1st in a Four-Part Series

Winning SBIR & STTR Grants: The Basics (April 18, 2019)

SBIR & STTR – Phase II: Beyond the Basics (May 1, 2019)

Funding Your Innovation (May 23, 2019)

Roadmap to Commercialization: I-Corps (June 13, 2019)
SBIR “Deal Killer” (Avoidance) Program

1) Registration for SBIR/STTR Applications
2) Preparing a Fundable Study Approach
   ▪ Research Design/Protocol
   ▪ Writing Hypotheses and Aims
3) Writing Your Phase II Commercialization Plan

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Date: 6/3/2019 - 8/30/2019
Time: 8:00 AM - 12:00 PM (PDT)
Status: Open - 15 places remaining
Registration Deadline: 7/15/2019 8:00 AM (PDT)
Fee: $350.00

Program Format: Multi-session Course
1) A facilitated peer learning work group – Target: the NIH September 5, deadline
2) In each session, instructors to guide the conversation toward a successful application
3) Not a guarantee that you will receive a SBIR; we will not write + submit an application for you

Topics include
- Understanding the requirements of an SBIR
- Preparing to apply for an SBIR (company formation, registration, identifying the best PI
- Assembling all the necessary parts of the application (letters of support, sub-contract quotes and letters, facilities to execute the grant, and research plan)
- Composing a competitive research plan
- Understanding and assembling a budget and justification
- Composing competitive innovation and significance sections as well as specific aims
- Searching for program announcements and finding opportunities
- Assembling and filing (completing the 424 correctly and filing on time)
Industry Specific: (e.g. Life Sciences)

Commercialization (Navigation Roadmap)

- Coding, Coverage; Joint FDA/CMS Parallel Review
- Analytical Validity, Clinical Validity; Clinical Utility
- Economics (Cost/Benefit Impact)
- Health Technology Assessment (HTA)
- FDA Regulatory Affairs
- Licensing Best Practices, Optimal Alliance/Partnership Structuring
- Enterprise Economic Value Management; Strategic Accounts

FDA, CMS, AMA, BS/BC (Evidence Street), Evicore, Hayes, ECRI, Aetna, Precision Medicine, New Ventures Funds, Quest, American Healthcare Research & Quality (AHRQ), U.S. Preventive Services Task Force, Palmetto GBA; CLSA
**Future: BRINK I-Corps Site/Accelerator**

**Fixed Term: 7 – 8 Weeks**

1) Business Models & Customer Development
2) Value Proposition
3) Customer Segments
4) Distribution Channels
5) Customer Relationships
6) Revenue Streams
7) Partnerships/Alliances
8) Resources, Activities, & Costs

**Seed Fund/Equity Stake**

1) Investor Presentations, Documents
2) Terms Sheets, Deal Terms, other Related Funding issues
3) Types of Funding Vehicles
4) Sales & Marketing Strategies
5) Management Policies/Procedures
6) Hiring & Staffing Issues -- Including cash and stock compensation for Other Team Members
7) Board of Directors Acquisition/Compensation
8) Advisory Board Creation, Utilization & Compensation
9) Board Governance Issues
10) Strategic & Tactical Planning

Candidacy to National Cohort

Slide # 4

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Where I’m Coming From . . .

1) National Science Foundation I-Corps Adjunct Faculty; NIH I-Corps

2) Six Launches; Two Exits
   - RegeneMed
   - InSilicoMed
   - SpyFinder (Sold)
   - Sal-Flex (Sold)
   - + RefluxMD

3) Also: Not-For-Profit 501 (c) 3 – Venture Philanthropy

4) SBIR/STTR: NSF, NIH, DoD, DOE, DoEd, USDA, Coulter, Drexel; Univ of California

5) Times Mirror, American Healthcare Systems, General Electric, Roche Diagnostics, Toshiba America Medical Systems

6) $55.8 MM in Capital & Grants 2016 – Q4 2018
What is Your Odyssey?
Essential Rules

1. Ask Questions
2. “Jump In”
3. Participate

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SBIR/STTR: The Basics

I. The PROGRAM BASICS (DOE, NIH, DoD, NSF, USDA et al.)
   ▪ Legislative/Regulatory Affairs; Registration; Funding; Specifics

II. THE CONTENT – WHAT’S IMPORTANT: Understanding Criteria
   ▪ Writing to the Reviewers: Understanding Their “Marching Orders”; Study Approach; Commercialization Plan
   ▪ Key Criteria: Scoring, Ranking and Evaluation (“Go/No-Go”)

