit, you can apply under the Other Topics (OT) category.

- Advanced Manufacturing and Nanotechnology (MN)
- Advanced Materials and Instrumentation (AMI)
- Biological Technologies (BT)
- Biomedical Technologies (BT)
- Chemical and Environmental Technologies (CET)
- Educational Technologies and Applications (ET)
- Electronic Information, Robotics and Wireless Technologies (EIRW)
- Information Technologies (IT)
- Internet of Things (IoT)
- Semiconductors (S) and Photonic Devices and Materials (PDM)
- Smart Health (SH)
- Other Topics (OT)

Download a searchable PDF of the full list of technology topic areas that also includes descriptions of the subtopics.

NSF: How to Apply
https://seedfund.nsf.gov/apply/
Portfolio

Since 2012, America's Seed Fund powered by NSF has made nearly 2,500 awards to startups and small businesses. Since 2010, our awardees have had 62 exits and have received $3.2 billion in private investment. We encourage you to explore this list of assorted companies we've funded.

Search America's Seed Fund awardees

FEATURED ALUMNI AND EXITS

Perismon Technologies Corporation
Eeko Bionics, Inc.
Bioso Scientific Corporation
IntraLase Corporation

Jasa (formerly Tixeagle, Inc.)
Novan, Inc.
Bludef Lab, Inc.

NSF Portfolio 30 Biological Technologies (BT)

Company Location

Advidia Corporation
Advanced Biological Marketing, Inc.
APPLIED LIFESCIENCES & SYSTEMS, LLC
APSE, Inc.
Arch InnoTek, LLC
Axson Technologies LLC
Biomersa Systems LLC
Calux Inc
Certis, LLC
CienaTech, Inc.
Culture Robotics, Inc
Dextra, Inc
Fermlogia
Genencor Probiotics Inc

Arch InnoTek, LLC

Current awardees: Phase I current awardees

Current awardees are those who are still conducting research related to their Phase I projects, and who haven't yet received the extended seed grant.

30/17/2018
NSF: How to Apply

Program Director listed with each topic

**Biological Technologies (BT)**

**BT1. Agricultural and Food Safety Biotechnology**

New approaches for meeting the world’s future nutritional needs that involve the development of new technology that is primarily based in the biotechnology area. For Plant Biotechnology, target areas for improvement may include (but are not limited to) drought tolerance, improved nutritional value, enhanced disease resistance, and higher yield. Proposers should give consideration to technologies that enhance biodiversity, produce less carbon dioxide, and use less water and fertilizer. For Animal Biotechnology, which includes aquaculture, the target emphasis may include (but is not limited to) animal health and productivity, and reducing environmental impacts. For Food Safety Biotechnology, this may include handling, preparation, and storage of food in ways that prevent foodborne illness, as well as origins of food including the practices relating to food tracking, hygiene, additives, and certification systems.

**BT2. Biosensors**

Biosensors are sensors that contain a biologically-based sensing element. Proposed projects might include (but are not limited to) real-time sensors, microbial component-based sensors, sensors for monitoring fluxes of...
NSF: How to Apply

3 Get pre-submission feedback (optional)

You can send an executive summary to one of our program directors to discuss your work and get feedback. Complete our short executive summary form—a program director will get back to you shortly.
DoD’s SBIR/STTR focus

- Topics are Mission-driven
- Primary focus on the warfighter
  - Some additional service requirements
- Topics across many technologies & products
- Topics and rules are Component-Specific
13 DoD Components Participate

- Air Force
- Navy
- Army
- Missile Defense Agency (MDA)
- DARPA
- Defense Microelectronics Activity (DMEA)
- Defense Health Program (DHP)
- Office of the Secretary of Defense (OSD)
- Chemical & Biological Defense (CBD)
- Special Operations Command (SOCOM)
- Defense Threat Reduction Agency (DTRA)
- Defense Logistics Agency (DLA)
- National Geospatial Intelligence Agency (NGA)

SBIR is 3.2% of RDT&E in FY17
STTR is .45% of RDT&E in FY17
DoD is >50% of Federal SBIR Budget

DoD SBIR/STTR Budget by Component

- SBIR is 3.2% of RDT&E in FY17
- STTR is .45% of RDT&E in FY17
- DoD is >50% of Federal SBIR Budget

**DoD Budget FY16**

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<th>OSD</th>
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<th>DLA/DMEA</th>
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DoD Solicitation Topics

- Only proposals submitted in response to topics in solicitation accepted!
- DoD scientists and engineers author solicitation topics
- Awarding Component
  - Component-specific instructions
  - Unique topics

TPOC/Topic Author

- Technical Point of Contact
  - Responsible for monitoring the technical performance of a contract
  - Often the author of the topics that appear in solicitations; Topic Author is sometimes synonymous with TPOC
  - Can be an excellent champion for the small business
DoD Three-Phase Program

Each component has unique guidelines and rules

- **Phase I awards**
  - Total $100,000 - $150,000
    - $80-150K Base + (if applicable) $50-70K Option
  - Total 6 to 18 months
    - 6-7 mo. Base + (if applicable) 4-6 mo. Option
- **Phase I Option (not used by all components)**
  - May be exercised to fund interim Phase I activities while a Phase II contract is being negotiated
  - Only Phase I efforts selected for Phase II awards are eligible to have the Phase I Option exercised
  - Technical proposal, Cost proposal & Timeline must separate the Base and Option periods
  - It is VITAL to demonstrate feasibility within the Base period

- **Phase II awards**
  - Awarded on the basis of
    - results of Phase I
    - scientific, technical, and commercial merit of Phase II proposal
  - Typically $1,000,000
  - Generally ~ 24 months (subject to negotiation)
  - Expected to produce well-defined deliverable prototype
DoD Three-Phase Program

- Phase II continuation funding is to encourage transition of SBIR research into DoD acquisition programs.
- Phase II Enhancement/Phase II Plus
  - SBIR/STTR matching investment funds the company obtains from non-SBIR/non-STTR sources such as DoD acquisition programs or private sector.
  - Can extend Phase II contract up to 1 yr. and match up to $500K of non-SBIR/non-STTR funds.
  - FastTrack no longer available after 2013.1/2013.A.
- Sequential Phase II
  - Phase II contractor may receive up to one additional, sequential Phase II award for continued work on the project, up to $500K.
- TALK TO YOUR TPOC DURING Phase II.

DoD Three-Phase Program (cont’d)

Phase III

- Commercialization phase
- “Derives from, extends or logically concludes efforts performed under” prior SBIR/STTR funding agreements from any agency.
- Must be funded by sources outside of SBIR/STTR (private sector and/or non-SBIR Government).
- Develop prototype into viable product/service for sale in military and/or private sector markets.
- Within DoD, often initial customer is prime contractor for a major weapon system or program of record”, not DoD directly.
DoD 2018 SBIR/STTR Solicitation Schedules*

<table>
<thead>
<tr>
<th>Program--SBIR &amp; STTR</th>
<th>Topics/Presolicitation</th>
<th>Solicitation Open</th>
<th>Solicitation Close</th>
</tr>
</thead>
</table>

You may communicate directly with the TPOC (Technical Point of Contact) ONLY between Presolicitation & Solicitation Open dates. After that, questions must be posted to DoD’s SBIR/STTR Interactive Topic Information System (SITIS). sbir.defensebusiness.org/topics

*Dates subject to change
Each DOD SBIR/STTR topic contains:

- Topic Number
- Title
- Research & Technical Area
- Topic Author (TPOC)
- Acquisition Program
- Special Considerations
- ITAR Restrictions
- Objective
- Description
- Phase I Requirements
- Phase II Requirements
- Phase III / Dual Use Military and Commercial Applications
- References
- Keywords
DoD SBIR 2015.1 Solicitation Topics

A15-051: Next-Generation Adenovirus Vaccine
A15-052: Novel Adjuvants To Enhance the Immunogenicity of Dengue Vaccine
A15-053: Micron Immunostimulation Using Novel Vectors for Delivery of Proteins or Genes
A15-054: High-Throughput Bacteriophage Isolation and Characterization

DoD SBIR Solicitation Topic Examples

REFERENCE:
1. Food and Drug Administration (FDA). Center for Biologics Evaluation and Research (CBER). Adenovirus 4 and 7 Type 7 Vaccine, Live, Oral. Available at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm247309

Colonel Robert Kinschner
Phone: 601-319-0612
Email: robert.a.kinschner.mil@mail.mil
Talking to the TPOC in the “open” period

- Understand the DoD and component needs stated in the solicitation
  - Do your research before you call
- Develop a brief as a quad chart or white paper to summarize how your technology addresses the need
- Email the TPOC and request a phone discussion
  - Attach the brief you’ve prepared
- Questions to ask
  - Where/how did the topic originate?
  - Is our approach to your problem responsive to the topic solicitation?
  - Is there an identified acquisition program?
    - If not, how do you see this project transitioning to Phase III?
  - What group/lab leads this research topic within the Component?

