Overview of the HHS SBIR/STTR Programs: Research & Educational Opportunities at NIH

NASA HBCU/MSI Technology Infusion Road Tour
University of Nevada - Las Vegas
January 10 - 12, 2017

Robert Vinson
SBIR/STTR Program Manager; Office of Extramural Research, NIH
What are SBIR and STTR Programs?

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

In Fiscal Year 2016, NIH’s SBIR and STTR programs will invest over $70 million dollars into health and life science companies that are creating innovative technologies that align with NIH’s mission to improve health and save lives. A key objective is to translate promising technologies to the private sector and enable life-saving innovations to reach consumer markets.

We invite you to explore our website to learn more about NIH’s SBIR & STTR programs, or get started on an application!

http://sbir.nih.gov
New to SBIR/STTR?

SBIR/STTR Application Process Infographic

Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click through the chart for answers to your related questions.

http://sbir.nih.gov/infographic
**SBIR/STTR Program Overview**

**3.2% SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**
Set-aside program for small business concerns to engage in federal R&D - with potential for commercialization

**0.45% SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**
Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions - with potential for commercialization
SBIR Purpose and Goals

- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

Small Business Innovation Development Act of 1982
P.L. 112-81 Re-Authorizes program through FY2017
STTR Purpose and Goals

- Stimulate and foster scientific and technological innovation through cooperative research and development carried out between small business concerns and research institutions
- Foster technology transfer between small business concerns and research institutions

Small Business Research and Development Enhancement Act of 1992

P.L. 112-81 Re-Authorizes program through FY2017
### Agencies with SBIR and STTR Programs

<table>
<thead>
<tr>
<th>Agency</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Defense (DOD)</td>
<td>$1.070B</td>
</tr>
<tr>
<td>Department of Health and Human Services (HHS), including the National Institutes of Health (NIH)*</td>
<td>$797M</td>
</tr>
<tr>
<td>Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)</td>
<td>$206M</td>
</tr>
<tr>
<td>National Aeronautics and Space Administration (NASA)</td>
<td>$180M</td>
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<tr>
<td>National Science Foundation (NSF)</td>
<td>$176M</td>
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### Agencies with SBIR Programs

<table>
<thead>
<tr>
<th>Agency</th>
<th>Budget</th>
</tr>
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<tbody>
<tr>
<td>U.S. Department of Agriculture (USDA)</td>
<td>$25.3M</td>
</tr>
<tr>
<td>Department of Homeland Security (DHS): Science and Technology Directorate (S&amp;T) and Domestic Nuclear Detection Office (DNDO)</td>
<td>$17.7M</td>
</tr>
<tr>
<td>Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*</td>
<td>$8.4M</td>
</tr>
<tr>
<td>Department of Transportation (DOT)</td>
<td>$7.9M</td>
</tr>
<tr>
<td>Department of Education (ED)</td>
<td>$7.5M</td>
</tr>
<tr>
<td>Environmental Protection Agency (EPA)</td>
<td>$4.2M</td>
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</table>
### HHS Program Funding

<table>
<thead>
<tr>
<th>2016 Budget</th>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td>NIH</td>
<td>$763M</td>
<td>$114M</td>
</tr>
<tr>
<td>CDC</td>
<td>$9.0M</td>
<td>N/A</td>
</tr>
<tr>
<td>ACL (NIDILRR)</td>
<td>$2.7M</td>
<td>N/A</td>
</tr>
<tr>
<td>FDA</td>
<td>$1.6M</td>
<td>N/A</td>
</tr>
<tr>
<td>ACF</td>
<td>$94K</td>
<td>N/A</td>
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</table>
Three-Phase Program

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

**Discovery**

**Phase I Feasibility Study**
- **Budget Guide:** $150K for SBIR and STTR
- **Project Period:** 6 months (SBIR); 1 year (STTR)

**Development**

**Phase II Full Research/R&D**
- $1M for SBIR and STTR, over two years

**Phase IIB Competing Renewal/R&D**
- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, IC’s participate
- Varies~$1M per year; up to 3 years

**Commercial**

**Phase III Commercialization Stage**
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
SBIR Eligibility Criteria

- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the US (with few exceptions)
- Individual Ownership:
  - Greater than 50% US-owned by individuals and independently operated OR
  - Greater than 50% owned and controlled by other business concern/s that is/are greater than 50% owned and controlled by one or more individuals OR
  - Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (For FOAs after 1/28/2013 NIH; 7/10/14 CDC)

Determined at Time of Award
STTR Eligibility Criteria

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- US Research Institution
  - College or university; other non-profit research organization; Federal R&D center
- Intellectual Property Agreement
  - Allocation of rights in IP and rights to carry out follow-on R&D and commercialization
Important Facts to Remember

• Eligibility is determined at **time of award**
• PD/PI is **not** required to have a Ph.D./M.D.
• PD/PI is required to have expertise to oversee project scientifically and technically
• Applications **may be** submitted to **different agencies** for similar work
• Awards may not be accepted from different agencies for **duplicative projects**
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
SBIR/STTR Budget Allocations FY’16