III. “Why Was I Rejected?”: COMMON PROBLEMS

IV. BRINGING YOUR INNOVATION TO MARKET
Part II: Beyond The Basics

I. Designing and Defending a Fundable STUDY APPROACH
   a) Research Design, Protocol Essentials

II. PHASE II Award Criteria
   a) Winning Phase II during Phase I

III. Budgeting, Accounting & Government AUDITS
   a) “Firm Fixed Price Award” (FFP) to “Cost Plus Fixed Price” (CPFP)
   b) “Pre-Award Accounting Audit”

IV. COMMERCIALIZATION PLAN/Business Model Generation
   a) The Role of I-Corps, “Tech Assess” and Other Programs
PART I:
THE BASICS/ORIENTATION
Introduction

- **SBIR – Small Business Innovation Research**
  - Small Business Development Act of 1982
  - Small Business Reauthorization Act of 2000 (through Sep 2022)
  - 3.2% Extramural Research Agencies w/ Budget > $100 MM
  - Mission: Stimulate Innovation; Economic Growth

- **STTR – Small Business Technology Transfer**
  - Small Business Technology Transfer Act of 1992
  - Reauthorized through September 2022
  - 0.45% of Agency Budget (Budget > $1B)
  - Collaboration Between Small Business and NFP Research
SBIR: 6% by 2028 (S 2812) 
4.5% by 2022 (HR 4783)

STTR: 0.6% by 2022 in the House bill 
1% in the Senate bill

Latest Action:  
S. 2812 (Jeanne Shaheen S-NH; April 18, 2016): Senate - 12/20/2016 By Senator Vitter from Committee on Small Business and Entrepreneurship filed written report under authority of the order of the Senate of 12/10/2016. Report No. 114-417  
(There are related bills introduced & pending.)
SBIR: 6% by 2028 (S 2812)
4.5% by 2022 (HR 4783)

STTR: 0.6% by 2022 in the House bill
1% in the Senate bill

SBIR & STTR reauthorized; SBIR stays at 3.2%; STTR: 0.45%

The government was initially funded through a series of five temporary continuing resolutions. The final funding package was passed as an omnibus spending bill, the Consolidated Appropriations Act, 2018, enacted on 03/23/18.
Base Program Remains . . .

. . . “pilot” programs expired, then rejuvenated
They’re Back (through 2022):

- Direct to Phase II
- Phase 0 Proof of Concept Centers
  (Commercialization Readiness Program: CRO Studies; IP Strategies; FDA Guidelines)
- Expand Technical Assistance
  1) Phase I $6,500/year (up from $5,000/year)
  2) Phase II $50,000/project (up from $5,000/year)
  3) SBC hire own vendor or use agency vendor
Technical & Business Assistance

Access to a Network of Scientists and Engineers

— Wide range of technologies
— Product sales
— IP protections
— Market Research & Validation
— Regulatory Plans
— Manufacturing Plans, or
— Access to Technical and Business Literature (on-line data bases)

- Request in F. Other Direct Costs lines 8-10 on SBC budget
- Label as “Technical Assistance”
Proof-of-Concept Centers (Hubs)

GOAL: “De-risked technologies with well-designed business cases primed for licensing or startup company formation.

1. Infrastructure
2. Feasibility; Prototype; POC
3. Access to Expertise
4. Skills Development

Matthew Portnoy PhD
Program Manager
Office of Extramural Research
https://ncai.nhlbi.nih.gov/ncai/aboutncai/mission

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NIH Centers for Accelerated Innovations (NCAI): Boston Biomedical Innovation Center, Cleveland Clinic Innovation Center, UC BRAID Center for Accelerated Innovation

Research Evaluation and Commercialization Hubs (REACH): University of Minnesota, Long Island Biomedical Hub, University of Louisville

National Institutes of Health + NSF, FDA, USPTO, CMS, Kaiser

Source: Matthew Portnoy PhD

Accelerate translation of scientific discovery into commercial products

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DoD Commercialization Readiness Program (CRP) stays in force through SEP 30, 2022

DoD Rapid Innovation Fund (RIF): $250 MM in Phase III funds (permanent)
Eleven Agencies

- Five (5) Have an STTR Program
- Early Stage, High Risk, High Payback
- Foster Socially/Economically Disadvantaged
- Transformative; Significant Societal Impact
- Strong Chance For Commercial Success
  - Credible Commercialization Plan
  - (I-Corps Programs “Linked to” SBIR)

1) Department of Commerce - National Institute of Standards and Technology
2) Department of Commerce - National Oceanic and Atmospheric Administration
## FY 2019 SBIR & STTR Budget (est.)