Insert Topic Title/# Here

- Designate Focus Area(s) here

Problem, Hypothesis and Military Relevance

- State the problem to be studied, or
- State the hypothesis to be tested
- Concisely outline the rationale for the research project
- Describe military relevance (relationship to selected focus area(s) in announcement)
- Describe why your company/technology is appropriate

Proposed Solution

- Describe objectives of the proposed research project
- Summarize the specific aims
- Concisely identify anticipated study outcomes including TRL expected at each Phase
- Brief description of why your company is uniquely qualified to conduct the project
- You may reduce font size if needed, but 12 point minimum is recommended

Timeline and Cost

<table>
<thead>
<tr>
<th>Activities</th>
<th>FY 11</th>
<th>FY 12</th>
<th>FY 13</th>
<th>FY 14</th>
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<tbody>
<tr>
<td>Enter description of major activity or phase 1: insert or delete rows as needed</td>
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<tr>
<td>Enter description of major activity or phase 2: insert or delete rows as needed</td>
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<tr>
<td>Enter description of major activity or phase 3: insert or delete rows as needed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Estimated Budget ($K)

Insert a picture or graphic here that represents the proposed work

PI: Insert PI name here

Org: Insert performing organization name here
NIH SBIR/STTR Program

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
### HHS SBIR/STTR Program Funding - 2017

<table>
<thead>
<tr>
<th>Budget</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>$814 M</td>
<td>$114 M</td>
</tr>
<tr>
<td>CDC</td>
<td>~$9.0 M</td>
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<tr>
<td>FDA</td>
<td>~$1.6 M</td>
<td></td>
</tr>
<tr>
<td>ACF</td>
<td>~$94 K</td>
<td></td>
</tr>
<tr>
<td>*ACL (NIDILRR)</td>
<td>~$2.7 M</td>
<td></td>
</tr>
</tbody>
</table>

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

### 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.
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](http://grants.nih.gov/grants/funding/funding_program.htm)
### NIH SBIR & STTR Grant Activity Codes

<table>
<thead>
<tr>
<th>Activity Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R41 *UT1</td>
<td>Small Business Technology Transfer (STTR) Grants - Phase I</td>
</tr>
<tr>
<td>R42 *UT2</td>
<td>Small Business Technology Transfer (STTR) Grants - Phase II</td>
</tr>
<tr>
<td>R43 *U43</td>
<td>Small Business Innovation Research Grants (SBIR) - Phase I</td>
</tr>
<tr>
<td>R44 *U44</td>
<td>Small Business Innovation Research Grants (SBIR) - Phase II</td>
</tr>
</tbody>
</table>

The U Activity Code is a Cooperative Agreement with substantial NIH involvement.

### NIH SBIR/STTR 3-Phase Program

- **Discovery Phase I**
  - Feasibility
  - Up to $225K
  - 6-12 months

- **Development Phase II**
  - Full R/D
  - Up to $1.5M
  - 2 years

- **Competing Renewal Award Phase IIIB**
  - $3M for up to 3 years
  - Additional R/D
  - Only Some ICs Participate

- **Commercialization Phase III**
  - NIH is not usually the end customer

[Diagram showing the phases and funding details]
Simultaneous submission and review of Phase I & II
• Phase I is awarded
• Milestones/aims of Phase I are assessed by program staff prior to Phase II award

NIH Fast-Track

Are you ready?
- Convincing preliminary data
- Clear, measurable, achievable milestones
- Well-conceived commercialization plan
- Letters of Phase III support/interest
- Track record of commercialization
- Discussed with NIH program staff
NIH Phase IIb Competing Renewal

- SBIR/STTR Phase II awardee
- Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval
- Awards up to $1M/year for up to 3 years
- IC must accept Competing Renewal applications
  - (NIA, NIAAA, NIAID, NICHD, NIDA, NIDCD, NIDDK, NEI, NIGMS, NHLBI, NIMH, NINDS, NCATS, ORIP, NCI)

Contact NIH Program Staff to discuss!

NO Direct to Phase II

- Direct to Phase II is EXPIRED

The Congressional authority for SBIR Direct Phase II has expired.
## Contract Solicitation

**NIH National Institutes of Health**

**Office of Extramural Research**

**Contract Solicitation**

**RRO Contract Solicitation**
**SBIR Phase I Fast-Track**
**Contract Solicitation, PHS 2018-1**

**Closing Date:** October 27, 2017, 6:00PM EDT

**Contracts**

- Acquisition mechanism
- Follows FAR and SBIR Policy Directive
- NOT Investigator Initiated
- Narrow, well defined topics
- RFP: Offeror: Contractor Proposal
- Only contact is Contracting Officer
- eCPS - New (used to be on paper)

**Grants**

- Assistance mechanism
- Follows Grants Policy and SBIR PD
- Investigator Initiated
- Broad or narrow topics
- PA, PAR, RFA: Applicant; Grantee: Application
- Call PO anytime for anything
- SF424, grants.gov, eRA Commons

## sbir.nih.gov

**NIH Technical Assistance Program**

**CELEBRATING OVER 11 YEARS**

**What are SBIR and STTR Programs?**

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

In Fiscal Year 2017, NIH’s SBIR and STTR programs will invest over $2.0 billion dollars into health and life sciences.
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 & STTR Omnibus:
- Released Jan 2018 for due dates:
  - Apr 5 2018
  - Sep 5, 2019, Jan 5 2019, Apr 5 2019
- NEW: Clinical Trials vs. No Clinical Trials options

2018 Omnibus Funding Opportunities
- New Omnibus released in Jan 2018
  - Apr 5, 2018 due date
  - Sep 5, 2018, Jan 5, 2019, Apr 5 2019
2018 Omnibus Funding Opportunities

**FOUR 2018 SBIR/STTR Omnibus Solicitations:**

- **PA-18-574** PHS 2018-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed)
- **PA-18-575** PHS 2018-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] Clinical Trial Not Allowed)
- **PA-18-573** PHS 2018-02 Omnibus Solicitation of the NIH for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Required)
- **PA-18-576** PHS 2018-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] Clinical Trial Required)

**CLINICAL TRIALS or HUMAN SUBJECTS?**

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

**NIH's Definition of a Clinical Trial**

A study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) or procedures (which may include prescribed treatments or rudimentary diagnosis) to evaluate the effects of those interventions or procedures on the subject(s). Your human subjects study may meet the NIH definition of a clinical trial.
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

Targeted SBIR/STTR Solicitations
See individual SBIR/STTR targeted solicitations

Solicitation Information

- Date
- Program Announcement
- Topic
- Description
- Due Date
- Contact Information

SBIR and STTR Funding Opportunities (79 Records - Sorted by Release Date)

<table>
<thead>
<tr>
<th>Announcement Number</th>
<th>Office of Small and Disadvantaged Business Utilization</th>
<th>Due Date</th>
<th>Program Name</th>
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<tbody>
<tr>
<td>PAR-15-022</td>
<td>NIAID</td>
<td>03/02/2018</td>
<td>U44</td>
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<td>PA-15-023</td>
<td>NIH</td>
<td>03/05/2018</td>
<td>U44</td>
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<td>PA-15-031</td>
<td>NIBIB</td>
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<td>PAR-15-017</td>
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<td>02/16/2010</td>
<td>R42</td>
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<tr>
<td>PAR-15-013</td>
<td>NINDS</td>
<td>02/16/2010</td>
<td>R44</td>
</tr>
</tbody>
</table>
SBIR Omnibus Solicitation FOA

PhS 2019-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Applications (Parent SBIR [R43/R44])

Activity Code: N01-OH-00-643
Announcement Type: Notice of PA-17-302
Noted Notices: • Not for Clinical Use
Funding Opportunity Announcement (FOA) Number: PA-18-574

SBIR Omnibus Solicitation PA-18-574: Non-CT

Key Dates
- April 5, 2018
- Sept 5 2018
- Jan 5 2019
- Apr 5 2019

Letter of Intent Due Date(s): Not Applicable

Application Due Date(s): Standard due date by 5:00 PM (local time) of applicant organization.
- Note: Due date is NIBIB/ETT Standard Due Date

Allow adequate time to make any corrections to minor errors in the applications during the submission process by the due date.

Scientific Merit Review: Standard-1-100

Panel/Scientist Review: Standard-2-100

Research Start Date: Standard-2-100

Expiration Date: April 4, 2019
SBIR Omnibus Solicitation PA-18-574: Non-CT

You must find a fit!

SBIR Omnibus Solicitation FOA

Clinical Trial Required
SBIR Omnibus Solicitation PA-18-573: CT Required

If I/C not listed:
- Review SBIR/STTR Solicitations
- Review I/C website
- Contact I/C SBIR/STTR program manager

You must find a fit!

