The Basics of SBIR/STTR Grants and Other Public & Private Funding Sources for Innovation and Technology

Weill Cornell CTSC
February 27, 2009
New York, NY

Rosemarie Filart, MD MPH MBA
NIH Program Officer
National Center of Research Resources, NIH
Topics to Discuss Today

- Reasons to be interested
- General Information
- Funding Opportunities
- Eligibility Requirements
- Submitting an Application
- Avoiding Pitfalls
- Peer-Review Process
- Keeping Connected
**Terms**

- **SBIR**
  - *Small Business Innovation Research Grant*

- **STTR**
  - *Small Business Technology Transfer Research Grant*

**Phase 1:** To establish the technical/scientific merit and feasibility of the proposed research/ R&D efforts.

**Phase II:** To continue the research/ R&D efforts initiated in Phase I.
NIH Mission

Improve human health through biomedical and behavioral research, research training and communications.
Key Points

- Spur innovation.
- Facilitate Translational Research from bench to bedside and back.
- Facilitate research in innovation and successful product development to benefit human health.
- Invite sound research plans for submission.
- Encourage clear, literature supported, measurable, and concise scientific research proposals.
- Promote success stories of the NIH SBIR STTR program awardees.
Reasons to Seek SBIR & STTR Grant Funding

- Provides funding for innovative technology development projects and proof of concept.
- Provides recognition, verification and visibility.
- Can be a leveraging tool to attract other funding (VC, etc.) and promotion.
- Retain intellectual property rights with the small business concern.
- Is Not a loan.
Examples of Topic Interests

- **Biomedical**: basic science tools, sensors, biomechanics components, drug delivery systems, reagents, imaging, management techniques,…

- **Education and Training**: videos, tools, software, intervention programs, prevention and medical management protocols, research programs, decision making systems, communications,…

- **Clinical and Medical Devices & Systems**: computer based, mobile, communications, telemedicine, assistive devices, orthotics, prosthetics, robotics, diagnostics, implantable, economical, accessible,…
Examples of Topic Interests

- **Software and informatics**: secure tools, communications, video/audio capable, databases, social networking, data analyses systems, EHR/PHR, interoperability, visualization,…

- **Therapeutics**: proteomics, genomics, drugs and agents, probiotics, immune modulators, vaccines, probes, nanotechnology,…

- **Energy Efficiency and Renewable Energy Systems**: medical devices, imaging, batteries, monitoring technologies, macromolecular resources, diagnostics, pharmaceutical development, metabolic engineering, modeling,…
<table>
<thead>
<tr>
<th>2008 Budget</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>$580M</td>
<td>$70M</td>
</tr>
<tr>
<td>CDC</td>
<td>~8.1M</td>
<td>N/A</td>
</tr>
<tr>
<td>FDA</td>
<td>~0.8M</td>
<td></td>
</tr>
<tr>
<td>AHRQ</td>
<td>~2.0M</td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>$100K*</td>
<td>$100K*</td>
</tr>
<tr>
<td></td>
<td>6 months*</td>
<td>1 year*</td>
</tr>
<tr>
<td>Phase II</td>
<td>$750K*</td>
<td>$750K*</td>
</tr>
<tr>
<td></td>
<td>2 years*</td>
<td>2 years*</td>
</tr>
</tbody>
</table>
Key Take Home Message

Propose a Realistic and Appropriate Budget for the Research
Extramural R&D Set Asides:
SBIR = 2.5%
STTR = 0.3%

$580 M (SBIR)
$ 70 M (STTR)
Total: $650 M
NCRR Funding FY2008

- SBIR - $27 M
- STTR - $3.2 M

Award level range 2000-2007:
- Phase 1: $77 K - $1.9 M
- Phase 2: $162 K - $1.8 M
NIH SBIR/STTR Solicitations and Funding Opportunities

- SBIR/STTR *Grant* Opportunities
- SBIR *Contract* Opportunities
- NIH Guide for *Grants & Contracts*
Omnibus Solicitation of the NIH, CDC and FDA for SBIR/STTR Grant Applications

- SBIR Parent Funding Opportunity Announcement (FOA): (PA-09-080)
- STTR Parent (FOA) (PA-09-081)
- SBIR/STTR Program Descriptions and Research Topics
- General Submission Dates: April 5, Aug. 5, Dec. 5

| NIH (23 ICs) – SBIR & STTR | FDA – SBIR only | CDC – SBIR only |
Small Business Research Funding Opportunities