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<th>STTR</th>
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<td><strong>$430M</strong></td>
<td><strong>$3.6B</strong></td>
<td><strong>$756</strong></td>
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Characteristics

PHASE I: Merit, Feasibility, Commercial Potential
- ALSO: Your Quality & Performance w/ a small amount of money
- Amounts Vary; 6 – 12 Months: $163,952 +/- 50% (FY ’18)
- There may be a Hard Cap Waiver

PHASE II: Complete R & D; Efficacy, Potential, Merit
- Amounts Vary; 24 Months: $1,093,015 MM + 50% (FY ‘18)
- Phase IIB (NIH; DOE: Sequential)
- Special/Supplemental (e.g. DOE, NSF)
- Commercial Potential: Past Record; Funding + “Commitments”

PHASE III: Commercialization
- Unfunded; Non-Cash; In-Kind Support
To Be Eligible (SBIR) . . .

1. SBC¹ Organized For-Profit; based in the U. S.
2. No more than 500 employees (incl. Affiliates, PT & Temp.)
3. ≥ 50.1% directly-owned or controlled by 1 or more permanent citizens or resident aliens (‘Green Card’ & ‘Substantial Presence’)²
4. A Joint Venture wherein each entity meets the above
5. 1/3 of Funded Work May Be Sub-Contracted
6. Principal Investigator Must Be > 50% “Employed” By You

1) Proprietorship, Partnership, LLC, Corporation, Joint Venture, Association, Cooperative
2) Thirty-one (31) days in current year; 183 days past three years – including current
Eligibility (STTR) . . .

1. Organized **For-Profit**; based in the U. S.; ≤ 500 employees
2. ≥ 51% directly-owned or controlled by 1 + permanent citizens or resident aliens; Other small businesses meeting the above criteria
3. **Research Institution Partner:**
   - Located in the US; Nonprofit college or university; Domestic Nonprofit Research Organization; Federally Funded R&D Center (FFRDC)
4. **Must Have an IP Agreement:** Allocation, Research, Commercialization
5. **Company Performs 40% - 70%;** NFP Partner Does 30% - 60%
6. **Principal Investigator** Does Not Need To Be SBC Employed
And Other News . . .

- **Cross Program Awards**
  - Agency Discretion: Can Allow STTR Phase I Awardee to receive SBIR Phase II Award/Other Way as Well

- **Cross Agency Awards**
  - Phase I Awardee May Receive Phase II Award From Another Agency

- **All Phase I Awardees** Must be Allowed To Apply For Phase II

- **Second Sequential Phase II (NIH, DOE)** May Be Awarded
Performance Benchmark . . .

. . . Transition Rate Requirement

- Applies to SBIR & STTR Phase I Applicants Having Received More Than 20 Phase I Awards Over The Past 5 Years
- There must be a Minimum Number of Phase II Awards Received For A Given Number of Phase I Awards (In Order To Remain Eligible For Phase I)
- Minimum Transition Rate = 0.25 (25%)
Commercialization Benchmark

1) Applies if you have received more than 15 (16 or more) Phase II awards over the past 10 fiscal years, excluding last two years.

2) You must have received, to date, an average of At Least $100,000 of sales and/or investments per Phase II award received

3) ... OR have received a Number of Patents resulting from SBIR work equal to or greater than 15% of the number of Phase II awards received during the period.
Consequence . . .

. . . of Failure to Meet Benchmarks

- SBA identifies on June 1 each year those who fail to meet either benchmark.
- They will be **not be eligible to receive a Phase I award** for a period of one year from that date.
1) Can a VC (HF, PEF) owned company apply for a SBIR grant?
   - VC, HF, PEF can hold minority shares
   - Affiliation Rule: majority VC-owned companies (Total ≤ 500 employees)

2) Can a Single VCOC (HF, PEF) hold a majority share (> 50%)?
   - NO. They can hold a Minority Share + Not Have Control. No single VC, hedge fund or private equity firm may own more than 50%
   - EXCEPT: VCs owned/controlled by 1 + US Citizens, permanent resident aliens

3) NDAA authorizes NIH, CDC, & DOE (Advanced Research Projects Agency – “ARPA-E”) to award SBIR Funds to VC Majority-owned
   - BUT ONLY IF no one VC/HF/PEF owns more than 50%
VC, Hedge Fund, Private Equity

1) **What about STTR?** Companies that are more than 50% owned by multiple VCs, hedge funds, or private equity firms or any combination are **NOT** eligible to apply.