Program Descriptions and Research Topics

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

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

NIH, CDC, and FDA Program Descriptions and Research Topics

SUBMISSION DATES
APRIL 5, 2018, SEPTEMBER 5, 2018, JANUARY 7, 2019, AND APRIL 5, 2019
National Institutes of Health (SBIR and STTR)
Centers for Disease Control and Prevention (SBIR)
Food and Drug Administration (SBIR)
Program Descriptions and Research Topics

TABLE OF CONTENTS

NATIONAL INSTITUTES OF HEALTH (NIH)

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NATIONAL INSTITUTES OF HEALTH (NIH)

4. Budget

NATIONAL INSTITUTES OF HEALTH (NIH)

5. Conclusion

NATIONAL INSTITUTES OF HEALTH (NIH)

6. Acknowledgments

NATIONAL INSTITUTES OF HEALTH (NIH)

7. References

Initial contact person:

Dr. Natalia Kuchin
SBIR/STTR Program Coordinator
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
240-559-2903, Fax: 240-559-2904
Email: natalia.kuchin@nih.gov

For administrative and business management questions, contact:

Ms. Deanna L. Ingersoll
Grants Management Specialist
National Institute of Allergy and Infectious Diseases
240-559-2005, Fax: 240-559-2006
Email:ingersoll.deanna@nih.gov

Ms. Artasha Y. Edron
Grants Management Specialist
National Institute of Allergy and Infectious Diseases
240-559-2005, Fax: 240-559-2006
Email: Artasha.Edron@nih.gov

Initial contact person:
SBIR/STTR Instructions


Annotated Form Set (FORMS-E Series)

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

NIH Reporter

projectreporter.nih.gov
Decoding Your NIH Grant Number

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Activity Code</th>
<th>Institute Code</th>
<th>Serial Number</th>
<th>Support Year</th>
<th>Extension</th>
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<tr>
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<td>12345</td>
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<td>A1</td>
</tr>
</tbody>
</table>

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 = NIAMSS
AT = NCCAM
CA = NCI
DA = NIDA
DC = NICD
DE = NIDCR
DK = NIDDK
EB = NIBIB
ES = NIEHS
EY = NEI
GM = NIGMS
HD = NICHD
HG = NHGRI
HL = NHLBI
LM = NLM
MD = NCMD
MH = NIMH
NR = NINR
NS = NINDS
RR = NCRR
TW = FIC

Unique, up to six digits
Years of Continuous Funding
A1 = resubmission
S1 = supplement
**Title:** Development of an Alzheimer's disease specific antibody biomarker for tau oligomer detection.

**Abstract:** The prevalence of Alzheimer's disease (AD) is increasing worldwide due to demographic shifts and an aging population and currently there are no disease-modifying drugs. It is the most costly disease in the US with a financial burden of over $1 trillion annually in direct costs that is estimated to increase to $2 trillion by 2050. There is an urgent need to halt the development of brain biomarkers for the early detection and staging of AD. This lack of accurate, objective, and well-standardized biomarker is a rate-limiting factor for identifying effective treatments. To date, no specific tau biomarkers have been at high priority due to the high correlation with neurofibrillary tangles within the brain of all patients. Utilizing newly developed exocytometry activity, that is believed to result in the impairment of synaptic function and loss of memory and is in line with the spread of pathology. Oligomeric tau has been demonstrated to be highly predictive of AD and to be detected. The study aims to identify biomarkers at specific time points that can be used to detect the progression of AD. The study will be conducted using exocytometry activity of specific cells in the brain of AD patients and AD patients with early-stage disease. The study will contribute to the development of a new diagnostic tool for the early detection and monitoring of AD.
Budget limit is $150-225K unless.....
National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations

1/1/2018

NIH has received approval from SBA for the topics listed within for budgets greater than $225,000 for Phase I SBIR/STTR awards and greater than $1,500,000 for Phase II SBIR/STTR awards for 2018-2019. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award budget in excess of these amounts. Applicants are also required to follow NIH institute- and Center-specific budget guidance found in all SBIR and STTR funding opportunity announcements.

**NATIONAL CANCER INSTITUTE (NCI)**
A. Therapeutics (e.g. Small Molecules, Biologies, Radiomodulators, and Cell-based Therapies)
B. In Vitro and In Vivo Diagnostics (e.g. Companion Diagnostics and Prognostic Technologies)
C. Imaging Technologies (e.g. Agents, Devices, and Image-Guided Interventions)
D. Devices for Cancer Therapy (e.g. Interventional Devices, Surgical, Radiation and Ablative Therapies)
E. Agents for Cancer Prevention (e.g., Vaccines, but not "Technologies for Cancer Prevention")
F. Development of Low Cost Technologies for Global Health
G. Development of Digital Health Tools

<table>
<thead>
<tr>
<th>Awarding Component</th>
<th>Scientific/Research Contact</th>
<th>Financial/Grants Contact</th>
</tr>
</thead>
</table>
| National Institute on Aging  
http://www.nia.nih.gov/ | Dr. Michelle A. Kenney  
Phone: 301-496-7163  
Fax: 301-496-3543  
Email: mkenney@nia.nih.gov | Ms. Linda Whipp  
Phone: 301-496-1472  
Fax: 301-496-3562  
Email: Linda.Whipp@nih.gov |
| National Institute on Alcohol Abuse and Alcoholism  
http://www.niaaa.nih.gov/ | Maggie Guay, M.B.A.  
Phone: 301-496-6026  
Email: mguay@nih.gov | Ms. Judy Fox  
Phone: 301-496-6034  
Fax: 301-496-2891  
Email: Judy.Fox@nih.gov |
| National Institute of Allergy and Infectious Diseases  
http://www.niaid.nih.gov/ | Dr. Natalia Koutchko  
Phone: 301-496-2519  
Fax: 301-496-2512  
Email: koutchko@niaid.nih.gov | Ms. Veerathiga Anandam, M.D.  
Phone: 301-496-2503  
Fax: 301-496-2502  
Email: vveerat@niaid.nih.gov |
| National Institute of Arthritis and Musculoskeletal and Skin Diseases  
http://www.niams.nih.gov/ | Dr. Xin Liang  
Phone: 301-496-2564  
Fax: 301-496-2534  
Email: xliang@niams.nih.gov | Ms. Azadeh S. James  
Phone: 301-496-3393  
Fax: 301-496-3392  
Email: azadjah@niams.nih.gov |
| National Institute of Biomedical Imaging and Bioengineering  
http://www.nibib.nih.gov/ | Mr. Todd Schwartz  
Phone: 301-496-6550  
Fax: 301-496-1014  
Email: tscott@nibib.nih.gov | Ms. James Poll  
Phone: 301-496-4780  
Fax: 301-496-3375  
Email: jpoll@nibib.nih.gov |
| National Cancer Institute  
http://www.cancer.gov/ | Mr. Michael Vukovancevic  
Dr. Greg Evans  
Mr. Andrew Karp  
Phone: 301-251-2566  
Fax: 301-251-1330  
Email: evansc@mail.nih.gov | Ms. Jacqueline Sanfelice  
Phone: 301-496-3577  
Fax: 301-496-3575  
Email: sanfel@nih.gov |
| Eunice Kennedy Shriver National Institute of Child Health and Human Development  
http://www.nichhd.nih.gov/ | Lisa A. Quammen, Ph.D.  
Phone: 301-496-6235  
Fax: 301-496-6232  
Email: QuammenL@nih.gov | Mr. Ted Williams  
Phone: 301-594-6648  
Fax: 301-594-6647  
Email: williamt@nih.gov |
How to Contact NIH Program Staff

Before you write your proposal

- Send Program Director an intro email
  - Request a phone call to discuss your SBIR/STTR project and its relevance to their institute
  - Send one-page Specific Aims summary prior to call
- Items to discuss:
  - Relevance to Institute goals & priorities
  - Budget ($150K guideline? $225K hard cap? Something greater for topics with a waiver?)
  - SBIR vs. STTR
  - Phase I vs. Fast-track or Direct to Phase II
  - Other special solicitations
  - Other ICs that might be a fit
  - Optional: SBIR/STTR Study Section assignment

Grant Writing 101:

Understand the Review Process
a.k.a.- make the reviewers job easy...
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
CSR – Division of Receipt and Referral

Electronic SF424 R&R submitted through grants.gov

CSR Referral Office assigns the application

to a study section (SRG)
  Conduct review
    - Write critique
    - Assign impact score

to an NIH Institute (IC)
  - Make Funding Decision

Application assessed for completeness & eligibility
Notice of assignment available in eRA Commons in 4 weeks.

