

Secrets of NIH Small Business Grant Applications

Gregory Milman
 National Institute of Allergy
 and Infectious Diseases
gmilman@niaid.nih.gov
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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.
- Besides, I would prefer my opinions remain secret.






NIH Small Business Research Funding Opportunities
<http://grants.nih.gov/grants/funding/sbir.htm>




- Funding Opportunities
 - Small Business Innovation Research (SBIR)
 - Small Business Technology Transfer Research (STTR)
- Eligibility
- Receipt dates
- Program descriptions and research Topics
- Electronic submission information
- Application review process
- Policy information
- Grant preparation resources
- NIH Small Business Conference information















SBIR and STTR Are Multiphase Programs




- Application Guide budget information
 - SBIR Phase I normally \$100K for 6 months
 - STTR Phase I \$100K for 1 year
 - SBIR & STTR Phase II \$750K for 2 years
- FY2008 Awards
 - Average Phase I \$160K per Year for 1 or 2 years
 - Average Phase II \$375 per Year for 2 or 3 years
- 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 per 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.





Leveling the Playing Field

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.

Potential NIH Funds per Project (Total Cost)

Grant	Years	per Year	Total	Subcontract
Phase I	2	\$0.3M	\$0.6M	~\$0.3M
Phase II	3	\$1.0M	\$3.0M	~\$1.5M
Renewal Phase II	3	\$1.0M	\$3.0M	~\$1.5M
Total	8		\$6.6M	~\$3.3M
Average			\$8.25K	~\$4.13K

FY2008 average 1R01 = \$3.93K/year (Total Cost)

STTR
 Small Business **T**echnology **T**ransfer **R**esearch

- 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

















Innovation and Research Definitions

- Innovation**
 - New technologies
 - Significant improvement of existing technologies
 - New applications for existing technologies
- Research**
 - Collection and analysis of data
 - Does not necessarily have to be innovative if the product is innovative
- Virtual companies ineligible**
 - Company facilities required
 - Company work required






Advantages of SBIR and STTR Awards

- SBIR over STTR**
 - No research institution partner necessary
 - SBIR success rates higher than STTR
 - Flexibility to increase or decrease subcontracting
 - Academic scientist consultant fees on top of salary
 - Fy2008 SBIR success rates better than STTR
- STTR over SBIR**
 - Company lacks credible PI
 - Contact PI role essential to academic scientist
 - Potentially better access to academic facilities, intellectual property and support
 - Higher percent Phase I subcontract possible.
- Changes between SBIR and STTR are not permitted from Phase I to Phase II (may change)






SBIR
 Small Business **I**nnovation **R**esearch

- 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






FY2008 NIH Phase I Applications

Type	Received	Funded	Award Rate
SBIR All	3062	739	24.1%
Initial	2255	478	21.2%
Revision	661	208	31.5%
STTR All	805	109	13.5%
Initial	521	49	9.4%
Revision	222	38	17.1%
R01 All	30624	5852	19.1%

FY2008 NIH Phase II Applications


Type	Received	Funded	Award Rate
SBIR All	675	269	39.9%
Initial	401	161	40.1%
Revision	196	76	38.8%
STTR All	130	43	33.1%
Initial	73	24	32.9%
Revision	37	10	27.0%
R01 All	30624	5852	19.1%









Application Components Relating to Review Criteria (Before January 25, 2010)






APPLICATION COMPONENT	REVIEW CRITERIA
SF424 R&R Descriptive Title of Project	Significance, Innovation
Biographical Sketches	Investigator, Environment
PHS398 Research Plan (15 page limit)	
Section	
2. Specific Aims	All Criteria
3. Background and Significance	Significance, Innovation
4. Preliminary Studies	Approach, Investigators
5. Research Design and Methods	Approach, Innovation
Research and Related Project Information	
Project Summary/Abstract	All Criteria
Bibliography	Investigators
Facilities, Resources, Equipment	Environment