2) **Joint Venture?** Still ‘No’ (& each party must meet ownership requirements)

3) **Each VC must have a U.S. place of business AND be created or organized in the U.S.; operate under U.S. laws**
Part II: Getting Started
Registration

1. DUNS
2. System for Awards Management (SAM)
3. Grants.gov
4. SBA
   ▪ eRA Commons (National Institutes of Health)
   ▪ Also: National Science Foundation (NSF): research.gov
   ▪ Also: Department of Defense (DoD): Separate Registration
   ▪ Department of Energy Portfolio Analysis and Management System (PAMS)

Can take 6 – 8 weeks
Sequential

1. Dun and Bradstreet Universal Numbering System (DUNS) number. (See http://www.sba.gov/content/getting-d-u-n-s-number)
   - To get an EIN: https://www.irs.gov/businesses/small-businesses-self-employed/how-long-will-it-take-to-get-an-ein

2. After DUNS: System for Award Management (SAM) and (for NIH) eRA Commons registrations.

3. The SBA (SBIR) registration is the most recent requirement for a SBC (Small Business Concern) Control ID
To get a DUNS number online, go to this link: http://fedgov.dnb.com/webform/displayHomePage.do;jsessionid=81407B1F03F2BDB123DD47D19158B75F. You will be guided through the request protocol beginning on https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm: “Find DUNS or Request New DUNS”

Memo: You can use your home address as your business address for a startup.
You will need 2 documents to complete this process. The documents must reflect the Correct Legal Business Name at the Current Physical Address. (See examples of accepted documentation below).

Example of Accepted Documents for New DUNS
- Secretary of State Articles of Incorporation
- Taxpayer Identification Number (TIN) Confirmation Letter
- Employer Identification Number (EIN) Confirmation Letter
- DBA / Assumed Name Certificate Filing
- Lease Agreement
- Utility Bill
Memo: for NIH applicants, use this link (it provides a “simple” step-by-step way to get through this.):
System for Award Management (sam.gov)

1) Provide your company’s “DUNS number” and bank account information.

2) Submit a notarized letter stating that you are the authorized Entity Administrator before your registration will be activated.

How to Submit a Notarized Letter Formally Appointing an Entity Administrator

https://fsd.gov/fsd-gov/answer.do?sysparm_kbid=d2e67885db0d5f00b3257d321f96194b&sysparm_search=kb0013183

Step 1: Find template at the above site
Step 2: Complete the template and print on your entity’s letterhead*
Step 3: Sign the completed letter in the presence of the notary
Step 4: Mail the completed, signed, notarized letter to:

FEDERAL SERVICE DESK
ATTN: SAM.GOV REGISTRATION PROCESSING
460 INDUSTRIAL BLVD
LONDON, KY 40741-7285
UNITED STATES OF AMERICA

* Or enter your SBC legal business name & physical address at the top of the letter.
Register With The SBA

Company registration is meant for small businesses to register and gain access to the SBIR.gov system. Completed registrations will receive a unique SBC Control ID to be used for submissions at any of the participating agencies in the SBIR or STTR programs.

https://www.sbir.gov/registration
Grants.gov, registration See the “Get Registered” tab (http://grants.gov/applicants/get_registered.jsp).

- While Grants.gov registration is a one-time only registration process, it involves several steps & will take some time.

- To complete this process **start early** allowing at least six (6) weeks to complete all the steps before actually submitting an application through Grants.gov.
NIH Applicants

Register with the Electronic Research Administration (eRA Commons) via the below link:

https://era.nih.gov/erahelp/commons/default.htm#cshid=1026
To Register with the NSF for proposal submission, access https://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&_pageLabel=research_home_page

- ‘click’ on “Register” on the upper right side of the page to go to https://www.research.gov/accountmgmt/#/registration
The Department of Defense requires separate registration - even though you have already registered in SAM.gov and at SBA.gov.

(https://sbir.defensebusiness.org/user/register)

Department of Energy applicants will need to register with the DOE Portfolio Analysis and Management System (PAMS) to create an account:

https://pamspublic.science.energy.gov/WebPAMSExternal/Interface/Registration/CreateAccount.aspx
The ensuing discussion generally applies to the other agencies also.
At least 3 technical reviewers

1 Reviewer for the Phase II commercialization plan

Review Criteria (equally weighted)
1) Strength of the Scientific/Technical Approach
2) Ability to Carry Out Project Cost Effectively
3) Impact

Panel Composition/Affiliation:
1) National Laboratory (49%)
2) University (32%)
3) Government (10%)
4) Private Sector (9%)
Not Required (except for the DOE)

Letter of Intent/Inquiry

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Letters of Intent (DOE)

LOI required by a specified due date to be eligible to submit an application (Due 3 weeks after FOA issued)

- Why: to begin reviewer assignments/reduce award cycle time
- You will not receive a response unless your proposed R & D is non-responsive to selected topic
- Up to 10 LOIs and 10 applications per FOA
- Submit electronically through the DOE Office of Science Portfolio Analysis and Management System (PAMS) website https://pamspublic.science.energy.gov/.