1st Month
2nd Month

NIH Review Process

Applicant initiates research idea
Small Business Concern confirms Eligibility
Submits SBIR/STTR grant application to NIH electronically
NIH Center for Scientific Review assigns to IC and IRG

IC staff prepare funding plan for IC Director
Advisory Council or Board recommend Approval
Scientific Review Group evaluates scientific merit

2-4 Months
3 Months
1-2 Months

IC allocates funds
Grantee conducts research
### Timeline: New Applications

<table>
<thead>
<tr>
<th>Due Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (earliest)</th>
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<td>Sept 5</td>
<td>Oct/Nov</td>
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<td>Feb/Mar</td>
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<td>April 5</td>
<td>June/July</td>
<td>Aug</td>
<td>Sept or Dec</td>
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</table>

### 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.
### Roster Index for Small Business and Technology Transfer (SBIR/STTR) Study Section

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

<table>
<thead>
<tr>
<th>Study Section</th>
<th>Study Section Description</th>
<th>SRO</th>
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<tbody>
<tr>
<td>AARR (10)</td>
<td>Small Business: HIV/AIDS Innovative Research Applications</td>
<td>Rubert, Mark</td>
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<tr>
<td>BCMS (10)</td>
<td>Small Business: Drug Discovery and Development</td>
<td>Ruvimov, Sergei</td>
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<td>BIST (10)</td>
<td>Small Business: Biomanufacturing, Delivery, and Nanotechnology</td>
<td>Rosenzweig, Nimoa</td>
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<td>CVRS (10)</td>
<td>Small Business: Cardiovascular Sciences</td>
<td>Chandler, Margaret</td>
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<td>Small Business: Respiratory Sciences</td>
<td>Ahibera, Sara</td>
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<td>Small Business: Digestive Sciences</td>
<td>Garcia, Martha</td>
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<td>CKUS (11)</td>
<td>Small Business: Renal and Urological Sciences</td>
<td>Sahai, Atul</td>
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<td>ETMM (10)</td>
<td>Small Business: Diabetes, Metabolism, Nutrition and Obesity</td>
<td>Chang, Clara</td>
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<td>Small Business: Clinical Neurophysiology, Devices, Neuroprosthetics and Biosensors</td>
<td>Backman, Cristina</td>
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<td>ETTH (11)</td>
<td>Small Business: Drug Discovery for Aging, Neurodegenerative and Neurologic Disorders</td>
<td>Rudolph, Joseph</td>
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<td>ETTH (13)</td>
<td>Small Business: Neuroscience Assay, Diagnostics and Animal Model Development</td>
<td>Gillmor, Susan</td>
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<td>HDM (11)</td>
<td>Small Business: Health Informatics</td>
<td>Ferguson, Yvonna</td>
</tr>
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</table>
NIH Review Criteria

- Significance
  - Significant Science
  - Significant Product
  - Significant Commercial Opportunity

- Investigators

- Innovation

- Approach

- Environment

IMPACT
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

Significance / Impact

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

Summary Statements

<table>
<thead>
<tr>
<th>Project</th>
<th>Year</th>
<th>Budget</th>
<th>Requested</th>
<th>Estimated Total Cost</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,526,327</td>
<td>1,516,321</td>
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| 4       | 375,674 | 381,431
|         | TOTAL  | 696,911 | 696,344     |

Principal Investigator: [Name]

Applicant Organization: [Affiliation]

Meeting Code: [Code]

Council: [Council Name]

POC: [POC Name]

Requested Start: [Date]

Dual Use: [Yes/No]

Project Title: [Title]

SRO: [SRO Name]

Impact/Priority Score: [Score]

Human Subjects: [Yes/No]

Animal Subjects: [Yes/No]
Summary Statements

CRITIQUE 1:

Significance: 3
Investigators: 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 $1.5B. 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, biologists, 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.

Review Criteria

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

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?
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?

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?
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?

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?
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?

Reviewers are not necessarily experts

- Reviewers are often asked to evaluate grants that are not in their specific field.
- Your proposal must be written so that any competent scientist working in your general scientific area can evaluate the application.
- Target an educated non-expert
- Avoid jargon and acronyms where possible.
- Tell the whole story.
Reviewer Comments

- “Don’t make reviewers search for reasons to fund your work—learn to address the importance of your intended research and avoid invoking the “so what?” response from your peers.”
- “… the body of the research plan should begin with a basic but thorough introduction to the subject. Many applicants automatically expect reviewers to be familiar with their field of research and so they skip over basic information that can help clarify their research project. “People don’t realize how diverse the audience is.”
- “… reviewers need to be educated by the proposal writer. Without basic information to help reviewers fully understand a proposal, reviewers can “get lost in a sea of detail. Assume your audience is uninformed, but infinitely intelligent.”
- “Ideally, you want to “guide the reviewer through the entire proposal. Feed them everything they need to know slowly.”

More Reviewer Comments

- “Your research plan is like a very high-level sales plan. Don’t let your reviewer’s mind wander or jump. Give them absolutely everything. Be explicit. And don’t shy away from stating the obvious.”
- They want to know why you want to accomplish these aims. This is where many applicants fall flat. They fail to make a compelling case for their proposed research project, leaving reviewers with no answer to the big question: So what?
- Reviewers will not likely excuse a poorly organized or otherwise unappealing application. It won’t matter how elegant your science is if your reviewers can’t find or understand information they seek.
- In the world of NIH funding, success requires impact. You’ll need to lay out a convincing case that your project can make a high impact in its field. Be explicit because reviewers cannot read your mind.”
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

Components of an NIH SBIR/STTR
- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Bibliography and Refs Cited
- Facilities & Other Resources
- Equipment
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- Project Budget
- Subaward Budget
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- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Appendix
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- PHS Assignment Request
- PHS Human Subjects and Clinical Trials Information

Clinical Trials PA: Includes inclusion enrollment information
No Clinical Trials PA: Does not include inclusion enrollment information
NIH SBIR/STTR Proposal Preparation

Specific Aims Section (1 page): A summary of....

- 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?

Hypothesis-Driven Research

LOOK, HALF THE WORK IS DONE! ALL YOU NEED TO DO IS FILL IN THE TOP PART SO WE CAN LEGALLY SAY THE BOTTOM PART.

CONCLUSION: EATING CHOCOLATE WILL MAKE YOU LOOK YOUNGER AND SLIMMER.

DATA:
Specific Aims Page

- Single and most important page of application
- An Executive Summary of the Proposal
- One page sets the tone for the reviewer
  - Is the project compelling?
  - Are the outcomes significant?
  - Will the project have impact?
  - Is it well written?
  - Do I want to read more?

Aims vs. Activities

- **Specific Aims = Objectives/Outcomes**
  - Either achieved or not
  - Have measurable, desired end points
  - Do not yield results/data

- **Tasks = Activities**
  - Steps to achieve your aims/objectives
  - Make up your work plan
  - They are performed or carried out
  - Yield results &/or data
The Specific Aims

- Support a significant, testable hypotheses appropriate for the Phase of development
- Should be stated succinctly in one sentence each
  - Aims test the hypothesis
  - Experiments (as described in the research strategy section) support aims
- Should be independent
- Should be achievable within the budget and time frame
- Should have “criteria for acceptance” so that you will know when you’ve achieved them and the reviewers therefore know that you will know!

Define the Problem

- Formulate the missing knowledge or technology in qualitative and quantitative terms.
- Why is there a need to fill the gap in knowledge or technology?
- Significance of the gap in knowledge or technology.
- Is there a negative impact resulting from the gap in knowledge or technology?
- Is progress technically feasible?
Hypothesis

(A hypothesis isn't essential)

State your central hypothesis clearly, specifically, and with simple language. One sentence.

Demonstrate to the reviewers that you have a hypothesis-driven proposal that is testable.

Why do you need a central hypothesis?
- Because that's what reviewers expect
- It anchors your different Specific Aims to a common theme
- Following a central hypothesis keeps you focused with both writing the proposal and actually doing the research

(A hypothesis isn't essential)

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
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

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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
Introduction – 1. Who are you?

The Company

- Introduce yourself (the company) in one sentence
- No need to name individual's names
- Are you a spinout from the university?
  - E.g. SmallPharm tech is a startup medical device company formed to commercialize technology developed in the Med Center at MidWest U.

Introduction – 2. What are you doing?

- What are you doing in this SBIR/STTR?
  - Tell us clearly what your goal is
  - Start with “The goal of this SBIR is…”
  - The goal of an SBIR is always to:
    - Develop a product that solves a problem
    - Tell us about both
- The Goal of an SBIR is not:
  - To study…
  - To investigate…
  - To evaluate…
Significance

- **Problem to be solved**
  - Take a step back
  - Give context
  - Define it
  - Tell us how big it is
  - Numbers are good
  - Why do we care? So what?
  - What is done now? Current standard of care?

- **Gap in knowledge**
  - What do we still need to know?

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Significance

- **Preliminary studies**
  - Introduce your technology
  - Tell us what your approach is and why it’s better.
  - Tell us what preliminary work you or your team have done
  - Tell us where you are now. What is the current status of your technology.
  - Phase I: What do you still need to do to prove feasibility?
  - Phase II: How did you prove feasibility in Phase I
The Product

- Define the Product
  - What is it?
  - What does it do?
  - Who uses it?
  - What does it achieve?
  - The product of this SBIR is…

- Technological Innovation
  - What is novel about it?
  - How does it change the status quo?

- Impact

Long Term Goal

- Think impact!
- The Big Picture
- Think ahead
- It’s not all about you
- It’s not all about $$$
- Improvement in clinical outcomes
- Benefits?
  - Who, how, how much?
- Think big
- Make it compelling
- Remember the Mission of the NIH
Tips on Specific Aims

- Aims should test the hypothesis
- Aims should have some detail but not too much
- Aims should not be dependent or too descriptive or ambitious
- Aims should not introduce new characters
- Aims should ideally result in something you can measure
- Avoid descriptive phrases like: To correlate... To describe... To develop...
- No “fishing expeditions” – microarray experiments, expression cloning, etc.

- Every aim needs a MILESTONE.

What are milestones?