- Focus On A 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.
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- New SBIR & STTR Application Components (After January 25, 2010)
- | Pages | Section |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Introduction – Resubmitted or New Applications Only |
| 1 | Specific Aims (All Criteria) |
| 6 | Research Strategy <ul style="list-style-type: none"> a. Significance b. Innovation c. Approach <ul style="list-style-type: none"> Preliminary Studies for New Applications Progress Report for Renewal/Revision Applications Research Design: Strategy, Methodology, Analyses |
| N/A | Environment – How do resources contribute to project? |
| 4 | Investigator – Biographical Sketch <ul style="list-style-type: none"> a. Personal Statement –Qualifications for Project b. Publications – Maximum of 15 Relevant to Project |
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- Application Review Criteria
- Five Core Review Criteria – My Interpretations
 - 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!
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- 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.
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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
11. Rapid, Low Cost, Point-of-Care Diagnostic Device for Group B Streptococcus
12. Potential Benefits of Personalized Interferons




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Background and Significance
 (Now Separate Sections in New Format)




- Describe the Public Health Problem (**Significance**)
 - Single 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 and products are needed?
- Product (**Innovation**)
 - Why is your product innovative (better, faster, at lower cost, etc.)?
 - What are the public health implications?
 - What are the products financial projections?
 - What is your commercialization plan or exit strategy?
 - After Phase II, what additional steps will be necessary before your company can realize a profit?




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Biographical Sketches
 (Investigator, Environment)




- Follow instructions to include biographical sketches for all PI, Key Personnel, and other Significant Contributors.
- Reviewers use biography information to evaluate both the investigator and the environment.
- The lists of ongoing and completed research support demonstrate research management experience.
- **New**
 - Personal Statement of qualification
 - Maximum 15 relevant publications

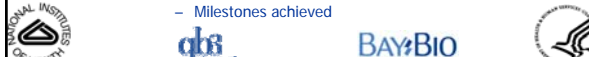


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Preliminary Studies
 (Approach, Investigators)




- Preliminary data for Phase I applications
 - Omnibus Solicitation states "Preliminary data are not required."
 - But, most applications present preliminary data.
 - Reviewers want to see preliminary data but do not give too much information.
 - 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 I Progress report for Phase II applications
 - Milestones proposed
 - Milestones achieved




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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
 - End point specific aims as opposed to a best effort
 - A best effort specific aim is "to evaluate a number of potential drug candidates."
 - An end point specific aim is "to select the best drug candidate for Phase II study."



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Research Design
 (Approach)








- Research design and methods should be described in parallel to specific aims.
 - Organize by Specific Aims and include Timeline
 - Rationale, innovation, supporting data, and references
 - Expected results, limitations, potential difficulties, and planned statistical analysis if relevant
 - Criteria for evaluating success, failure, or other possible interpretations
 - Hazards anticipated, precautions proposed
 - Reagents, animals, human subjects, equipment, etc. Follow NIH guidelines.
 - Purpose of collaborators, if any, and letters of agreement



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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
- A required separate Project Narrative is three sentences or less on the relevance of your project to public health.

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More Tips






- Propose just enough work in Phase I
- 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

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Bibliography & References Cited (Investigator)

- Follow instructions for the "Bibliography and References Cited" component.
- Reviewers may examine your references to see:
 - Are they current?
 - Are they sufficiently inclusive?

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Propose Just Enough Work in Phase I Larger Balloons Are More Likely to Be Popped

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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

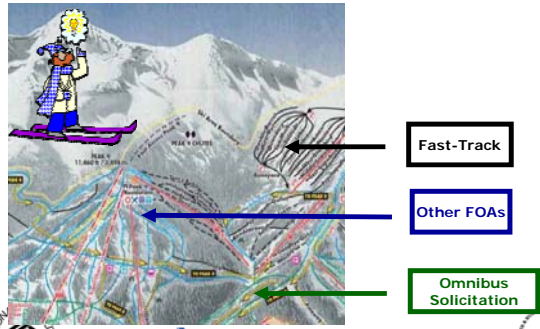











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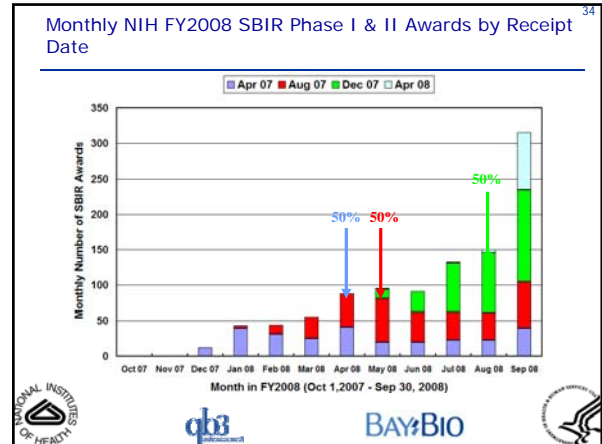
Stick to the Omnibus Solicitation Master the Beginner Slopes First


