Secrets of NIH Small Business Grant Applications

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SBIR
Small Business Innovation Research

- Business applies for and receives award
- 2.5% of NIH extramural research budget
- About $550M in FY2008 NIH awards
- Principal Investigator (PI) in single PI application must be employed over 50% by company.
- Multiple PI applications allowed
  - Leadership plan required
  - Contact PI employed over 50% time by company.
  - Academic PI allowed but not as a Contact PI
- Subcontracting allowed but not required
- Maximum subcontracting nominally
  - 33% in Phase I
  - 50% in Phase II
  - actual amount somewhat flexible with justification

STTR
Small Business Technology Transfer Research

- Requires research institution partner that conducts a minimum of 30% of the work (funds)
- Business must conduct minimum of 40% of work
- Remaining funds, if any, can be used for consultants or other subcontractors
- Business applies for and receives award
- Contact PI
  - Must commit 10% effort
  - Need not be employed by business
  - Full-time academic employee allowed
  - Need not receive salary from award
- 0.3% of NIH extramural research budget
- About $72M in FY2008 NIH awards

Revealing Secrets Levels the Playing Field

Beware of Secrets

- The secrets I share are my opinions.
- Opinions are not facts.
- My opinions are based on experience.
- But, my opinions may not be shared by everyone
  including reviewers and other NIH staff.
- Caveat emptor applies.
- My opinions are not official, so don’t quote me.
Agenda

- Real budget and time limitations
- Award rates for Phase I and II
- My interpretations of NIH Review Criteria
- My application advice
  - Focus on a single narrow but significant problem
  - Decide on a single product to address the problem
  - Write your title first (On Line Exercise)
  - Limit your specific aims for Phase I
  - Describe approach including preliminary data, timeline, and anticipated results and problems
  - Explain access to resources important to project
  - Justify appropriate budget and fee
  - Prepare exciting non-proprietary project summary
- More tips

SBIR and STTR Are Multiphase Programs

- Application Guide budget information
  - SBIR Phase I normally $100K for 6 months
  - STTR Phase I $100K for 3 year
  - SBIR & STTR Phase II $750K for 2 years
- FY2008 Awards
  - Average NIH Phase I $160K per Year for 1 or 2 years
  - Average NIH Phase II $375 per Year for 2 or 3 years
- Fast-Track - Combined Phase IIII application
  - Compete with other Phase II applications
  - Award up to $1M per year for 2 to 3 years
- Phase III
  - Remaining steps of commercialization
  - Not funded by NIH. Funded by other sources, e.g., angels, venture capital, etc.

FY2008 NIH Phase I Applications

<table>
<thead>
<tr>
<th>Type</th>
<th>Received</th>
<th>Funded</th>
<th>Award Rate</th>
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<td>739</td>
<td>24.1%</td>
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<tr>
<td>R01 All</td>
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FY2008 NIH Phase II Applications

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<tr>
<td>R01 All</td>
<td>30624</td>
<td>5852</td>
<td>19.1%</td>
</tr>
</tbody>
</table>

Ways Academics Can Tap into SBIR and STTR Grants

- Consultant on small business grant
- Subcontractor on small business grant
- Principal investigator on small business grant
  - Contact PI on STTR grant
  - Non-Contact PI on Multiple PI SBIR grant
- Start a small business with grant funds
My Interpretations of NIH Application Review Criteria

- **Five Core Review Criteria**
  - Significance – How important is the problem?
  - Investigators – How qualified are the investigators?
  - Innovation – How important is the product?
  - Approach – How well designed is the research?
  - Environment – How critical are the collaborators and the facilities?

- **Overall Impact:** The overall impact of proposed research is not an average of five Core Review Criteria.

- **Significance and Innovation are the most important criteria!**

Application Components Relating to Review Criteria

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<th>Section</th>
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<tr>
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<tr>
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<td>Introduction - Resubmitted or New Applications Only</td>
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<td>1</td>
<td>Specific Aims (Significance, Innovation, Approach)</td>
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<td>Research Strategy</td>
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<td>b. Innovation</td>
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<tr>
<td></td>
<td>c. Approach</td>
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<tr>
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<td>a. Preliminary Studies for New Applications</td>
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<td></td>
<td>b. Progress Report for Renewal/Revision Applications</td>
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<tr>
<td></td>
<td>c. Research Design: Strategy, Methodology, Analyses</td>
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<td>N/A</td>
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<td>4</td>
<td>Biographical Sketch - Investigators, Environment</td>
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<td></td>
<td>a. Personal Statement - Qualifications for Project</td>
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<tr>
<td></td>
<td>b. Publications - No More than 15 Relevant to Project</td>
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Significance (Public Health Problem)

- Single narrow disease is best because the application will be assigned to a reviewer who knows and cares about that disease.
- What are the number and composition of the population affected?
- What discoveries are needed? (gaps, roadblocks, etc.)