- A finding or set of findings that signal the achievement of a specific aim in your research plan.
- Applicants must propose one or more milestones for each Specific Aim.
- Specify the quantitative criteria for measuring success and related rationale.
- Quantitative criteria should be robust and consistent with the state-of-the-art in the field.
- May also be used for making go/no-go decisions.
Examples of Quantitative Milestones

- Detect one cancer cell in 106 normal blood cells.
- Increase the therapeutic index of an agent >3-fold by nanoparticle-based therapeutic solution relative to the non-nanoparticle bound agent.
- Achieve >95% selectivity in targeting mixed cell populations in vitro

Plans for Phase II

- What will you do after proof of concept?
- Be as specific as possible (but brief)
- What are the next R&D steps?
Components of an NIH SBIR/STTR

- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Bibliography and Refs Cited
- Facilities & Other Resources
- Equipment
- Biographical Sketches (5 pg ea.)
- Project Budget
- Subaward Budget
- Introduction to Application (resubmission only -1pg)
- Specific Aims (1 pg)
- Research Strategy (6 or 12 pg)
  - Significance
  - Innovation
  - Approach
- Progress report/Publication List (Phase II only)

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<tbody>
<tr>
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</table>

Research Strategy

- Significance
- Innovation
- Approach

Phase I: 6 pages
Phase II: 12 pages
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.
Significance

Demonstrate:

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

Use references!

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.
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?

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.
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?

Data Planning

- Provide information on the number of observations (experiment runs, human subjects, animals…) that need to be made to obtain statistically significant findings
- Describe how the data will be analyzed to verify scientific validity.
Convey impact with less detail

- Focus on your strategy, rather than detailing all experiments.
- Detail experiments that let you shine.
- Limit your aims
- Know when detail is needed:
  - Give preliminary data to show you are on the right track.
  - Give more detail for unique or new methods.
  - Cite refs & use Biosketch statement.

Research Strategy

- Significance
  - Significant product
  - Significant science/technological innovation
  - Significant commercial opportunity

- Innovation
  - Clearly state the technological innovation
  - Will success improve the “State-of-the-art”, establish new research directions, change clinical practice?

- Approach
  - Do experiments relate to the Specific Aims?
  - Are the end-points/milestones clearly defined?
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

Research Strategy – BBC Outline

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

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

---

**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
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 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?

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
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

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.)
### Gantt Chart (who, when, where?)

<table>
<thead>
<tr>
<th>Specific Aims</th>
<th>Month</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>1</td>
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<tr>
<td>Specific Aim 1</td>
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<td>Experiment 1</td>
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<tr>
<td>NewCo. Labs</td>
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<tr>
<td>A.N. Scientist, Ph.D.</td>
<td></td>
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<tr>
<td>NewCo. Labs</td>
<td></td>
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<tr>
<td>Specific Aim 2</td>
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<td>Experiment 1</td>
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<td>A. Engineer, M.S.</td>
<td></td>
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<td>MidWest University</td>
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<td>Experiment 1</td>
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<td>Research Co. 2</td>
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### Components of an NIH SBIR/STTR

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- Authentication of Key Biological and/or Chemical Resources
- Appendix
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- PHS Assignment Request
- PHS Human Subjects and Clinical Trials Information
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.

Rigor & Reproducibility and Authentication of Key Biological and/or Chemical Resources

New requirement with release of Forms D

- From Application Guide, Page B-92:
  - If applicable to the proposed science, briefly describe the methods used to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. No more than one page is suggested.
  - Refer to NOT-OD-16-011 and NOT-OD-17-068, and embedded FAQs and website on "rigor and reproducibility"
  - Refer to NOT-OD-16-012 for details on "Implementing Rigor and Transparency"
New: Authentication of Key Biological and/or Chemical Resources

Components of an NIH SBIR/STTR

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

Clinical Trials PA: Includes inclusion enrollment information
No Clinical Trials PA: Does not include inclusion enrollment information
Research involving Human Subjects

Chart 1: Is an Activity Research Involving Human Subjects?

View text version of Chart 1

February 19, 2016

Activity is research. Does the research involve human subjects?

- Yes
- No

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? (45 CFR 46.102(k))

- Yes
- No

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

Does the research involve obtaining information about living individuals? (45 CFR 46.102(l))

- Yes
- No

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? (45 CFR 46.103[2])

- Yes
- No

Is it conducted or supported by NIH? (45 CFR 46.103[3])

- Yes
- No

Is the information private? (About behavior that occurs in a context in which an individual can reasonably

NIH Definition of a Clinical Trial

- A research study in which one or more human subjects are \textit{prospectively assigned} to one or more \textit{interventions} (which may include placebo or other controls) to evaluate the effects of those interventions on \textit{health-related biomedical or behavioral outcomes}

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

Clinical Trial or NO Clinical Trial

- You MUST submit your proposal to the correct solicitation for applications on/after 1/25/2018
  - Clinical Trial Required Omnibus Solicitations: PA-18-573 (SBIR) and PA-18-576 (STTR)
  - NO Clinical Trail Omnibus Solicitations: PA-18-574 (SBIR) and PA-18-575 (STTR)
- It is important to know if you are doing a clinical trial to:
  - Select the correct PA
  - Write the Research Strategy and Human Subjects sections of your application
  - Comply with appropriate policies and regulations
Clinical Trial vs Clinical Study

- Questions:
  - Does the study involve human participants?
  - Are the participants prospectively assigned to an intervention?
  - Is the study designed to evaluate the effect of the intervention on the participants?
  - Is the effect being evaluated a health-related biomedical or behavioral outcome?

Clinical Trial or Not?

- If the answers to the 4 questions are yes, your study meets the definition of a clinical trial, even if...
  - You are studying healthy participants
  - Your study does not have a comparison group (e.g., placebo or control)
  - Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
  - Your study is utilizing a behavioral intervention
- Studies intended solely to refine measures are not considered clinical trials.
- Studies that involve secondary research with biological specimens or health information are not clinical trials.
For Clinical Trials or Human Subjects

If you have human subjects

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

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
- Various online certification options
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)

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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.

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.
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

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.
Appendices

NO APPENDICES

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Key Personnel: Build a Strong TEAM!

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

*SBC = Small Business Concern in SBA-speak
Components of an NIH SBIR/STTR

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(BBC’s opinion….)

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.
Biographical Sketches

**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
<table>
<thead>
<tr>
<th>Position where you will be doing the work</th>
</tr>
</thead>
</table>

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

---

**Personal Statement**

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

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

Therefore start this paragraph out with 1-2 sentences as follows:
- "In my role as {-----------} I will be responsible for {-------- -----}. I am qualified because....."
Don’t forget relevant items such as patents or other product development accomplishments

- All key persons should include
- You may cite up to 5 contributions
- Up to 4 relevant publications or research products

Full publication list can be cited here:


D. Research Support

Opening Research Support

R01 DA019357  Hunter (PI)  08/01/08-07/31/16

Health trajectories and behavioral interventions among older substance abusers

The goal of this study is to examine the effects of substance abuse interventions on health outcomes in an urban population of older opiate addicts.

Role: PI

R01 MH02731  Mentle (PI)  12/07/04-11/30/05

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

The goal of the project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Role: PI

Completed Research Support

Template, instructions and samples can be found at:

http://grants.nih.gov/grants/forms/biosketch.htm

Note to Self: Pay Attention
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.

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

Phase II: briefly summarize here; details in commercialization plan
Equipment

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

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Contractual Arrangements & Letters of Support **

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

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

Critical for Phase II:

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

Validate your resources and opportunity

**contingent commitment**
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

Resource Sharing Plans

- **Data Sharing Policy**
  - Investigator-initiated applications with direct costs greater than $500,000 in any single year must provide data sharing plan
  - One-paragraph description of how final research data will be shared, or explain why data-sharing is not possible.

- **Sharing Model Organisms**:
  - All applications where the development of model organisms is anticipated
  - Include a description of specific plan for sharing/distributing unique model organism research resources
  - OR state appropriate reasons why such sharing is restricted or not possible.
Resource Sharing Plans

- Although not specifically required unless you fall under one of the three categories, we advise all of our clients to attach a Data Sharing Plan to their proposals.
- Address the following questions:
  - What data will be shared?
  - Who will have access to the data?
  - Where will the data to be shared be located?
  - When will the Data be shared?
  - How will researchers locate and access the data?

Cover Letter & Assignment Request Form

- The Cover Letter is no longer used for CSR assignments.
- NEW: PHS ASSIGNMENT REQUEST FORM
  - Awarding Component Assignment Request
  - Study Section Assignment Request
  - List individuals who should not review and why
  - Identify scientific areas of expertise needed to review application
- If you use ASSIST Form will NOT show up in “Preview Application” feature (upon submission it is extracted by CSR and kept separate from the rest of the application)
BBC strongly encourages you to use these fields!!!
***but that means you have to do your homework!!!
The Cover Letter

Why?
- Reason for late application (but DON’T BE LATE)
- Explanation of why a subaward isn’t active in all periods of the proposed project
- Statements regarding agency approval documents
- Intent to submit a video as part of an application
- Indication that the proposed study will generate large scale human or non-human genomic data

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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.

