SBIR/STTR Overview & NIH SBIR/STTR Programs

Matthew Portnoy, Ph.D.
NIH SBIR/STTR Program Coordinator
Office of Extramural Research, NIH
To support scientific excellence and technological innovation by providing investment of Federal R&D funds into small businesses to work on critical national priorities and build a stronger economy.
Congressionally Mandated Programs

**SET ASIDE**

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

- **3.2%**

**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

- **.45%**
• 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. 114-328 Re-Authorizes program through FY2022
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. 114-328 Re-Authorizes program through FY2022
Best Things about SBIR
For Small Businesses

• Non-Dilutive Capital – The funding agency cannot take an equity position or ownership of your firm (pros and cons to this)

• IP/Data Rights protection – Government can’t share reports or data with anyone outside of the federal government for 5 years (DoD) or 4 years (other agencies)

• Direct follow on Phase III awards – No need for further competition, which benefits both the government and small businesses
### SBIR/STTR Budgets by Agency FY16

**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>$1.288B</td>
</tr>
<tr>
<td>Dept of Health and Human Services (HHS), Inc National Institutes of Health (NIH)*</td>
<td>$891.0M</td>
</tr>
<tr>
<td>Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)</td>
<td>$228.6M</td>
</tr>
<tr>
<td>National Science Foundation (NSF)</td>
<td>$187.7M</td>
</tr>
<tr>
<td>National Aeronautics and Space Administration (NASA)</td>
<td>$183.4M</td>
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**Agencies with SBIR Programs**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Budget</th>
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<tbody>
<tr>
<td>U.S. Department of Agriculture (USDA)</td>
<td>$28.8M</td>
</tr>
<tr>
<td>Department of Homeland Security (DHS)</td>
<td>$17.0M</td>
</tr>
<tr>
<td>Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*</td>
<td>$12.5M</td>
</tr>
<tr>
<td>Department of Transportation (DOT)</td>
<td>$11.6M</td>
</tr>
<tr>
<td>Department of Education (ED)</td>
<td>$7.5M</td>
</tr>
<tr>
<td>Environmental Protection Agency (EPA)</td>
<td>$4.9M</td>
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</tbody>
</table>

**SBIR: $2.5 Billion**

**STTR: $361 Million**

Across all agencies

- Grants
- Contracts

*Provides grants and contracts*
• SBIR/STTR programs reauthorized for 5 year FY18 through FY22
• Pilot programs extended through 2022
  o SBIR Direct Phase II
  o Commercialization Readiness Pilot Programs
  o 3% Agency SBIR Admin funds
  o NIH Phase 0 Proof of Concept Centers
• Expand Technical Assistance
  o Phase I $6,500/year (up from $5,000/year)
  o Phase II $50,000/project (up from $5,000/year)
  o SBC hire own vendor or use agency vendor
Program 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:
  o Greater than 50% US-owned by individuals and independently operated OR
  o 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
  o 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 some agencies)

Determined at Time of Award
• Applicant is a Small Business Concern

• Formal Cooperative R&D Effort
  o Minimum 40% by small business
  o Minimum 30% by US research institution

• US Research Institution
  o College or university; other non-profit research organization; Federal R&D center

• Intellectual Property Agreement
  o Allocation of rights in IP and rights to carry out follow-on R&D and commercialization
NIH SBIR/STTR 3-Phase Program

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

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

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

**Phase III Commercialization**
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
### SBIR and STTR Critical Differences

<table>
<thead>
<tr>
<th></th>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td>Partnering</td>
<td>Permits partnering</td>
<td>Requires a non-profit research institution partner (e.g. university)</td>
</tr>
<tr>
<td>Requirement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work Requirement</td>
<td>Guidelines: May outsource 33% (Phase I) 50% (Phase II)</td>
<td>Minimum Work Requirements: 40% small business 30% research institution partner</td>
</tr>
<tr>
<td>Principal</td>
<td>Primary employment (&gt;50%) must be with the small business</td>
<td>PI may be employed by either the research institution partner or small business</td>
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<tr>
<td>Investigator</td>
<td></td>
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**Award is always made to the small business**
Some of our Home Runs

23andMe  illumina®  enchroma.