3.00% SBIR  $763M
.45% STTR  $114M
FY’16  $877M
FY’17  TBD
<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>SBIR/STTR</th>
<th>Phase</th>
<th>Number Applications Reviewed</th>
<th>Number Applications Awarded</th>
<th>Success Rate</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>SBIR</td>
<td>Fast Track</td>
<td>337</td>
<td>66</td>
<td>19.6%</td>
<td>$18,157,545</td>
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<tr>
<td>2015</td>
<td>SBIR</td>
<td>Phase I</td>
<td>3,425</td>
<td>514</td>
<td>15.0%</td>
<td>$117,110,555</td>
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<tr>
<td>2015</td>
<td>SBIR</td>
<td>Total Phase II</td>
<td>823</td>
<td>241</td>
<td>29.3%</td>
<td>$179,946,727</td>
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<tr>
<td></td>
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<td>Regular Phase II</td>
<td>442</td>
<td>163</td>
<td>36.9%</td>
<td>$113,088,150</td>
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<tr>
<td></td>
<td>SBIR</td>
<td>Direct Phase II</td>
<td>347</td>
<td>65</td>
<td>18.7%</td>
<td>$55,150,363</td>
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<tr>
<td></td>
<td>SBIR</td>
<td>Phase IIB</td>
<td>34</td>
<td>13</td>
<td>38.2%</td>
<td>$11,708,214</td>
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<tr>
<td>2015</td>
<td>STTR</td>
<td>Fast Track</td>
<td>61</td>
<td>10</td>
<td>16.4%</td>
<td>$2,171,909</td>
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<tr>
<td>2015</td>
<td>STTR</td>
<td>Phase I</td>
<td>911</td>
<td>149</td>
<td>16.4%</td>
<td>$33,782,224</td>
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<td>2015</td>
<td>STTR</td>
<td>Total Phase II</td>
<td>87</td>
<td>31</td>
<td>35.6%</td>
<td>$21,597,183</td>
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<tr>
<td></td>
<td>STTR</td>
<td>Regular Phase II</td>
<td>87</td>
<td>31</td>
<td>35.6%</td>
<td>$21,597,183</td>
</tr>
<tr>
<td>2015</td>
<td>FY TOTAL</td>
<td></td>
<td>5,644</td>
<td>1,011</td>
<td>17.9%</td>
<td>$372,766,143</td>
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https://sbir.nih.gov/funding
NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation

“Parent” FOAs:  
**SBIR:** PA-16-302  
**STTR:** PA-16-303

Release: June 3, 2016  
Standard Due Dates: September 5th, January 5th, April 5th

SBIR Contract Solicitation (NIH, CDC)

Program Solicitation **PHS 2017-1** (SBIRs Only)

NIH Guide Notice **NOT-OD-16-123**

Released: Aug. 1, 2016  
Closed: Oct. 21, 2016 (5pm EDT)

NIH Guide for Grants and Contracts

Release: Weekly receipt dates specified in each FOA
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<th>Due Dates</th>
<th>Omnibus</th>
<th>Targeted</th>
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<tbody>
<tr>
<td>Standard Due Dates</td>
<td>Standard</td>
<td>Customized Due Dates</td>
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<thead>
<tr>
<th>Review</th>
<th>Omnibus</th>
<th>Targeted</th>
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<tbody>
<tr>
<td>SBIR/STTR panels at CSR</td>
<td>SBIR/STTR panels at CSR OR SBIR/STTR panel at IC</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Application Instructions</th>
<th>Omnibus</th>
<th>Targeted</th>
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<tbody>
<tr>
<td>Follow SF424 R&amp;R</td>
<td>SBIR/STTR Application Guide &amp; Annotated Form Set</td>
<td>SBIR/STTR Application Guide &amp; Annotated Form Set AND any additional instructions in FOA</td>
</tr>
</tbody>
</table>

*Read FOA very carefully!*
SBIR/STTR grant applications and SBIR contract proposals must be submitted electronically.

Registrations are required!!!
- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

- Helpful NIH Grants Registration Infographic

- For contracts, submit proposals with electronic Contract Proposal Submission (eCPS) website
What is a **Women-Owned Small Business** (WOSB)?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women (who must be US citizens)
- The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry
- SBCs self certify on the SF 424 (R&R) Form

What is a **Socially and Economically Disadvantaged Business** (SDB)?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged
- The firm must be small, according to SBA’s size standards
- You must self-certify by registering your business in the **System for Award Management**
**Application & Review Process**

1. **Applicant initiates research idea**
2. **Small Business Concern confirms Eligibility**
3. **Submits SBIR/STTR grant application to NIH electronically**
4. NIH Center for Scientific Review assigns to IC and IRG
   - **1-2 Months**
5. **Advisory Council or Board recommend Approval**
6. **Scientific Review Group evaluates scientific merit**
   - **3 Months**
7. **IC staff prepare funding plan for IC Director**
   - **2-4 Months**
8. **IC allocates funds**
9. **Grantee conducts research**
Helping companies cross the “Valley of Death”

Phase I

Phase II

Phase III

Niche Assessment Program (NAP)

Commercialization Accelerator Program (CAP)

Phase IIB
Technical Assistance Programs

Niche Assessment Program Foresight S&T (Phase I awardees)
- Identifies other uses of technology
- Determines competitive advantages
- Develops market entry strategy

Commercialization Accelerator Program Larta, Inc. (Phase II awardees)
- “Menu” of technical assistance/training programs in:
  - Strategic/business planning
  - FDA requirements
  - Technology valuation
  - Manufacturing issues
  - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting
Multi-IC Technology Development Programs
(open to eligible Awardees from participating ICs)

I-Corps™ at NIH
An intensive Entrepreneurial Immersion course for scientists

12 Participating ICs + CDC

Facilitating Partnerships
Select your educational or career level to find a funding opportunity to support your training or career development goals.
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- Subscribe to the SBIR/STTR Listserv:
  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: subscribe SBIR-STTR your name

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- Email: sbir@od.nih.gov