Patents on Intellectual Property



- Do not submit a grant application until you have applied for patents on your intellectual property.
- Patent protection is an absolute requirement for a business. Describe your strategy if existing patents block the market for your product.
- Core technology must be protected (patented, patent pending, or provisional patent pending).
- Company must own title to patent or have exclusive license to it.
- Provisional Patent Application
 - Allows one year to file full application
 - Not examined on merits
 - Should be prepared by professional
 - 2009 Provisional Application Filing Fee

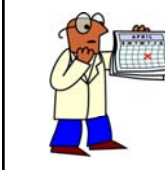
Just-in-Time – Our Time, Not Yours




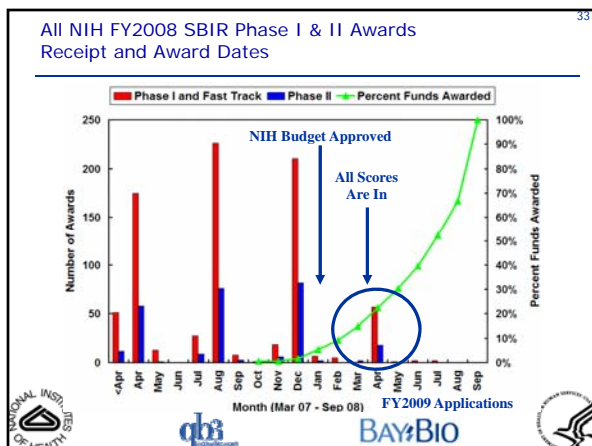
- Other support data for PI and all key personnel
- Lease agreement
- PI and applicant institution eligibility verification
- Human subjects Federalwide Assurance (FWA) number
- Institutional review board (IRB) approval certification date
- Human subjects education certification
- Institutional animal care and use committee (IACUC) assurance number and approval date



Receipt, Review, and Award Dates



	Awards Within Payline		
	~ 33%	~ 33%	~ 33%
Receipt (AIDS)	Apr 5 (May 7)	Aug 5 (Sep 7)	Dec 5 (Jan 7)
Review	Jun-Jul	Oct-Nov	Feb-Mar
Council	Sep-Oct	Jan-Feb	May-Jun
Estimated Award	Nov	Mar	Jul
50% Awarded	~Apr	~May	~Aug





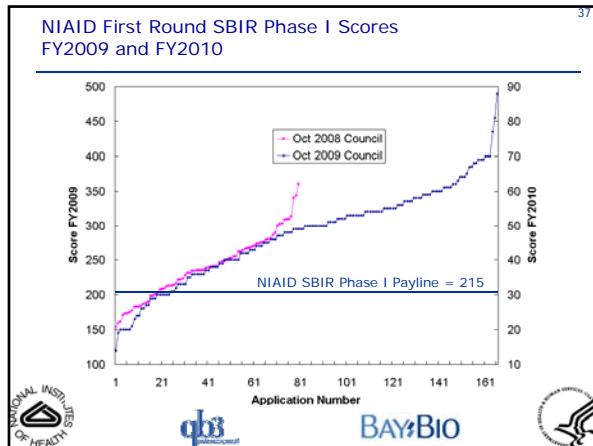
Comparison Old and New NIH Scoring Systems NIAID SBIR Phase I Scores FY2009 & FY2010

	FY2009 1 st Round	FY2010 1 st Round
Applications	144	298
Scored	~ 55%	~ 55%
Score Range	100-500	10-90
Actual Range	150-360	14-88
NIAID Payline	215	??
Awards	24	24 ??
Award Rate	17%	8% ??

Score Comparisons:

- New Score = 10 + (Old Score - 100)*80/400
- New Score 30 = Old Score 200
- New Score 31 = Old Score 215





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Links to More Information

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

Narrated Animated Advice on SBIR and STTR Applications
<http://www.niaid.nih.gov/ncn/sbir/pres.htm>

Gregory Milman, Ph. D.
Division of Extramural Activities
NIAID, NIH, DHHS
6700-B Rockledge Drive; Room 2130
Bethesda, MD 20892-7610
Tel (301) 496-8666
Fax (301) 402-0369
Email gmilman@niaid.nih.gov

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