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Budget limitations

- **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
- 2018 Topics eligible for budget waiver
- Read the solicitation carefully:
  - NIH has a salary cap ($185,100) – be real in your request

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
Budgets

- **Direct Costs**
  - E.g., Salaries, supplies, equipment, travel, consultants fees, subcontract costs

- **Indirect Costs (F&A)**
  - ≤ 40% of TOTAL direct costs for Phase I (Includes fringe benefits)
  - OR
  - Request higher rate IF you can support it through a negotiation with DFAS

- **Fee**
  - 7% of total costs (direct and indirect)

- **Unallowable Costs**

---

**SBIR Preliminary Budget**

<table>
<thead>
<tr>
<th>Objective #1</th>
<th># Hours</th>
<th>Who</th>
<th>Where</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task A</td>
<td>800</td>
<td>Company</td>
<td>In-house</td>
<td>$68,000</td>
</tr>
<tr>
<td>Task B</td>
<td>600</td>
<td>Subcontract</td>
<td>Out-source</td>
<td>$36,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective #2</th>
<th># Hours</th>
<th>Who</th>
<th>Where</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task A</td>
<td>200</td>
<td>Company</td>
<td>In-house</td>
<td>$17,000</td>
</tr>
<tr>
<td>Consultant</td>
<td>160</td>
<td>AJ Burns</td>
<td>Out-source</td>
<td>$12,000</td>
</tr>
<tr>
<td>Supplies</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$5,000</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$12,000</td>
</tr>
</tbody>
</table>

Total $150,000

Make sure to justify your direct costs extremely well.
When a cap or restriction is enforced

Work backwards to determine the direct dollars

<table>
<thead>
<tr>
<th>Budget Cap</th>
<th>$100,000</th>
<th>$150,000</th>
<th>$225,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct (67%)</td>
<td>67,000</td>
<td>100,500</td>
<td>150,750</td>
</tr>
<tr>
<td>Indirect (40%)</td>
<td>26,800</td>
<td>40,200</td>
<td>60,300</td>
</tr>
<tr>
<td>Fee (7%)</td>
<td>6,566</td>
<td>9,849</td>
<td>14,773</td>
</tr>
<tr>
<td>Total</td>
<td>$100,366</td>
<td>$150,549</td>
<td>$225,823</td>
</tr>
</tbody>
</table>

Direct Costs

- Any item, service or labor that is used for the **sole purpose** of any one particular project.
- The item cannot be used on any other contract or corporate purposes.
Direct Costs

Examples
- Salaries/wages (senior key persons and other personnel)
- Equipment (items that will have more than 1 year of life and more than $5k)
- Travel
- Materials/Supplies
- Consultants
- Sub Award/Consortium

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

- PD/PI is always considered a senior/key person
  - Technical lead
  - Listed on company budget – auto filled from cover page
- Key persons must have a role on the project, Sr. Scientist, Programmer, etc.
- Other Personnel
  - Technicians, junior staff

Roles: Contract Employee

Self-employed individuals, paid by the hour.

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

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

Roles - Subcontractor

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

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

Materials/Supplies

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

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

Indirect costs

- Any item, service or labor that is used to “support or complete” the project but also benefits other projects/activities. E.g.
  - Utilities
  - Rent
  - Benefits
Indirect Costs (F & A/Overhead)

- Fringe Benefits
  - Payroll taxes
  - Insurance – health, disability, workers compensation
  - Retirement plan contributions
  - Paid leave – vacation, sick, holiday

- General & Administrative (overhead)
  - Office supplies
  - Rent
  - Phone
  - Technology – web, email
  - Administrative wages

Unallowable Costs

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

www.acquisition.gov/far/html/subpart%2031_2.html
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.
Budget Justification

- **Direct Costs – by item**
- **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.

Subaward

- What do you need from the sub award?
  - Biosketches of all key persons
  - Budget and budget justification
  - Facilities description and equipment lists
  - Letter(s) of commitment
4/17/2018

Budget Forms

3 pages per budget period plus cumulative budget
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
Proposal Format

- Read the solicitation!
- NIH Font and Page limits (REFER TO CURRENT SOLICITATION)
  - Recommended Fonts: Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana (text color black)
  - 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
- File names <50 characters; do not use &; only 1 space between words and it counts as a character;

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- 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 (30 lines)
- Public Health Relevance Statement/Narrative
- Biographical Sketches (5 pg ea.)
- Facilities & Other Resources
- Equipment
- Project Budget
- Subaward Budget
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- Forms
FY 2018 NIH Changes

- Forms E took affect Jan, 25 2018
  - MUST use for Sept. 5, 2018
    - Refer to NOT-OD-17-062

Forms

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You must use one of these submission options to submit the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.
   - Apply Online Using ASSIST

- USE ASSIST!
- Downloadable forms being phased out
### FORMS E INSTRUCTIONS

#### Application Form Instructions

<table>
<thead>
<tr>
<th>Application Instructions</th>
<th>Description</th>
<th>SF424 (R&amp;R) - Version D</th>
<th>SF424 (R&amp;R) - Version E</th>
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<tr>
<td>General Instructions</td>
<td>Comprehensive guidance for research, training, fellowship, career development, multiyear, and small business applications</td>
<td>HTML/PDF</td>
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<td>Filtered Application Instructions</td>
<td>Guidance for research only</td>
<td>PDF</td>
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<td>Guidance for career development only</td>
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<td>Training Instructions</td>
<td>Guidance for training only</td>
<td>PDF</td>
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<tr>
<td>Relationship instructions</td>
<td>Guidance for fellowship-apply only</td>
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<td>PDF</td>
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<tr>
<td>Multi-Project Instructions</td>
<td>Guidance for multi-project only</td>
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</tr>
<tr>
<td>SBIR/STTR Instructions</td>
<td>Guidance for small business only</td>
<td>PDF</td>
<td>PDF</td>
</tr>
</tbody>
</table>

#### Supplemental Instructions

Instructions on preparing the protection of human subjects section of the research plan and human subjects research policy, as well as additional policies, assurances, definitions, and other information.


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### SBIR/STTR Instructions

[SBIR/STTR INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES](http://grants.nih.gov/grants/how-to-apply-application-guide.htm)

Guidelines developed and maintained by NIH for preparing and submitting applications to the SBIR and STTR programs using the SF424 (R&R)
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 and proof your proposal.**
  - Reviewers assess science, BUT they are influenced by the writing and appearance of your application.
Grammar and punctuation are important.
I like cooking my family and my pets.

Use commas.
Don’t be a psycho.

Don’t ask me to proofread my own writing.
I always end up seeing what I thought I wrote!
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)

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
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.”
**Day 2 Agenda**

- Registrations
- Submitting your proposal
- Post-award (JIT)
- Commercialization Plan Development

### Registrations Required

<table>
<thead>
<tr>
<th>Registration Type</th>
<th>Agency</th>
</tr>
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<tbody>
<tr>
<td>EIN</td>
<td>NIH</td>
</tr>
<tr>
<td>DUNS</td>
<td>DoD</td>
</tr>
<tr>
<td>SBIR.gov (company registration)*</td>
<td>NSF</td>
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<tr>
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<td>Grants.gov</td>
<td>DoE</td>
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<td>USDA</td>
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<td>FastLane</td>
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<td>dodsbir.net</td>
<td>EPA</td>
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<tr>
<td>PAMS (DOE Office of Science</td>
<td>DoE</td>
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<tr>
<td>Portfolio Analysis &amp; Mgmt System)</td>
<td>DoEd</td>
</tr>
<tr>
<td>ASAP</td>
<td>DHS</td>
</tr>
</tbody>
</table>

*SAM registration is not required to complete SBIR.gov registration
**DoD does not require SAM registration until time of award but encourages it before submission
Registrations

All organizations submitting proposals to NIH must have the following:

- Prerequisites:
  - EIN – Employee Identification Number (IRS)
  - DUNS – Data Universal Number (D&B)
  - Bank Account
  - SAM – System for Award Management
  - SBIR.gov Company Registry

- Two additional required registrations:
  1. Grants.gov registration
  2. NIH Electronic Research Administration (ecommons)

NIH Registrations:
Two Separate, but Linked Systems

- Grants.gov
  - Federal-wide portal to find and apply for Federal grant funding
    - Used by all 26 Federal grant-making agencies

- eRA Commons
  - NIH Agency system that allows applicants, grantees and Federal staff to share application/grant information
    - Used by NIH and a few other HHS divisions

IMPORTANT: Each system has its own registration and validations requirements.
Grants.gov registration assistance

Registering with Grants.gov

Applicants
1. Complete the required form fields.
2. Confirm your email address.
3. Add an organization applicant profile or individual applicant profile after registering.

Learn more on the Applicant’s Registration page.

Grantors
1. Complete the required form fields.
2. Confirm your email address.
3. Ask your agency point of contact to associate your email address with the agency.

Learn more on the Grantor’s Registration page.

How to Register With Grants.gov
Know your role - @ Grants.gov

- **E-Business Point of Contact (POC)**
  - Responsible for the administration and management of grant activities in the organization.

- **Authorized Organization Representative (AOR)**
  - Submits a grant application to Grants.gov on behalf of a company, or institution.
  - Authority to sign grant applications and the required certifications and/or assurances.

Register

- Create account using contact information and account details
- Register your organization
  - Create AOR profile
  - ePOC receives email requesting acknowledgement of AOR
  - ePOC must log in and assign role of AOR
eRA Commons Registration

What is eRA Commons?

eCommons is an online interface where grant applicants, grantees and federal staff at NIH and grantor agencies can share information relating to research applications/grants.