- PHS 2009-2 Omnibus Solicitation for SBIR/STTR Grants Now Available
- SBIR/STTR Applications to Transition to Adobe-based Forms Beginning January 8, 2009
- New NIH Policy on Resubmission (Amended) Applications
- SBIR Program Extended Temporarily Until March 20, 2009

Funding Opportunities

2009 SBIR and STTR Omnibus Solicitations of the NIH, CDC, and FDA

| SBIR Parent Funding Opportunity Announcement (PA-09-080) |
| STTR Parent Funding Opportunity Announcement (PA-09-081) |
| Program descriptions and Research Topics (PDF - 1.7 MB or MS Word - 1.5 MB) |

Standard Receipt Dates:
- April 5, Aug 5, Dec 5
- AIDS and AIDS-Related Receipt Dates: May 7, September 7,
NIH SBIR/STTR Research Topics: 200+ pages

- Mission of Awarding Components (Institutes/Centers)
- IC Program Descriptions
- “Suggested” technical topics
- Broad Descriptions
- Trans-NIH Opportunities

http://grants.nih.gov/grants/funding/sbirsttr_news.htm#20090122
Examples of NIH Guide Targeted Announcements

**RFA-EB-09-01**: Development and Translation of Medical Technologies that Reduce Health Disparities (SBIR)

**PAR-07-160**: Innovations in Biomedical Computational Science and Technology (SBIR)*

**PA-08-142**: Tools for Germplasm Cryopreservation (SBIR)*

*Parallel STTR
**RFA-EB-09-01**: Development and Translation of Medical Technologies that Reduce Health Disparities (SBIR)

**Objective**: Development and translation of medical technologies aimed at reducing disparities in healthcare access and health outcomes

**Unique Features**:
- Due dates: *Feb 20, May 20, Sept 22, 2009*
- NIBIB, NCMHD, NCRR, NIMH
- $200/yr for 2 yrs – Phase I
- $400/yr for 3 yrs – Phase II
Eligibility Requirements

Links:
SBIR/STTR Eligibility Requirements

- Applicant is the Small Business Concern.
- Organized for-profit U.S. business.
- Legal form of an individual business.
- 500 or fewer employees, including affiliates.
- Must be:
  - At least 51% U.S.-owned by individuals and independently operated or
  - At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals.
SBIR Eligibility Requirements

- Principal Investigator’s primary employment must be with the Small Business Concern at the time of award and for the duration of the project period.

- Subawards are permitted
  - May outsource 33% activities in Phase I.
  - May outsource 50% activities in Phase II.
STTR Eligibility Requirements

- Principal Investigator’s primary employment may be with either the Small Business Concern or the research institution.
- If the primary employment is with the research institution, the PI must have a formal appointment or a commitment to the small business applicant.
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by U.S. research institution
  - Each PI commits a minimum of 10% effort to the project.
- U.S. Research Institution
  - College or University
  - Other non-profit research organization
  - Federal R&D center
- Intellectual Property Agreement
  - Defines allocation of IP rights and rights to carry out follow-on R&D and commercialization.
SBIR and STTR Programs (Critical Differences)

- **Permits** research institution partners (e.g., universities)
- Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities
- **Requires** research institution partners (e.g., universities)
- 40% of the work must be conducted by the small business concern (for profit) and 30% by a U.S. research institution (non-profit)

Award always made to the small business
SBIR STTR Multiple PI/PD: Encourages Team Science

- Small business concern (SBC) is ALWAYS the applicant/awardee organization.
- Research institution is a subcontractor to the SBC.
- STTR applicant organization must officially affiliate the PD/PI with the SBC if the PD/PI is not an employee of the SBC.
- Small business submitting the application will be the lead organization.
- Contact PD/PI must be located at the lead organization.
- Other collaborating institutions/organizations will be supported through subcontracts.
- Multiple PD/PIs at different institutions/organizations use the traditional subcontracts.

http://grants.nih.gov/grants/multi_pi/sbirsttr_faq.htm
Submitting an Application
Keys to a Strong Application

- Significant, innovative, and focused *science*.
- Translational research projects should involve the appropriate collaborators.
- Attention to all the Enhanced Review Criteria.
- Other Evaluation factors:
  - Protection of Human Subjects
  - Inclusion of Women, Minorities, and Children
  - Animal Welfare
  - Budget and Period Support
  - Select Agent Research
  - Resource Sharing Plans
Know NIH Review Criteria: Highlights

Significance
- Commercial potential?
- Address an important problem or a critical barrier?
- Change this field?