- Title: A descriptive title of the planned R&D
- Topic & Subtopic
- Principal Investigator name (and contact information if not previously registered)
- Business official name (and contact information if not previously registered)
- Name(s) of any proposed subcontractor(s) or consultant(s), if any
- 500-Word Abstract
Submit LOI online directly to the DOE Portfolio Analysis & Management System (PAMS) website: https://pamspublic.science.energy.gov/

- Select “Create New PAMS Account” (if you do not have an account)
- Submit your LOI as a PDF file
- Utilize the LOI instructions available at the DOE website to ensure that you submit all the required information
- For additional details on the LOI submission process, see the Funding Opportunity Announcement
**U.S. Department of Energy Interests**

- **Goal 1**: Catalyze the timely, material, and efficient transformation of the nation's energy system and secure U.S. leadership in energy technologies.

- **Goal 2**: Maintain a vibrant U.S. effort in science and engineering as a cornerstone of our economic prosperity, with clear leadership in strategic areas.

- **Goal 3**: Enhance nuclear security through defense, nonproliferation, and environmental efforts.

*Source: Chris O’Gwin, DOE SBIR/STTR Programs Office; SBIR/STTR Con 19, UC Riverside, March 12, 2019*
NIH Budget Has Increased for 2019

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<th>2019 Budget</th>
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<tr>
<td>CDC</td>
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<td>ACL (NIDILRR)</td>
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<tr>
<td>FDA</td>
<td>~$1M</td>
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Slide # 52
Success Rate by Phase

Source: Matthew Portnoy (March 12, 2019)

Note: STTR Ph2B 1 application, no award.
Award Dollars in Millions 2012-2016

Source: Matthew Portnoy
(March 12, 2019)
Three-Phase Program

Discovery Phase I
- Feasibility
- Fast-Track
- Direct to Phase II

Development Phase II
- Full R/D

Competing Renewal Award Phase IIB
- $3M for up to 3 years

Commercialization Phase III
- Commercialization Readiness Pilot (CRP)
- Congressional Authority Back! Re-implemented Fall/Winter
- $3M for up to 3 years

Only some institutes and centers participate

Source: Matthew Portnoy (March 12, 2019)
1. Significance
2. Innovation
3. Approach
4. Investigators
5. Environment

Focus: Key Criteria

NIH Reviewer “Marching Orders”

Title
Abstract
Problem
Solution
Specific Aims
Research
Strategy
Facilities
Biographies

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Slide # 56
Overall Impact

Assessment of the likelihood for the project to 
*exert a sustained, powerful influence on the research field(s) involved*
Additional Review Criteria

- Commercial Potential (Phase I)
- Commercialization Plan (Phase II)

1. Project Value, expected outcomes, societal & educational benefits
2. Company information
3. Market, customer, and competition information
4. Intellectual property protections
5. Finance plan
6. Production and marketing plan
7. Revenue stream generation
### Scoring System and Procedure

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<th>Score</th>
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<tr>
<td>NR</td>
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1) Preliminary Scores  
2) Criterion Scores  
3) Impact Score  
4) Non-Numeric Scores  
5) Final Impact Score

- See “What’s Next?”
- Program Officer


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DoD Evaluation Factors

1) Military & Program Relevance
2) PI/Key Personnel Qualifications
3) Research Objectives
4) Scientific Excellence
5) Impact/Outcomes
6) Facilities
7) Budget
8) Commercialization Strategy

SBIR/STTR Desk Reference:
“Evaluation & Selection” -
(http://www.acq.osd.mil/osbp/sbir/sb/resources/deskreference/02_eval.shtml)
We need YOUR solutions

Robert Smith, Director, DON SBIR/STTR & Special Programs
robert.l.smith6@navy.mil
The 2019 BAA Schedule is as follows:

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<td>24 September 2019</td>
<td>23 October 2019</td>
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Source: [https://sbir.defensebusiness.org/topics](https://sbir.defensebusiness.org/topics)
- Intellectual Merit
- Impact on Society

1. Advance Knowledge and Understanding
2. Benefit Society

3. Creative, Original and Transformative
4. Well-reasoned; well organized; sound rationale; mechanism to assess success
5. Your Qualifications and Resources
NATIONAL SCIENCE FOUNDATION

New SBIR/STTR Protocol
NEW: Submit a “Project Pitch” (required)

Invitation Process:
- NSF “only accepts proposals from companies that have been officially invited to submit (via the Project Pitch process).”
- See the current SBIR solicitation or STTR solicitation to get a sense of NSF’s objectives.
- Processing time: About three (3) weeks
Three-Page Project Pitch

1) Each small business can only submit one Project Pitch at a time and up to two Project Pitches per submission window.