- Agency system that allows applicants, grantees and federal staff to share application/grant information
- Used by NIH and a few other HHS divisions
  - AHRQ, CDC, FDA
- As part of the registration process you will assign roles
- NIH has a 2-week "good faith effort" for Commons registrations
Registration – eRA Commons

Process:
1. Add Institutional and Accounts Information
2. Submit – notice of successful submission
3. SO receives “verify email address”
4. SO receives user name and password
5. SO assigns roles – PI, AA, FSR

Know your role - @ eRACommons

- **The PI/Principal Investigator (PI)**
  - Directs the project or activity being supported by the grant.
  - Accountable to the grantee for the conduct of the project or activity.
  - Can view information for all their applications at NIH

- **The SO/Signing Official**
  - Authority to legally bind the institution in grants administration matters.
  - May have any number of titles in the grantee organization.
  - Can register the institution, and create and modify the institutional profile and user accounts.
Registration—Tips for Success

- Begin at least 8 weeks before the deadline
  - Once you have a DUNS number and registered at SAM, Grants.gov and eRA Commons registrations can be done in tandem
  - NIH 2-week “good faith effort” for Commons registration
- Set-up multiple AOR and SO accounts
- Log in to accounts prior to deadline to check your access
- Update System for Award Management (SAM) information annually

Registration – More Tips for Success

- Do not combine SO and PI roles on single Commons account
- PIs get one Commons account that follows them throughout their careers
  - If PI is already registered, “affiliate” their existing account rather than creating a new one
- PIs should update their Commons profile prior to submitting
Electronic Submission

Three CRITICAL steps:
1. You **must** be REGISTERED
2. You **must** submit** ON TIME
3. You should VERIFY

** an error free application

Overview of Electronic Application @ NIH

Company registers to use ASSIST

PI completes application & AOR submits to Grants.gov through ASSIST

eRA retrieves application from Grants.gov, checks for compliance

PI and AOR/SO view assembled application in eRA Commons or through ASSIST.
NIH SBIR/STTR Application Guide

- SF424 (R&R) Application Packages.
- Read and follow application guide instructions
- Instructions are specific to SBIR/STTR applicants
- Revised 12/29/17

NIH SBIR/STTR Application Guide Changes

**G. 120 - Significant Changes**

The Application Instructions are updated and revised 3-5 times per year as needed. Additionally, minor revisions may be made occasionally of these updates. Minor revisions do not detail significant changes and revisions refer to the instructions since the last major revision.

- Web version: use your mouse to hover over the word and read an exploration of the change.
- In a text version, no exploration note will be displayed. There are minor instructions, see the exploration in the Significant Changes section below.

**Revision Notes - December 29, 2017**

- See Revisions made to instructions in Significant Changes Request Form.

**Release Notes - September 25, 2017**

- Revised - Application Guide and Format Page Changes:
  - Created a new Section 2.5 “Other Direct Costs” that is accessible through the Main Application Area.
  - Minor updates to the instructions for the Institutional Grant Application, including:
    - Table 8 - removed language to exclude unfunded travel from the average time to complete Part C Program Statistics.

- SF424 Research and Related (R&R) Form Changes:
  - FORMS-F application package incorporates the latest versions of the Federal-wide forms managed by ASPE/NIH.
  - Additional forms: ADP/Matching, RAD Budget and associated RAD Subaward Budget Attachments Form.
  - Added new “Total Costs and Financing” calculation to budget periods and cumulative budget.
  - Added instructions under the “Other Direct Costs” section about requesting direct costs related to the use of single Institutional Review Board (IRB) for multi-site human subjects research in order to ensure compliance.

**FORMS-F Application Package**

- Includes the latest versions of the Federal-wide forms managed by ASPE/NIH.
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- Added instructions under the “Other Direct Costs” section about requesting direct costs related to the use of single Institutional Review Board (IRB) for multi-site human subjects research in order to ensure compliance.
Electronic Application – the process

- Prepare to apply
- **Find opportunity and INITIATE in ASSIST**
- Prepare application
- Submit application to grants.gov
- Check status in eRACommons (NIH)
- Check assembled application

What is ASSIST?

**Application Submission System & Interface for Submission Tracking**

ASSIST is NIH’s online system for the preparation, submission & tracking of grant applications through grants.gov to NIH
Step by Step ASSIST

1. Find the funding announcement, select "Apply Online Using ASSIST"
2. Make a submission plan, who will be responsible for entering data
3. Login in to ASSIST & initiate your application
4. Provide application access to your team
5. Enter application data
6. Finalize your application and prepare for submission
7. Submit your application
8. Track your application and view assembled image

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 keep the tracking and accession numbers
Where’s my money?

- Just-in-time Information
- Assurances
- Financial Information
**JIT – Just in Time Information**

- 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

---

**Reporting Requirements**

- **Federal Financial Report**
  - [http://www.dpm.psc.gov/](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](http://technet.sba.gov)
  - Register prior to applying for Phase II
Bayh-Dole Act

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

Bayh-Dole Act Background

The Bayh-Dole Act is a legislation passed with the intent to encourage innovation and increase the commercialization of inventions made under federally funded research by requiring grantee institutions to disclose inventions to the granting agency.

Principal Features of the Bayh-Dole Act

1. **Grantee Disclosure**
   - A grantee institution must disclose inventions made under a federal grant.
   - The disclosure must be made within a certain timeframe.
   - The disclosure must include information about the invention, such as the inventor, the date of disclosure, and the nature of the invention.

2. **Review Process**
   - The grantee must review the disclosure to ensure accuracy and completeness.
   - The grantee must determine if the invention is patentable and if it meets other criteria for patentability.

3. **Filing of Invention Reports**
   - The grantee must file an invention report with the granting agency within a specified timeframe.
   - The invention report must include information about the invention, the grantee, and the grantee's plans for the invention.

4. **Exclusivity Determination**
   - The grantee must determine if the invention is exclusive.
   - If the invention is exclusive, the grantee must negotiate an exclusive license with the grantee institution.

5. **Invention Reporting Timeline**
   - The grantee must file an annual report with the grantee institution to report the status of the invention.
   - The grantee must also file a final report when the invention is licensed or abandoned.

6. **Invention Reporting Requirements**
   - The grantee must report all inventions that are made under a federal grant.
   - The grantee must also report any inventions that are abandoned or licensed.

7. **Dissemination of Inventions**
   - The grantee must disseminate inventions to the public.
   - The grantee must make the invention available to the public within a certain timeframe.

8. **Invention Reporting Through iEdison**
   - The grantee must report inventions through the iEdison system.
   - The iEdison system is a web-based application that allows grantees to report inventions.

9. **Invention Reporting Process**
   - The iEdison system provides a user-friendly interface for granting agencies.
   - The iEdison system allows granting agencies to track the status of inventions.

How do you report inventions?

Welcome to iEdison

Requests for waivers of the U.S. Manufacturing Requirement in Licenses to Extramural Inventions

iEdison (which stands for Interagency Edison) helps government grantees and contractors comply with a federal law, the Bayh-Dole Act. iEdison requires that government-funded inventions be reported to the federal agency who made the award.

Edison is interagency because it provides a single interface for grantees and contractors to interact with any participating agency.

Edison makes it easy to learn about the law and its regulations and report an invention or patent funded by any of the agencies listed on the right.

Edison Overview

What’s New

Bayh-Dole Act (37 CFR 401)

Invention Reporting Timeline

Frequently-Asked Questions
SBIR/STTR Goals

PHASE I = FEASIBILITY

PHASE II = FURTHER R&D

COMMERCIALIZATION
Important Reminder

A good idea is necessary but not sufficient

What is Commercialization?

- Ability to provide a solution to a problem in exchange for money
What it isn’t…

A Market Analysis is NOT a Commercialization Plan

Large Market ≠ Commercialization

Most Common Pitfalls

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
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<tr>
<td>Product Development</td>
<td></td>
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<tr>
<td>Business Development</td>
<td></td>
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</table>

Naïve Planning process

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Business Development</td>
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</tr>
</tbody>
</table>

Product Development and Business Development go hand in hand

Knowing your customer helps develop both simultaneously
The Philosophy of Commercialization

Know thy customer

Life is sales!

The Planning Process

- Describe the problem
- Identify the “target” customer
- Define the market (e.g., size, growth rate, distribution)
- List alternative solutions (i.e., competition)
- Define the “value proposition”
- Describe the business model
The Planning Process

Important Problem

Who has the Problem? Customer

How do they deal with it? Competition

How do we compare? Value Proposition

How many with the problem? Market

Business Plan

- Covers ALL products/services
- Defines the business model
- Provides extensive financials & assumptions
- Identifies milestones and risks for the company
- May be a request for funding
  --or--
- May be an internal ‘operating’ guide
Commercialization Plan

- Covers a SPECIFIC product or technology
- Defines the commercialization model (i.e. – route to market)
- Identifies milestones and risks related to commercialization of the product or service
- Provides financial information related to the product (i.e. – cost, price, sales projections, margin)

Commercialization Plan Elements

NIH Proposed Layout*

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

No more than 12 pages
Commercialization Plan Elements

a. Value of the SBIR/STTR Project, Expected Outcomes and Impact

- Lay description of proposed project and key technology objectives
  - (Don’t forget to clearly define the product and the innovation)
- Need addressed
  - Specify weakness in current approaches to meet the need
- What are the potential commercial applications of the research and the innovation?
  - Be sure to specify: 1) potential societal, educational, and scientific benefits; 2) Non-commercial impacts to the overall significance of the project
- Advantages compared to competing products, technologies or services
- How does project integrate into Company business plan?
Commercialization Plan Elements

b. Company

Are you a “real” company?