Approach
- Overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims?
- Potential problems, alternative strategies, and benchmarks for success presented?
- Establish feasibility and manage risky aspects?
Know NIH Review Criteria: Highlights

Innovation
- Shift current paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Novel to one field or in a broad sense? In what way?

Investigator
- Appropriate experience and training?
- Record of accomplishments that advance their field(s)?
- For multi-PD/PI, have complementary and integrated expertise with appropriate leadership, governance and organizational structure?
Know NIH Review Criteria: Highlights

**Environment**

- Contribute to the probability of success?
- Institutional support, equipment and other physical resources available and adequate?
- Project benefits from the scientific environment, subject populations, or collaborative arrangements?
Usefulness of Preliminary Data

- Solicitation states “Preliminary data are not required”
- Reviewers like to see preliminary data
- Preliminary data should support your proposal and the feasibility of the project
- Preliminary data may consist of your own publications and unpublished data from your laboratory or need assessment data for science education products and tools
Avoiding Pitfalls: Application

- Review and Comply with the eligibility criteria.
- Address the Enhanced Review Criteria in application.
- Submit a clear, literature supported, measurable, concise research proposal.
- Assure the best submitted application.
Avoiding Pitfalls: E-Processing

- Have PD/PI(s) and AOR/SO register under separate accounts in the NIH eRA Commons.
- Register Applicant organization (SBC) in both Grants.gov and NIH eRA Commons.
- Obtain at Grants.Gov, an Organization’s Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) several months ahead.
Changes in the NIH SBIR/STTR Solicitation

- Change in electronic submission
  - Grants.gov switching from PureEdge to Adobe Reader 8.1.3 or later.
  - Effective January 8, 2009, for SBIR/STTR.

- Change in resubmission (amended) policy
  - Resubmissions limited to one (A1) effective January 25, 2009.
  - Those submitted prior to January 25, 2009, will still be permitted two amendments (A1, A2).

- [http://grants.nih.gov/grants/funding/sbirsttr_news.htm#20090122](http://grants.nih.gov/grants/funding/sbirsttr_news.htm#20090122)
NIH Review Process

Small Business Concern

Applicant Initiates Research Idea

NIH Center for Scientific Review Assign to IC and IRG

Submits SBIR/STTR Grant Application to NIH Electronically

Scientific Review Groups Evaluate Scientific Merit

~2-3 months after submission

Advisory Council or Board Recommend approval

~2-3 months after review

IC Staff Prepare funding Plan for IC Director

Grantee Conducts Research

Funds
Application Evaluation Process

- External *peer* reviewers

- Change in Scoring System: from 1 – 9
  - Each criterion will receive an individual score.
  - Reflect the overall impact project likely to have on research field as scored by the peer reviewers.

- Access to the Peer Review Summary Statement through eRA Commons

Keeping Connected with NIH Program Officers

- Locate POs through the Solicitation’s narrative descriptions of the programs and research topics before submission.
- Communicate with your assigned PO as listed in your eRA Commons account.
- Review Summary Statements and obtain advice on resubmissions and options.
- Discuss progress of project.
- Share success stories.
Stay Informed through Listserves

- **NIH Guide for Grants and Contracts** (weekly notification)
  
  http://grants.nih.gov/grants/guide/listserv.htm

- **NIH SBIR/STTR Notification**

  Send email to LISTSERV@LIST.NIH.GOV with the following text in the message body:

  subscribe listname your name.
SAVE THE DATE

11th Annual NIH SBIR/STTR Conference

June 30 – July 1, 2009
Omaha, Nebraska
THANK YOU!

Rosemarie Filart MD MPH MBA
NIH NCRR, Division of Clinical Research,
Weill Cornell CTSC NIH Program Officer
SBIR STTR Program Officer
301-435-0178
filartr@mail.nih.gov

Links:
http://grants.nih.gov/grants/funding/sbir.htm
http://www.ncrr.nih.gov/research_funding/small_business_opportunities/