Submission windows: (a) March 4-June 13 & (b) June 14-December 12

3) Those with a pending Project Pitch must wait for a response before submitting another Project Pitch.

4) Any small business that has received an invitation to submit a full proposal must wait for a resolution of the full proposal before submitting a new or revised Project Pitch.
Four Key Elements:

1. The Technology Innovation. (500 words)

2. The Technical Objectives and Challenges. (500 words)

3. The Market Opportunity. (250 words)

4. The Company and Team. (250 words)
Upon Invitation

1) Register your company

2) Submit your full proposal
   - Submission window will close on June 13, 2019
   - Another submission window will open on June 14
   - 1-3 (July – September) months after the window closes: Applications undergo merit reviews.
   - 4-6 (October – December) months after the window closes: Notification whether proposal is accepted or declined.
   - Funding 5-6 months after the window closes
Partnerships for Innovation (PFI)

Source: Jesus Soriano Molla MD PhD MBA
Program Director
National Science Foundation
Industrial Innovation & Partnerships
NSF Innovation Programs

GOALI – Grant Opportunities for Academic Liaison with Industry
INTERN – Graduate Student non-Academic Internships
IUCRC – Industry University Cooperative Research Center
PFI – Partnerships for Innovation
I-Corps – Innovation Corps
SBIR/STTR – Small Business Innovation Research/Small Business Technology Transfer

Bridging the Gap
Public – Private Funds

Info Source: Jesus Soriano Molla MD PhD MBA
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Partnerships for Innovation (PFI)

Congressionally Mandated¹:

- Accelerate translation of research results to societal impact.
- Promote a sustainable university-based innovation ecosystem.
- Train faculty and students in technological innovation.
- Engage women and other underrepresented groups in innovation.

1. American Innovation and Competitiveness Act (Public Law No. 114-329)
Partnerships for Innovation

PFI-TT① grants are up to $250,000 over 18-24 months.
- Applied Research.
- Proof-of-concept demonstrations or prototypes.

PFI-RP② grants are up to $550,000 over 36 months.
- Same Goals as PFI-TT.
- Focused on Multidisciplinary, Multi-Organizational Teams.
- Requires an Industry Partner.

(1) PFI-TT – Partnerships for Innovation-Technology Translation
(2) PFI-RP – Partnerships for Innovation-Research Partnerships

Submission Deadlines: January and July
Not For All Of Us

- **Academic / Research US institutions**: includes universities and two- and four-year colleges (including community colleges) accredited in, and having a campus located in the US, acting on behalf of their faculty members.

- **Public or Non-profit, Non-academic US organizations**: located in the US that are directly associated with technology transfer activities.

- **Non-profit US organizations**: located in the US that partner with an institution of higher education.

- **A US consortium of 2 or more**: of the organizations described above.
The Industrial Partner (I)

- Mandatory in PFI-RP track, encouraged in PFI-TT
- U.S.-based
  - Foreign Public Entities or Foreign Organizations do not qualify.
- Established record of commercial revenue.
  - From sales or licensing
  - Majority of revenues cannot be from grants/government contracts
- For-profit or not-for-profit.
  - Non-profit, technology transfer organizations must meet revenues requirement
- Proven experience in bringing products or services to the proposed target market sector
The Industrial Partner (II)

- Demonstrates **strategic commercial interest** in PFI technology
- **Does not include** budgeted Vendors/Service Providers
- **SBIR/STTR companies** may act as Industrial Partner.
- **Subawards only to SBIR/STTR – funded businesses**
  - Small businesses must be eligible for SBIR/STTR
  - Must not be owned and/or controlled by proposing team/institution.
  - Subawards are not intended to complement or circumvent SBIR/STTR awards to small businesses or as a standing source of revenue for the small business
Intended Outcomes of PFI

- Commercialization of IP derived from NSF-funded research.
- Licensing of NSF-funded research outputs.
- Foster collaborations with industry.
- Training future innovation and entrepreneurship leaders.
- Increased participation of women, minorities, and persons with disabilities in innovation & entrepreneurship.