Focus On One Product, Not On Your Technology

- **Core technology builds a business.**
- A single use of core technology makes 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
  - Directs different uses of your technology to different ICs and different review groups
- Describe the public health and financial significance of your product.

Innovation (Product)

- **Why is your product innovative (better, faster, at lower cost, etc.)?**
- What are the public health implications?
- What are the product’s financial projections?
- After Phase II, what additional steps will be necessary before your company can realize a profit?

Title – One Product and One Problem in 81 Characters (Innovation and Significance)

- **Title should convey two pieces of information.**
  - What is your product? (Innovation)
  - What is the public health problem? (Significance)
- Decide on your title before you write your application!
- The remaining sections of your application are just details.
Titles of Real Phase I SBIR Applications

Do these include both a product and a problem?

1. Development of Antimicrobial Peptides
2. Antigen Detection Assay for the Diagnosis of Visceral Leishmaniasis
3. Enteric-coated Vector Microparticles for Oral Vaccination
4. Coupled Enzyme Reporter Assay for Proteases
5. An Immunoadhesin Therapy for Gastrointestinal Anthrax
6. Proteolytic Antibodies for Treatment of Psoriasis
7. A Dynamic Web-based Geospatial Data Visualization and Distribution System
8. Virus-like Particle (VLP) Vaccine for RSV
9. Molecular Screen for Antiviral Agents
10. Multi-antigen Peptide Assay for the Serodiagnosis of Lyme Disease

Limit Your Specific Aims for Phase I
Larger Balloons Are More Likely to Be Popped

Specific Aims (All Criteria)

- Paragraph 1
  - Problem and its significance
  - Current solutions, gaps, roadblocks
- Paragraph 2
  - Your product
  - Why it is an innovative solution to problem
- Specific Aims (two or three with bullets for each)
  - No more than necessary to justify Phase II
  - Timeline
  - Environment contribution if applicable
  - Easily assessed by a review committee

Approach – Preliminary Studies/Progress Report

- Phase I applications - Preliminary studies (Investigators)
  - Omnibus Solicitation states "Preliminary data are not required."
  - But, most applications present preliminary data.
  - Reviewers want to see preliminary data.
  - Preliminary data should support your proposal and the feasibility of Phase I and Phase II.
  - Preliminary data may consist of publications by you and your collaborators and your unpublished data.
  - Interpret preliminary data critically and evaluate alternative meanings.
- Phase II applications - Phase I progress report
  - Milestones proposed
  - Milestones achieved

Facilities and Resources (Environment)

- Company current or tentatively leased research facilities
- Company research resources necessary for project
- Unique company capabilities
- Not a virtual company
- Research resources of collaborating laboratories and institutions
- Subcontractor R&D Resources
- New - Explain why resources are important to project

Budget and Fee

- Request and justify Phase I for 2 years and $200-250K/year (STTR) or 250-300K/year (SBIR).
- Complete one year or more of Phase I research prior to Phase I funding.
- Charge up to 90 days pre-award research to grant.
- Apply for Phase II grant before first year of Phase I.
- Do not exceed the salary cap.
- A fee up to 7% can be used for expenses not allowed on your grant.
  - Patent costs
  - Market research
  - Expenses outside the U.S.
**Project Summary/Abstract**

(All Criteria)

- All reviewers read your abstract.
- Compose it after you complete rest of application.
- Concisely summarize application.
- Include no proprietary information.
- Write a few sentences on each:
  - Public health problem
  - Issues with current solutions
  - How your product addresses unmet needs
  - Summary of approach
  - Collaborators and unique resources and capabilities
  - Phase I specific aims
  - How anticipated results justify Phase II and further product development

**More Tips**

- Goal of Phase I is to get to Phase II
- Select project best for your company
  - Apply to Omnibus Solicitation
  - No need to search through Funding Opportunity Announcements (FOAs)
  - FOA success rate not any better than Omnibus
- Have patent protection before submission
- Have little time for "Just-In-Time" information
- Wait for an award is longer than you think

**All NIH FY2008 SBIR Phase I & II Awards**

**Receipt and Award Dates**

- NIH Budget Approved: FY2008 Applications
- All Scores Are In
- FY2009 Applications

**Receipt, Review, and Award Dates**

- Reviews: Jun-Jul, Oct-Nov, Feb-Mar
- Council: Sep-Oct, Jan-Feb, May-Jun
- Estimated Award: Nov-Mar-Jul
- 50% Awarded: ~Apr, ~May, ~Aug

**Expand Your Horizon**

- SBIR/STTR FUNDS: $2.3B
  - DOD: $1270M
  - NIH: $645M
  - NASA: $115M
  - DOE: $115M
  - NSF: $95M

**Links to More Information**

- Email Alerts and Funding News: http://www.niaid.nih.gov/newsletters/default_subscribe.htm
- Narrated Animated Advice on SBIR and STTR Applications: http://www.niaid.nih.gov/sbir/pres.htm

**CONTACT ME FOR LIVE PRESENTATION**

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