Biogen  Symantec  Qualcomm®

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.
NIH SBIR/STTR Website

https://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
<table>
<thead>
<tr>
<th>2019 Budget</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
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<tbody>
<tr>
<td>NIH</td>
<td>$1B</td>
<td>$141M</td>
</tr>
<tr>
<td>CDC</td>
<td>~$12M</td>
<td>N/A</td>
</tr>
<tr>
<td>ACL (NIDILRR)</td>
<td>~$3M</td>
<td>N/A</td>
</tr>
<tr>
<td>FDA</td>
<td>~$1M</td>
<td>N/A</td>
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NIH SBIR/STTR Budget Allocations FY2019

3.2% SBIR $1B
0.45% STTR $141M
Total FY19 $1.145B
NIH SBIR/STTR 2018
Success Rate by Phase

20.1% 20.9% 42.2% 38.1%
18.4% 20.9% 34.6% 0.0%

Note: STTR Ph2B 1 application, no award.
Percentage of New Applicant Companies and New Awardee Companies

- % New Applicant Companies
- % New Awardee Companies

- 2005: 32%
- 2006: 32%
- 2007: 31%
- 2008: 29%
- 2009: 31%
- 2010: 33%
- 2011: 34%
- 2012: 34%
- 2013: 33%
- 2014: 35%
- 2015: 34%
- 2016: 38%
Dollars of NIH Funded SBIR/STTR Awards in FYs 2012-2016 in Millions
Dollars Per Person of NIH Funded SBIR/STTR Awards in FYs 2012-2016
NIH SBIR/STTR
3-Phase Program

Discovery
Phase I
Feasibility

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 ICs Participate

Congressional authority back!
Re-implemented.

Fast-Track

Direct to Phase II

Phase I → Phase II

Direct to Phase II
Funding Opportunities Announcements (FOAs)
a publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

https://sbir.nih.gov/funding
NIH, CDC, & FDA SBIR/STTR Grant Solicitation “Parent” FOAs:

Clinical Trial Required

SBIR: PA-18-573    STTR: PA-18-576

Clinical Trial Not Allowed

SBIR: PA-18-574    STTR: PA-18-575

Release:  January 16, 2018
Standard Due Dates:  April 5\textsuperscript{th}, September 5\textsuperscript{th} (2018)
                   January 7\textsuperscript{th}, April 5\textsuperscript{th} (2019)
New Reforms & Initiatives

All Research Involving Human Participants

- New forms to collect human subjects information
- Use of a single Institutional Review Board (IRB) for domestic multi-site studies

Research that Meets the NIH Definition of a Clinical Trial

- Training in Good Clinical Practice (GCP)
- Clinical trial-specific Funding Opportunity Announcements (FOAs)
- New review criteria
- Expanded registration and results reporting in ClinicalTrials.gov
NIH Definition of a Clinical Trial

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

- **Prospectively Assigned:** a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

- **Intervention:** a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

- **Health-related Biomedical or Behavioral Outcome:** the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life.

Learn more at [https://grants.nih.gov/policy/clinical-trials/definition.htm](https://grants.nih.gov/policy/clinical-trials/definition.htm)
Determine if Your Study is an NIH-defined Clinical Trial

Does your study…

1. Involve one or more human participants?
2. Prospectively assign human participant(s) to intervention(s)?
3. Intend to evaluate the effect of an intervention on human participants
4. Have a health-related biomedical or behavioral outcome?

If “yes” to ALL of these questions, your study is considered a clinical trial

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm
Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

**NIH Definition of a Clinical Trial**

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

Your human subjects study may meet the NIH definition of a clinical trial.

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
Submit via ASSIST or Workspace

ASSIST

NIH’s web-based service for the preparation, submission and tracking of grant applications.

Learn more about preparing your application using ASSIST

Grants.gov Workspace

A shared, online environment managed by Grants.gov where multiple users may simultaneously work on different forms within an application package.

Learn more about preparing your application using Grants.gov Workspace

Institutional Solutions (System-to-System, S2S)

Institution’s own system to prepare and submit application data to Grants.gov complying with all application requirements.
<table>
<thead>
<tr>
<th>Due Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (earliest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 5th</td>
<td>May/June</td>
<td>Aug/Sept</td>
<td>October</td>
</tr>
<tr>
<td>Sept 5th</td>
<td>Oct/Nov</td>
<td>Jan/Feb</td>
<td>March</td>
</tr>
<tr>
<td>Jan 5th</td>
<td>Feb/Mar</td>
<td>May/June</td>
<td>July</td>
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NIH 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. IC staff prepare funding plan for IC Director
   - 2-4 Months

6. Advisory Council or Board recommend Approval
   - 3 Months

7. Scientific Review Group evaluates scientific merit

8. IC allocates funds
9. Grantee conducts research
Talk to a HHS Program Officer at least a month before a deadline for application specific advice.

Click here for the list of HHS SBIR Program Managers

Not sure who to contact? Email sbir@od.nih.gov
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**
NIH Technical Assistance Programs

**Niche Assessment Program-Foresight S&T**
(Phase I Awardees)

- Helps jump start commercialization efforts
- Determines competitive advantages
- Develops market entry strategy

**Commercialization Accelerator Program - Larta, Inc.**
(Phase II Awardees)

- 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
Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: subscribe SBIR-STTR your name

- **NIH Guide for Grants and Contracts** (weekly notification)

- Follow us on Twitter: @NIHsbir

- Read our **NIH SBIR/STTR Success Stories**

- Connect with Us

- Email: sbir@od.nih.gov