Overview of the NIH SBIR/STTR Program

Meet the Experts in NIH Peer Review for Small Business Grant Applicants

Matthew Portnoy, Ph.D.
SBIR/STTR Program Coordinator
Office of Extramural Research, NIH
SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in Federal R&D -- with potential for commercialization.

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and U.S. 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
• 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
**Overall Impact Score**

**Scored Review Criteria** (score 1-9)
- **Significance** (Real Problem/Commercial Potential)
- Investigators (PI and team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

**Additional Review Criteria** (not scored individually)
- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards
NIH SBIR/STTR 3-Phase Program

PHASE I Feasibility Study
- Budget Guide: $150K (SBIR); $150K (STTR) Total Costs
- Project Period: 6 months (SBIR); 1 year (STTR)

PHASE II Full Research/R&D
- $1M (STTR), $1M (SBIR) over two years

PHASE IIB Competing Renewal/R&D
- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, ICs participate
- Varies ~$1M/year; 3 years

PHASE III Commercialization Stage
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
• Capital is in the form of grants and contracts
• Strategic Investment in Innovation
• Non-diluted funding:
  – No repayment
  – No debt service
  – No equity forfeiture
  – No IP forfeiture
<table>
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<th>SBIR Eligibility Criteria</th>
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<td>From 1/28/2013 FOAs going forward</td>
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- Organized as **for-profit** U.S. business
- Small: **500** or fewer employees, including affiliates
- PD/PI’s **primary employment** must be with **small business concern** at time of award and for duration of project period
- Greater than **50%** U.S.- 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
STTR Eligibility Criteria

- Applicant is Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by U.S. research institution
- U.S. 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
PD/PI Eligibility on STTR

- PD/PI is **not** required to be employed by SBC
- PD/PI at RI must establish contract between RI and SBC describing PD/PI’s involvement
- PD/PI must commit a **minimum of 10% effort**
- PD/PI’s “signature” on application is agreement to conforming to Solicitation requirements
SBIR and STTR
Critical Differences

• Research Partner
  - SBIR: Permits partnering 33% Phase I and 50% Phase II
  - STTR: Requires partnering with research institution. Small business (40%) and U.S. research institution (30%)

• Principal Investigator
  - SBIR: Primary (>50%) employment must be with small business concern
  - STTR: PI may be employed by either research institution or small business concern

Award is always made to Small Business Concern
**Success Rate of SBIR/STTR 2012 and 2013 by Phase**

**SBIR**
- **Fast Track**:
  - 2012: 15.9%
  - 2013: 15.7%
- **Phase I**:
  - 2012: 15.6%
  - 2013: 13.2%
- **Phase II**:
  - 2012: 39.9%
  - 2013: 32.8%

**STTR**
- **Fast Track**:
  - 2012: 34.4%
  - 2013: 28.6%
- **Phase I**:
  - 2012: 20.3%
  - 2013: 18.7%
- **Phase II**:
  - 2012: 39.4%
  - 2013: 26.4%
What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are one of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

In Fiscal Year 2014, NIH’s SBIR and STTR programs will invest over 750 million dollars into early-stage, health and life science companies that are creating a wide range of innovative technologies that align with NIH’s mission to improve health and save lives. A key objective of this work is translating promising technologies to the private sector through strategic public and private partnerships, so that life-saving innovations reach consumer markets.

We invite you to explore our website to learn more about NIH’s SBIR & STTR programs, or get started...
NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation **

Omnibus FOAs: SBIR: PA-14-071   STTR: PA-14-072
New SBIR Direct to Phase II FOA PAR-14-088
Release: January
Standard Due Dates: April 5, Aug 5, Dec 5
(AIDS/AIDS-related: May 7, Sept 7, Jan 7)

SBIR Contract Solicitation (NIH, CDC)
Release: August 15    November 5 close date

NIH Guide for Grants and Contracts
Release: Weekly
Receipt dates specified in each FOA
(http://grants.nih.gov/grants/guide/index.html)
Important changes in this year’s Omnibus Grant Solicitations


1. NIH SBIR and STTR applicants may now switch programs at Phase II or Phase IIB.
   
a) Phase I STTR Awardees may apply for NIH SBIR or STTR Phase II.
b) Phase I SBIR Awardees may apply for NIH SBIR or STTR Phase II.

c) Phase II STTR Awardees may apply for NIH SBIR or STTR Phase IIB.
d) Phase II SBIR Awardees may apply for NIH SBIR or STTR Phase IIB.
2. NIH has issued a Pilot SBIR Direct to Phase II solicitation, **PAR-14-088**.

3. VC-backed companies (VCOC, Hedge fund, private equity firm) CAN apply to NIH SBIR FOAs (since May 2013).

4. SBA Company registry at SBIR.gov required for all submissions.
Stay Informed…

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

- **NIH SBIR/STTR Notification**
  
  Send email to LISTSERV@LIST.NIH.GOV with the following text in the message body:

  subscribe SBIR-STTR your name.
Matthew Portnoy, PhD
NIH SBIR/STTR Program Coordinator
Phone: 301-435-2688
Email: mportnoy@mail.nih.gov

Lenka Fedorkova, PhD
SBIR/STTR Program Manager
Phone: 301-435-0921
Email: lenka@nih.gov

Robert Vinson
SBIR/STTR Program Manager
Phone: 301-435-2713
Email: vinsonr@mail.nih.gov

Betty Royster
SBIR/STTR Communications Specialist
Phone: 301-402-1632
Email: roysterbr@mail.nih.gov

Julie Beaver
SBIR/STTR Statistician
Phone: 301-496-8807
Email: julie.beaver@nih.gov
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