- Do you have marketing and business expertise?
- If not, how and when will you bring it into the company
b. Company

- Brief description of the company, including:
  - Corporate objectives
  - Core competencies
  - Present Size
    - Annual sales
    - Number, type of employees
  - History of previous Federal and non-Federal funding
    - Regulatory experience
    - Subsequent commercialization
  - Current products/services with significant sales

- Succinct history of the company

- Vision for future
  - How will you grow/maintain a sustainable business entity
  - How will you meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity

---

**Business Models**

- License
- Joint development
- Contract manufacturing
- OEM
- Fully integrated manufacturing, marketing, distribution
- Distribution
b. Company

- Brief description of the company, including:
  - Corporate objectives
  - Core competencies
  - Present Size
    - Annual sales
    - Number, type of employees
  - History of previous Federal and non-Federal funding
    - Regulatory experience
    - Subsequent commercialization
  - Current products/services with significant sales

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  - How will you grow/maintain a sustainable business entity
  - How will you meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity

Commercialization Plan Elements

c. Market, Customer, and Competition
c. Market, Customer and Competition

- Describe the target market and market segments
- Customer profile
- Positioning (i.e. – product advantages)
- Hurdles to overcome to gain acceptance (i.e. – barriers to entry)
- Strategic alliances, partnerships, licensing agreements
  - To get FDA approval
  - To market and sell
- Marketing and sales strategy
- Competitive analysis
  - Current landscape
  - Future potential competitors

Customer

- Who is the initial target customer?
  - Who is most accessible? Influential
  - Where is the biggest opportunity?
  - Who has the greatest need?
  - Who is the best fit?
  - Where does the company have most access?
Market Opportunity

- Target market
- Customer profile
- Positioning (i.e., product advantages)
- Hurdles to overcome to gain acceptance (i.e., barriers to entry)
- Strategic alliances, partnerships, licensing agreements
- Marketing and sales strategy

Do your homework
(a.k.a. – MARKET RESEARCH)

For the computer savvy

For the socially adept

To Do: 346
Market Analysis

Potential → Addressable → Accessible

Competitive Analysis
Competitive Products

- What are the alternatives?
- How are these products sold now?
- What is their price?
- How big is their market share?
- What is their intellectual property position?

Competitive Analysis

<table>
<thead>
<tr>
<th>Product Feature</th>
<th>Company A</th>
<th>Company B</th>
<th>Our Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Speed</td>
<td>√</td>
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<tr>
<td>Price</td>
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- Describe the target market and market segments
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- Strategic alliances, partnerships, licensing agreements
  - To get FDA approval
  - To market and sell
- Marketing and sales strategy
- Competitive analysis
  - Current landscape
  - Future potential competitors

Commercialization Plan Elements

d. Intellectual Property Protection
d. Intellectual Property Protection

- How will you protect IP that results from this innovation
- What actions might you consider that will constitute at least a temporal barrier to others aiming to provide a similar solution

Note from NIH outline:

- Existing IP
  - List and describe importance to THIS project
  - Clearly explain the company’s right to use the intellectual property
  - Discuss how the IP fits into the broader base of IP in the competitive landscape

- How does your IP enable your business strategy?

“Rights” to Commercialize

- If you are an academic or employed elsewhere:
  - READ and KNOW your institution’s Intellectual Property Rights Policy
  - Assume the institution owns the IP unless proven otherwise
  - Beware of public disclosure
  - Beware of conflict of interest issues

- Transfer is based on negotiation and a viable business opportunity
Commercialization Plan Elements

e. Finance Plan

- Describe necessary fundraising to commercialize the product, process or service
  - Plans to raise requisite financing to launch into Phase II and begin revenue stream
  - Fundraising timeline

- Demonstrate through:
  - Letters of commitment of funding
  - Letters of intent or evidence of negotiations
  - Letter of support and/or in-kind commitment
  - Specific steps to secure Phase II funding
e. Finance Plan

From: SBIR/STTR Instructions For NIH dated March 24, 2017, page B-107:

Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product or service resulting from the SBIR/STTR grant.

Funding for Commercialization

**Debt:**
- $ Corporate investment
- $ Banks
- $ SBA Loans

**Equity:**
- $ Angel investment
- $ Venture capital
- $ Corporate investment
Other Sources

- Personal assets
- FFF (Friends, family and fools)
- Vegas, baby, Vegas!

Commercialization Plan Elements

f. Revenue Stream
f. Revenue Stream

- How will you bring in $$ to the company upon successful completion of project?
  Examples include (but are not limited to):
  - Manufacture and direct sell
  - Sales through resellers or distributors
  - Joint venture
  - Licensing
  - Service

- How will your staffing change to meet revenue projections?

### Revenue Model

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<tr>
<th>Item</th>
<th>Assumption</th>
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<tbody>
<tr>
<td>Grant Revenue</td>
<td>One Phase I &amp; one Phase II SBIR</td>
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<tr>
<td>License fees</td>
<td>$10k upfront; $5k/yr thereafter</td>
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<tr>
<td>Milestone payments</td>
<td>Pre-negotiated</td>
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<tr>
<td>Product Sales</td>
<td>Average selling price X # units</td>
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<tr>
<td>Royalties</td>
<td>5% of licensee’s net sales</td>
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<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
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<tr>
<td>Royalties</td>
<td></td>
<td>13,000</td>
<td>47,000</td>
<td>128,000</td>
<td>238,000</td>
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<tr>
<td>Total Revenue</td>
<td>$115,000</td>
<td>$53,000</td>
<td>$777,000</td>
<td>$305,000</td>
<td>$283,000</td>
<td>$573,000</td>
<td>$738,000</td>
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Regulatory Issues

- Animal use
- Toxicology studies
- Human use
- FDA
- GMP
- ISO 9001
- CE mark
- EPA/OSHA
- Quality control
- Internal Expertise or Outside Consultant?

Commercialization Plan Overview

<table>
<thead>
<tr>
<th>Activity</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tbody>
<tr>
<td>Conduct Phase II R&amp;D Project</td>
<td>xxxxxxx xxxxxxx</td>
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<tr>
<td>Execute a joint development agreement</td>
<td>*</td>
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<tr>
<td>Jointly complete product development</td>
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<tr>
<td>Execute a licensing agreement</td>
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<tr>
<td>Identify prospective investors</td>
<td>xxx</td>
<td>xxxxxxx xxx</td>
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<tr>
<td>Close Series A financing</td>
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<tr>
<td>Recruit marketing manager</td>
<td>xxx</td>
<td>xxx</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Identify contract manufacturer</td>
<td>xxx</td>
<td>xxx</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sign up international distributors</td>
<td>xxx xxx</td>
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<tr>
<td>Launch product internationally</td>
<td>*</td>
<td></td>
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</tr>
</tbody>
</table>
Commercialization Plan Elements

NIH Proposed Layout*

a. Value of SBIR/STTR project
b. Company information
c. Market, Customer, Competition
d. Intellectual Property Protection
e. Finance Plan
f. Revenue Stream

No more than 12 pages

*updated to 6 sections effective Sep 5, 2016
(ref application guide updated March 25, 2016)

What is Commercialization?

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

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

There is no such thing as the “Build it and they will come” commercialization strategy
BBCetc works with technology-based entrepreneurs and companies on strategies to advance R&D efforts to commercialization. We are nationally recognized for our success in helping clients win federal funding through the SBIR/STTR programs and use it tactically to propel growth. Services include training courses and one-on-one counseling in:

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

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For more assistance:

- SBIR/STTR Assessment Form at [www.bbcetc.com](http://www.bbcetc.com)

### BBC’s Grant Assistance

- Assessment of competencies and capabilities
- Strategic planning
- Training on all aspects of the process including in-depth proposal preparation
- Proposal development tools
- Pre-submission review and editing
- Assistance with revision and resubmission
- Post-award administrative assistance and grant management
BBC Team

- Becky Aistrup, MBA - DOD, DHS, NASA, NIH, NSF and commercialization planning
- Kris Bergman - Grants and contracts management, and budget and administrative support for all agencies
- Andrea Johanson, PhD - NIH grants and contracts
- Austin Dean, MBA - NIH, NSF
- Jerry Hollister - DOE, NSF, DOD, commercialization planning, post award management
- Shannon Bass – NIH, NSF, grants and contracts management
- Jayne Berkaw - Marketing and communications and training programs
- Jodi Bergman - Administrative support

SBIR/STTR Proposal Prep for NIH
Yale Office of Cooperative Research
April 18-19, 2018
New Haven, CT

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