Read solicitation NSF 19-506
Synopsis: Reviewer Criteria

Study Approach
Ability/Credentials
Impact

Significance
Innovation
Approach
Investigators
Environment
Impact

Relevance
Objectives
Scientific Excellence
Impact
Qualifications
Facilities
Budget
Commercialization

Intellectual Merit
Impact/Benefit
Advance Knowledge
Creative, Original,
Transformative
Well-Reasoned
Qualifications
Resources

Similar Criteria for the Other 7 Agencies
Phase I Success Rates

http://www.sbir.gov/competitiveness
PART IV: REJECTED?

1) They Don’t “Get It”
2) Problem Is Not Significant (Enough)
3) Not Innovative
4) We’re Not Qualified
5) Approach Needs Work

Common Problems
Common Problems (I)

1) Lack of new or original ideas
2) No Significance: unimportant problem, unconvincing case for commercial potential or societal impact
3) Inadequate consideration of scientific premise & rigor
4) Absence of an acceptable scientific rationale
5) Questionable reasoning in experimental approach
6) Diffuse, superficial, or unfocused research plan
7) Lack of sufficient experimental detail
8) Failure to consider potential pitfalls and alternatives
9) Lack of knowledge of published relevant work &/or technologies
10) Lack of experience in the essential methodology
11) Unrealistically large amount of work
Common Problems (II)

1) Proposal Is **NOT CLEARLY WRITTEN**
   - Use peer review improve solution and pitch

2) Proposal is **Not Innovative**
   - NOT CLEARLY DIFFERENTIATED: Position Technology Solution Relative to Current Standard & Alternative Solutions/Offerings
   - NOVEL COMBINATION Of Existing Approaches: emphasize Novelty AND Unmet (Evidence-Based) Need

3) Team is **NOT QUALIFIED**
   - Add collaborators and consultants
   - Create a Multi-PI Group (To Address Experience Issues)
More Common Problems

4) Not Working on a **SIGNIFICANT PROBLEM**
   - Sell on Problem Importance: Repercussions/Ramifications
   - Be More Specific and Quantitative
   - Get Letters of Support in re Problem and Buyers/End users

5) Reviewers Are Critical of **OUR APPROACH**
   - Respond to Their Criticisms
   - Revise the Approach
   - Have Others Review and Critique Approach
What We Often Find . . .

Evidence of Innovation & Sustainable Value is Lacking . . .

. . . Carefully Written Letters from Targeted Stakeholders are Vital
Study Approach

Statement of Aims

Project Description
“Deal Killers” for Some

Research Question

Purpose or Hypothesis

Specific Aims

Study Approach

[Literature, Pertinent Work to Date, . . .]

[Predictions, Variable Relationships, Cause & Effect, Possible Explanation(s) . . .]

[What is Measured, How, Controls, How Data Interpreted]

[Research Design]
Letter of Intent

Statement of Aims

Question – Aim(s) – Approach - Impact
Our Credentials
Our Team

- PI(s)
- Employees
- Subcontractor(s)
- Consultants
- Other Significant Contributors

(Think Ahead to Commercialization)

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Why 65% of SBIRs are Partnerships

Study Design
- e.g. Single/Double Blind
- Study Population
- Sample Size/Power Anal.
- Outcomes/Endpoints

Study Procedure
- e.g. Sampling Plan, Criteria
- Recruitment Procedure
- Screening
- Randomization (if applicable)
- Study Intervention
- Assessments & Activities

Analysis Plan
- Statistical Methods
- Background
We don’t need no stinking budgets!

“Budgets? We ain’t got no budgets. We don’t need no budgets. I don’t got to show you no stinking budgets!”

Alfonso Bedoya (“Gold Hat”), The Treasure of Sierra Madre (1948)

Budget Preparation Guide & Salary Validation:
- http://www.bls.gov/bls/blswage.htm
PART IV: “Crossing The Chasm”

Commercialization
Commercialization Plan

1. Company Information
2. Customer & Competition
3. Market
4. Intellectual Property
5. Financing
6. Assistance & Mentoring
From the NIH Reviewers Guide*

1) Your Project’s **Value**, Expected Study Outcomes, **Market Benefits**
   - Key Technology Objectives, Commercial Applications, Competitive Advantages

2) Corporate Objectives, Core Competencies, **Business Development Plans** (PLUS Background: History of Previous Funding; Regulatory Experience; Commercialization

3) **Market, Customer, and Competition**
   - Segment(s) Targeted; Competition(or) Analysis

4) Intellectual Property Protections (Patent & Provisional Status)

*”R41, R42, R43, R44 Guide For Reviewers” (February 8, 2011)
5) Financial Plan
   ▪ Letters of Commitment; Letters of Support; Specific Steps Taken for Phase III

6) Production & Marketing Plan
   ▪ Manufacturing, Marketing, Licensing, and Internet Sales

7) Revenue Stream Generations (aka “sales”)
   ▪ Manufacture & Direct Sales, Distributors, Joint Ventures, Licensing, Internet

(Reviewers evaluate Commercialization Plan in SIGNIFICANCE Criteria Section– Comment on its Strengths/Weaknesses)
“Can Your Dog Hunt?”

