Secrets of NIH SBIR & STTR Grant Applications

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My Agenda Today

- Description of NIH small business programs (SBIR/STTR).
- Electronic grant application concerns.
- NIH FY2007 award data.
- NIH offers more than funds.
- Information on other NIH R&D funding opportunities.
- You should consider other federal agencies.

NIH SBIR and STTR Programs Fund
About $650M/Year

- **SBIR** - Small Business Innovation Research funds support research by business.
  - 2.5% of NIH extramural research budget.
  - Principal Investigator (PI) must be employed over 50% by company.
  - No minimum outsourcing (subcontracting) requirement.
  - Maximum outsourcing is 50% in Phase II but is somewhat flexible.

- **STTR** - Small Business Technology Transfer Research funds support collaborative research between company and U.S. research institution.
  - 0.3% of NIH extramural research budget.
  - Minimum outsourcing is 30% and maximum outsourcing is 60% and % is not flexible.
  - PI need not be employed by company.

Advantages

- **SBIR over STTR**
  - No research institution partner necessary.
  - More flexible percent effort than STTR.
  - Academic scientist consultant may earn consultant fees on top of salary.

- **STTR over SBIR**
  - Company may lack credible PI.
  - PI role essential to academic scientist.
  - Potentially better access to academic facilities, intellectual property and support.
  - Higher percent Phase I subcontract possible.

Select carefully – changes not permitted from Phase I to Phase II.

NIH SBIR and STTR Eligibility Requirements

- Awardee must be for-profit company.
- Principal place of business must be in U.S.
- All SBIR/STTR funded research must be conducted entirely in the U.S.
- Awardee must have over 50% ownership by U.S. individuals.
- Awardee must control research facilities where SBIR/STTR research will be conducted.
- Awardee must have 500 or fewer employees in the small business and all its affiliates.

NIH SBIR and STTR Are Three Phase Programs

- **Phase I**
  - Proof of feasibility
  - Funding for 1 year, sometimes 2 years
  - Median NIH award $160K/year

- **Phase II**
  - Major research and development
  - Funding for 2 year, sometimes 3 years
  - Median NIH award $375K/year
  - Fast Track – Combined Phase I/II application
  - Competing Phase II renewal
  - For FDA related products
  - Compete with other Phase II applications
  - Award up to $1M/year for 2 to 3 years

- **Phase III**
  - Remaining steps of commercialization
  - Not funded by government. Funded by other sources, e.g., angels, venture capital, etc.
Focus On Your Product, Not Your Technology

- Core technology builds a business.
- A single use of core technology builds an SBIR/STTR application.
- Advantages of focus on single use.
  - Meets needs of specific problem.
  - Targets committed reviewers.
  - Demonstrates business acuity.
  - Allows additional applications using same core technology.
  - Can prepare applications for more than one agency.
- Describe the public health and financial significance of your product.

NIH Program Announcements Funding Opportunity Announcements

- Program Announcements (PAs, now often called FOAs) are NIH staff “wish lists.”
- Review committees usually evaluate an application responding to a PA no differently than any other application.
- You can handicap your application by trying to make it fit a PA.
- Respond to a PA only if the research you want to propose exactly matches the PA request.
- You do not need to respond to a PA to request an NIH Phase I award over $100 thousand or a Phase I award for 2 years.

NIH Electronic Submission Roles and Responsibilities

NY2007 SBIR & STTR Applications

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Revised FY2007 Phase I Applications
Try, Try, Again!

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FY2007 NIH SBIR & STTR Phase I Award Amounts

NIH Offers More Than Funds

- Material transfer agreements (MTA), licenses, and cooperative research and development agreements (CRADA)
- Pipeline to Partnerships (P2P) - partnership and licensing information
- http://www.ott.nih.gov/p2p
- Collaboration opportunities and research partnerships (CORP) - partnership and services information
- Technical assistance programs (TAP)
  - Market research assistance
  - Presentation assistance (dog & pony show)
  - Manufacturing assistance

NIH SBIR Technical Assistance Program (TAP) – Competitive

- Niche Assessment Program (NAP) for NIH Phase I awardees
  - Market analyses of technology
  - Strategic planning for technology
- Commercialization Assistance Program (CAP) for NIH Phase II awardees
  - Free 10 month program (except travel) to develop company's investor presentation
  - Presentation at venture forum
- Pilot Manufacturing Assistance Program (MAP) for NIH Phase II awardees
  - Partnership with NIST Manufacturing Extension Partnership
  - Free 2-3 month program requiring minimum 100 hours of company time
  - Supports product movement from research to manufacturing

Consider Other Award Activities

- Small Grant Program (R03)
  - $50K/year for up to 2 years.
  - Check participation by NIH Institute/Center.
  - Check Funding Opportunity Announcements.
- Basic Research Grant (R01)
- Exploratory/Developmental Grants Phase I (R21)
  - ~$275K/2 years.
  - Check Funding Opportunity Announcements, e.g., NIAID Microbicide Innovation Program
- Exploratory/Developmental Grants phase II (R33)
  - Only open to R21 recipients.
  - ~$300K/year for up to 3 years.
- Challenge Grant (RC1) $1M (total cost)/18 months

Pros & Cons
- No small business requirements.
- Direct cost grants.
- Open to academic investigators.
- Compete with academic investigators.

Expand Your Horizon

NIH SBIR/STTR FUNDS $2.3B

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Links to More Information

Email Alerts and Funding News
http://www.niaid.nih.gov/ncr/newsletters/default_subscribe.htm

Narrated Animated Advice on SBIR and STTR Applications

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