1) Your Past Record
2) Phase II Funding Commitments
3) Phase III Follow-On Commitments
4) Other Indicators
Commercialization Support

I. NIH: Phase I “Technology Niche Analysis” (TNA)
   ▪ NCAI, REACH (centers/hubs) as noted previously

II. NIH, NSF, DOE: Commercialization Assistance Program (P II)

III. NSF, NIH, DoD: The I-Corps Program - Innovation & Technology Commercialization Methodology (“Lean LaunchPad”)
   ▪ The Business Model Canvas
   ▪ The Customer Discovery & Validation Process

IV. NSF: Supplemental (e.g. Matching Funds)

V. DOE, DOT: Commercialization Assistance Program (CAP)
NIH Technical Assistance Programs

**Phase I Awardees**
Niche Assessment Program
Foresight Science & Tech

**Phase II Awardees**
Commercialization Accelerator Program
Larta, Inc.

- Jump-start commercialization efforts
- Determine competitive advantages
- Develop market entry strategy

**Technical Assistance/Training in:**
- Strategic/business planning
- FDA requirements
- Technology evaluation
- Manufacturing issues
- Patent and licensing issues

- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting
Phase I Awardees (also prep support)

- Kickoff Webinar
- Commercialization Readiness Assessment (CRA)
- Market Research
- Specialty Webinars
- Business Mentoring: Phase II Commercialization Plan

www.dawnbreaker.com
http://science.energy.gov/sbir/commercialization-assistance/
Phase II Match Funding (NSF “Phase IIB”)  

- Aim: Extend R & D Efforts Beyond Current P-II Grant  
- Further Accelerate Commercialization  

- Max Funding: 50% of Investment Funds up to $500,000  
- Must Start Process At least 30 Days Prior to Phase II Award Expiration; Investment Minimum of $100K  
- (See: https://www.nsf.gov/eng/iip/sbir/Supplement)
Commercial/Strategic Partnerships

- NSF: “Technology Enhancement for Commercial Partnerships”
- NSF Funding for additional research that goes beyond the Phase II project’s objectives to meet the technical specifications or additional proof-of-concept requirements. (Submit w/in 18 months of PII award)
- Additional research is anticipated to enhance the commercial potential and lead to partnerships with industrial partners & secure venture/angel investors.

- Max Funding: 20% of the Phase II award, up to $150,000
- Pre-submission Exec Summary + Letter from Commercial Partner
  (Reference: www.nsf.gov/eng/iip/sbir/Supplement/instructions.jsp)

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Commercialization Assistance

- Funding to secure the services of a third-party service provider to assist in commercialization activities.

- **Max Funding: $10,000 per Phase II award**

- Deadline: Within 12 months of the effective start date of Phase II award *(recommended)*

Seven (7) Week Curriculum
(Agency Grant-Funded: $40K - $70K)

- Precursor Competitive Programs
  - e. g. IN-LA “Zap” & “Boom”
  - e. g. U C Riverside Phase I & II

- Five + Week Site-Based Programs

- Apply Directly to NSF, NIH, DoD
EVERYONE has a plan until they get PUNCHED IN THE MOUTH.
No battle plan survives first contact with the enemy.
- Helmuth von Moltke¹

No Business Plan survives first contact with customers.
- Steve Blank²

(1) 19th-century head of the Prussian army; (2) Stanford & U C Berkeley (I-Corps)
Plans are worthless, but planning is everything.*

- Dwight D. Eisenhower

* National Defense Executive Reserve Conference, Washington DC, November 14, 1957
Five-Year Plans

Venture Capitalists

Soviet Union
Instead of creating business plans...

Today we discover business models.
Business Model Generation
(Customer Discovery & Validation)
7 Week Grant-Funded Cohorts
Business Model Generation . . .

. . . Customer Development
Behind Every Great Product is a Great Story

The Start-Up Curve!
(starring Us)

Paul Graham, avc.com
Hopefully some of this was helpful!

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